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THE EVALUATION AND MANAGEMENT OF A RECTOCELE IN A RESOURCE LIMITED SETTING

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Dr Etienne Wilhelm Henn

Promoter: Prof PH Wessels

A thesis submitted in fulfilment of the requirements in respect of the *Doctor of Philosophy in Obstetrics and Gynaecology* in the Faculty of Health Sciences, University of the Free State

January 2017

DEDICATION

Deo favente

To Elaine for your continued love and support not only with this project, but in all facets of our life together.

To Cecile, Elizabeth, Amelia and Catherine for your understanding of my commitment to this endeavour.

Aeternae memoriae patris mei

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Prof Gina Joubert form the Department of Biostatistics for her willingness to always help, even at short notice.

DECLARATION

I, Etienne Wilhelm Henn declare that the doctoral research thesis or interrelated, publishable manuscripts / published articles that I herewith submit at the University of the Free State, is my independent work and that I have not previously submitted it for a qualification at another institution of higher education.

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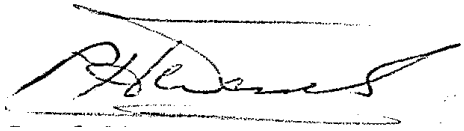
I, Professor P.H. Wessels, approve submission of this thesis as fulfilment for the Ph.D. (Obstetrics and Gynaecology) degree at the University of the Free State. I further declare that this thesis has not been submitted as a whole or partially for examination before.



Prof. P.H. Wessels (Promoter)

January 2017

ABSTRACT

INTRODUCTION: A rectocele can be expected in approximately 11-19% of women and is present in 40-85% of women requiring pelvic floor surgery for other disorders. There is considerable international variation in the evaluation and management of these women, particularly in regards to surgical treatment. The healthcare environment of the Free State is one with limited resources and innovative clinical approaches are often required to allow for optimal service provision to continue.

OBJECTIVES: The objective of this thesis was to research the assessment and management of women who presented with rectoceles in a resource limited setting through innovative and frugal methods, whilst maintaining a pragmatic clinical inclination.

METHODOLOGY: The methodologies included the linguistic and cultural psychometric validation of pelvic floor questionnaires, the randomized assessment of the clinical impact that transperineal ultrasound has on patient management, the randomized evaluation of the value which a rectopexy might add in combination with a sacrocolpopexy, the retrospective review of a rectocele plication and description of this novel surgical technique, the retrospective review of the benefit which a perineal body repair in combination with a posterior repair might confer as well as the randomized assessment for non-inferiority of a rectocele plication compared to a defect-specific repair in women with rectoceles.

RESULTS: The PFDI-20, PFIQ-7 and PISQ-12 pelvic floor questionnaires were validated in South African women for the languages of Afrikaans and Sesotho and shown to be responsive to clinical change. The integration of transperineal ultrasound findings resulted in an alteration of the definitive management plan in 37.6% of women and this was most evident for those with posterior compartment disorders. A rectopexy was not found to add significant clinical benefit in women with advanced multi-compartment pelvic organ prolapse who underwent an extensive sacrocolpopexy. The rectocele plication procedure, which involves the repair of the anterior rectal wall though a vaginal approach, was found to result in anatomic success of 88.6% after a mean follow-up period of 27 months with an associated significant improvement in symptoms and quality of life. The addition of a perineal body repair in those women who underwent a rectocele plication was not observed to be of any clinical benefit in this population. The randomized assessment of a rectocele plication compared to a defect-specific repair demonstrated that the new procedure was not inferior to the existing operation in regards to anatomic outcome. The anatomic success rates were 92.3% and 76.9% respectively ($p=0.2485$, 95% CI -13.6; 42.5). The rectocele plication did however demonstrate significantly superior symptomatic and functional outcomes compared to a defect-specific repair after 1 year. A significant observation was that of voiding dysfunction in this population of women with isolated rectoceles. This was the second most prevalent initial complaint and it was significantly improved ($p= 0.0011$) after surgical correction of a rectocele in both the retrospective and prospective evaluations.

CONCLUSION: This research compilation demonstrated that a thorough assessment of women with posterior compartment disorders through the use of validated

instruments and standardized investigations in combination with innovative surgical procedures resulted in clinical outcomes not inferior to those reported elsewhere in the literature. It emphasized that pragmatic innovation in a limited resource healthcare environment can produce internationally equivalent clinical results.

KEYWORDS: Defect-specific repair, limited resources, non-inferiority, perineal body repair, posterior compartment, quality of life, rectocele, rectocele plication, rectopexy, transperineal ultrasound.

ABSTRAK

INLEIDING: ‘n Rektoseel kan gevind word in ongeveer 11-19% van alle vroue en is ook teenwoordig in 40-85% van dames wat pelviese vloer chirurgie vir ander redes moet kry. Daar is beduidende internasionale variasie in die wyse hoe hierdie dames evalueer en hanteer word en dit is veral duidelik in terme van die chirurgiese behandeling van ‘n rektoseel. Die Vrystaat se gesondheidsorg het beperkte hulpbronne en innoverende kliniese benaderings moet dikwels gevolg word om dienslewering volhoubaar te laat geskied.

DOELWITTE: Die doelwit van hierdie tesis was om die evaluasie en hantering van dames wat presenteer met ‘n rektoseel in ‘n gesondheidsorg sisteem met beperkte hulpbronne na te vors deur gebruik te maak van innoverende en ekonomiese metodes, maar met die behoud van ‘n pragmatiese kliniese benadering tot hierdie dames.

METODIEK: Die metodologieë wat gebruik was tydens hierdie projek het die taalkundige en kulturele psigometriese bekragtiging van pelviese vloer vraelyste ingesluit, die gerandomiseerde evaluasie van die kliniese belang van ‘n transperineale ultraklank ondersoek op die behandeling van ‘n pasiënt, die gerandomiseerde evaluasie van die waarde wat ‘n rektopeksie byvoeg tot ‘n sakrokolpopeksie, die retrospektiewe evaluasie van ‘n rektoseel plikasie en die beskrywing van hierdie nuwe chirurgiese tegniek, die retrospektiewe evaluasie van die voordeel wat ‘n perineale liggaam herstel gesamentlik met ‘n posterior herstel mag hê, sowel as die

gerandomiseerde evaluasie vir nie-minderwaardigheid wat ‘n rektoseel plikasie in vergelyking met ‘n defek-spesifieke posterior herstel in dames met ‘n rektoseel het.

RESULTATE: Die PFDI-20, PFIQ-7 en PISQ-12 pelviese vloer vraelyste was bevind om geldig te wees in Afrikaans en Sesotho onder Suid-Afrikaanse dames en is ook bewys om akkuraat te reageer op kliniese veranderinge. Die integrasie van transperineale ultraklank bevindinge het gelei tot ‘n verandering in die finale hantering van 37.6% van dames en dit was mees betekenisvol in die pasiënte met posterior kompartement prolaps. Daar is bevind dat ‘n rektopeksie geen beduidende kliniese voordele inhou vir pasiënte wat ‘n omvattende sakrokolpopeksie ondergaan vir multi-kompartement pelviese orgaan prolaps nie. Die rektoseel plikasie prosedure, wat die vaginale herstel van die beskadigde anterior rektale wand behels, was anatomies suksesvol in 88.6% van pasiënte na ‘n gemiddelde tydperk van 27 maande en het ook gelei tot ‘n betekenisvolle verbetering in simptome sowel as algemene lewenskwaliteit. Die toevoeging van ‘n perineale liggaam herstel tot ‘n rektoseel plikasie het geen duidelike voordele ingehou in hierdie populasie nie. Die gerandomiseerde evaluasie van ‘n rekotseel plikasie en ‘n defek-spesifieke herstel het bevind dat die nuwe chirurgiese tegniek nie minderwaardig is as die bestaande tegniek ten opsigte van anatomiese sukses nie. Die anatomiese sukses was onderskeidelik 92.3% en 76.9% ($p=0.2488$, vertrouensinterval -13.6; 42.5). Die rektoseel plikasie was egter duidelik superieur tot die defek-spesifieke herstel ten opsigte van simptomatiese uitkomste na een jaar. ‘n Beduidende bevinding was die van urinêre disfunksie in hierdie populasie dames met geïsoleerde rektosele. Hierdie was die tweede mees algemene aanvanklike klagte waarmee hierdie dames gekom het en dit was betekenisvol verlig ($p=0.0011$) na die chirurgiese herstel van ‘n rektoseel in beide die retrospektiewe sowel as die prospektiewe analises.

GEVOLGTREKKING: Hierdie saamgestelde navorsingsprojekte het aangetoon dat ‘n volledige evaluering van dames met posterior kompartement abnormaliteite deur die gebruik van geldige vraelyste, gestandaardiseerde kliniese ondersoeke en gekombineerd met innoverende chirurgiese prosedures kan lei tot kliniese uitkomste wat geensins inferior is tot die wat elders ter wêreld gerapporteer is nie. Die geheelbeeld beklemtoon dat pragmatiese innovasie in ‘n gesondheidsisteem met beperkte hulpbronne kan lei tot internasionaal gelykwaardige resultate.

SLEUTELWOORDE: Beperkte hulpbronne, defek-spesifieke herstel, lewenskwaliteit, nie-minderwaarrdig, perineale liggaam herstel, posterior kompartement, rektoseel plikasie, transperineale ultraklank.

LIST OF ABBREVIATIONS

2D:	2 Dimensional
3D:	3 Dimensional
ACG:	American College of Gastroenterologists
AI:	Anal incontinence
ARA:	Anorectal angle
ATFP:	Arcus tendinous fascia pelvis
BMI:	Body mass index
CARE:	Colpopexy and urinary reduction efforts
CC:	Correlation coefficient
CI:	Confidence interval
CRADI-8:	Colorectal anal distress inventory-8
CRAIQ-7:	Colorectal anal impact questionnaire-7
DALY:	Disability-adjusted life year
DEP:	Defecating proctogram
DRE:	Digital rectal examination
DSR:	Defect-specific repair
EAS:	External anal sphincter
EMG:	Electromyography
FI:	Fecal incontinence
GH:	Genital hiatus
HIV:	Human immunodeficiency virus
IAS:	Internal anal sphincter
ICC:	Intraclass correlation coefficient

ICS:	International Continence Society
IUGA:	International Urogynecology Association
LOA:	Limits of agreement
MRI:	Magnetic resonance imaging
OAB:	Overactive bladder
ODS:	Obstructed defecation syndrome
PB:	Perineal body
PCSS:	Perineo-colpo-sacrosuspension
PEG:	Polyethylene glycol
PFD:	Pelvic floor dysfunction
PFDI-20:	Pelvic floor distress inventory-20
PFIQ-7:	Pelvic floor impact questionnaire-7
PISQ-12:	Pelvic organ prolapse/urinary incontinence sexual questionnaire-12
PISQ-IR:	Pelvic organ prolapse/urinary incontinence sexual questionnaire IUGA revised
PMDB:	Prevention and management of disruptive behaviour
PNTML:	Pudendal nerve terminal motor latency
POP:	Pelvic organ prolapse
POPDI-6:	Pelvic organ prolapse distress inventory-6
POPIQ-7:	Pelvic organ prolapse impact questionnaire-7
POP-Q:	Pelvic organ prolapse quantification system
PRH:	Pelonomi Regional Hospital
QOL:	Quality of life
RCT:	Randomized controlled trial

RPR: Rectocele plication repair

RVF: Rectovaginal fascia

RVS: Rectovaginal septum

RUTI: Recurrent urinary tract infection

SD: Standard deviation

STARR: Stapled transanal rectal resection

SUI: Stress urinary incontinence

TFS: Tissue fixation system

TPUS: Transperineal ultrasound

TVL: Total vaginal length

TVRR: Transvaginal rectocele repair

UAH: Universitas Academic Hospital

UDI-6: Urinary distress inventory-6

UI: Urinary incontinence

UIQ-7: Urinary impact questionnaire-7

UUI: Urge urinary incontinence

VAS: Visual analog scale

VMR: Ventral mesh rectopexy

WHO: World Health Organisation

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CHAPTER 1

BACKGROUND

1.1 INTRODUCTION

The posterior vaginal compartment has recently been labelled as “consistently inconsistent” in regards to its symptomatic unpredictability before and after treatment (Hale & Fenner 2016). Symptoms that have been associated with posterior compartment prolapse include vaginal bulging, dyspareunia, pelvic pressure, lower back pain, perineal ballooning, obstructed defecation, constipation, vaginal digitation, tenesmus, dyschezia and urinary incontinence amongst others. The association with functional and structural defecatory disorders are the most difficult to comprehensively explain (da Silva et al. 2006). Nichols summarized it well when he stated that there are many constipated women without rectocele, many women with rectocele who are not constipated and some women with constipation who have a rectocele (DH Nichols 1991).

Patient-reported outcomes are the primary determinant of successful treatment or not (Schwartz et al. 2016). As we move into a new era of medicine, quality of care and the fulfilment of patient expectation have moved to the fore. Rectifying a vaginal bulge is often not sufficient. It is thus essential to work towards understanding the symptoms behind pelvic floor disorders and unambiguously informing the patient on what surgery can and cannot do. The currently available literature leaves us with many questions that have no answer, and the majority of reviews recommend that new methods to studies are needed to achieve improved clinical outcomes (Hale & Fenner 2016)(Riss & Stift 2015)(Maher et al. 2013)(Ihnát et al. 2014).

1.2 RISK FACTORS

Pelvic floor dysfunction (PFD) is an umbrella term that incorporates disorders related to pelvic organ descent, bladder, bowel and sexual dysfunction as well as pelvic pain disorders. It is therefore conceivable that the risk factors for this spectrum of disorders should also be numerous. This is certainly the case with the knowledge base thus far. The recognized risk factors for PFD include pregnancy, levator avulsion, pelvic floor muscular dysfunction, genetic collagen composition and ethnic origin, obesity, constipation, menopause, ageing and previous pelvic surgery among others (Swift et al. 2001)(Walker & Gunasekera 2011)(de Boer et al. 2011)(Awwad et al. 2012)(Dietz et al. 2010)(Kudish et al. 2011)(Kudish et al. 2009). This risk profile is similarly shared by women who present with isolated rectoceles. The overall cause and effect relationship is however not clear, for dysfunction in a specific part is often associated with the development of subsequent symptoms and hence makes it problematic to correlate anatomy with symptomatology. It is also cause for difficulty in predicting outcome to treatment and predominantly for surgical treatment outcomes in the posterior compartment (Hicks et al. 2014)(Grimes & Lukacz 2012).

1.3 SOUTH AFRICAN HEALTHCARE SYSTEM

South Africa with its population of approximately 57 million people is classified as a developing country within the international context (Statistics-South Africa 2016). The healthcare system comprises of two poles. The South African healthcare system is embedded in a background of racial subordination and sexual violence against girls and women and of hierarchical male authority from youth to adulthood. Low wages, unemployment, urban overcrowding, inadequate sanitation, malnutrition, crime, and violence have contributed to economic and health inequality. The proportion of gross

national product spent on health care is slowly increasing and two-thirds of health expenditures are estimated to be consumed by the private sector at a time when the cost of health insurance has risen to more than three times the rate of the consumer price index (Younger 2016).The private healthcare system serves approximately 17% of the population and provides access to diagnostic and therapeutic services not inferior to those of any developed country. The public healthcare system serves approximately 83% of the population and is plagued with the burden of communicable disease – especially human immunodeficiency virus (HIV) - underfunding and maladministration. The National Department of Health has described this system as one of two tiers, divided along socioeconomic lines.

South Africa is one of the few developing countries experiencing an increase in the proportion aged 60 and over from 6.61% in 2002 to 8.01% in 2016. There is additionally a decrease in the total fertility rate and this indicates that South Africa's population is ageing. The growing proportion of elderly in South Africa will bring new challenges that needs to be addressed and it is universally recognized that pelvic floor disorders are predominantly conditions that affect the ageing female population. The majority of funding is however currently channelled to the treatment and prevention of the HIV infection, and not to quality of life (QOL) related conditions, such as pelvic floor disorders (Mayosi et al. 2012).

This research is conducted in the Free State province of South Africa. The provincial health department was placed under administration in 2013 due to chronic overspending of its annual budget and deficiencies in the delivery of basic healthcare services. The Free State province additionally has the highest prevalence of disability

in South Africa accompanied by one of the highest rates of unemployment (Statistics-South Africa 2016).

1.4 IMPACT OF PELVIC FLOOR DISORDERS

Pelvic floor disorders can impact all aspects of an affected individual's life. This not only include sexual, bladder, bowel and vaginal dysfunction, but also the ability to perform daily activities and social interactions (Yount 2013). The aspect that is less well understood is the severity of this impact on a person's QOL.

The World Health Organisation (WHO) estimates the morbidity of a condition through the use of the global burden of diseases concept. This concept utilises a summary of outcomes known as the Disability-Adjusted Life Year (DALY) and can be described as the sum of life years lost as a result of a disease or disability (Stein et al. 2007). Svihrova et al. examined this concept in women with pelvic organ prolapse (POP) (Svihrova et al. 2014). They found that the QOL of women with POP is severely affected and that the estimated DALY lost per year per 1000 women were 217.0 in a 50-year old woman compared to 324.8 in a 60-year old woman. This translated into 14.5 lost years in the average 50-year old woman compared to 10.3 lost years in the average 60-year old woman.

This requires to be placed into perspective. The Global Burden of Diseases, Injuries, and Risk Factors Study 2015 provides current data on multiple conditions and its DALY impact (GBD Risk Factors Collaborators 2016). The largest global contributors to DALYs were systolic hypertension, smoking, diabetes mellitus and obesity. Figure 1 from this article illustrates the proportional contribution of risk factors to DALYs and the regional variations.

Svihrova et al. calculated the DALY associated with POP to be 217-324.8 in their population. The similarly calculated DALY associated with smoking is 1708.9, with diabetes mellitus it is 1430.7 and with systolic hypertension it is 2118.1. The DALY calculated for occupational injuries is 134.9 and for diarrhoeal disease associated with unsafe sanitation is 400.05. It can therefore be appreciated that the impact of POP is significant in the context of certain global disease conditions, but likely underappreciated based on the lack of publications in this regard. This is however expected to change as the female population ages and in association with the prevalence of other risk factors such as obesity and constipation.

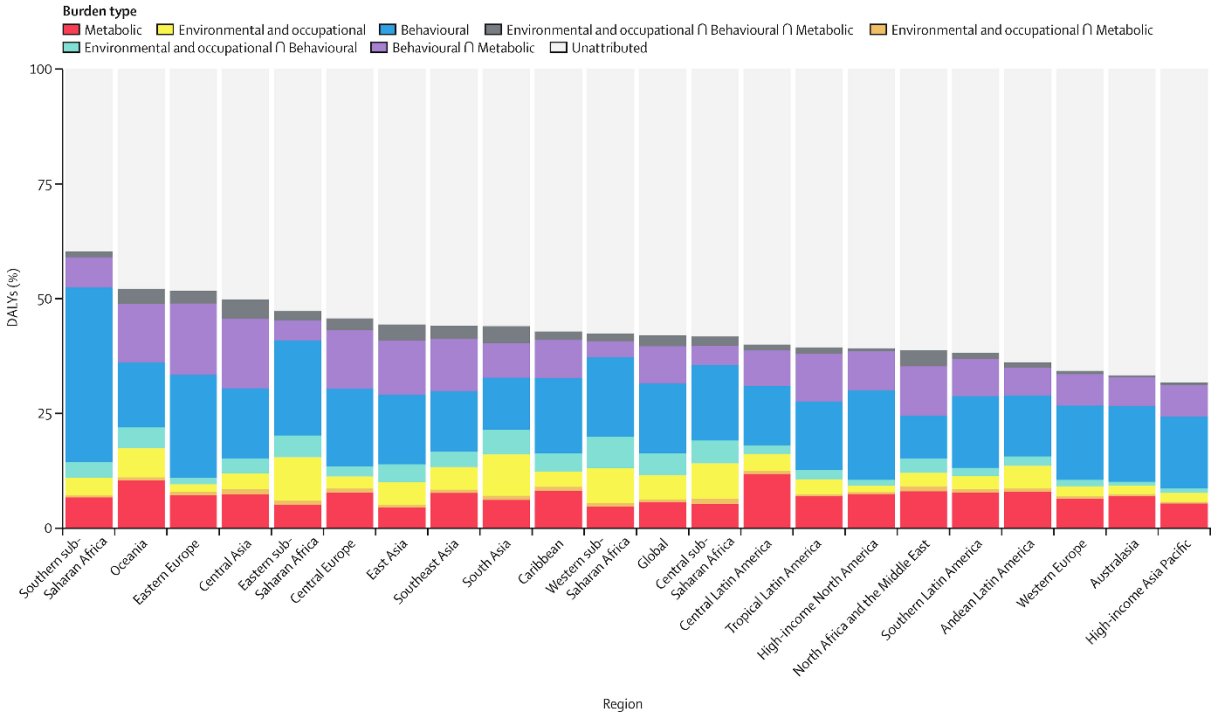

Figure 1. Global proportion of all-cause DALYs attributable to behavioural, environmental and occupational, and metabolic risk factors and their overlaps by region for both sexes combined in 2015. Locations are reported in order of total all-cause DALYs population attributable fraction. DALYs=disability-adjusted life-years. ∩=interaction. From: (GBD Risk Factors Collaborators 2016).

One can suppose that the change in DALYs will become more apparent in developed countries and only much later in the developing countries due to the significant behavioural contribution to disease and specifically communicable diseases in

developing countries. The true impact of pelvic floor disorders is therefore expected to emerge in the published literature as the aging population increases and this will in future be reflected in public health policies and funding models.

1.5 OBJECTIVE

The primary aim of this research is to describe and explore aspects pertaining to the evaluation and management of women who is found to have a symptomatic rectocele with the objective of identifying the most effective and accessible modalities in a healthcare setting with limited resource capabilities.

1.5.1 THE SECONDARY AIMS NECESSARY TO ACHIEVE THE PRIMARY OBJECTIVE

To evaluate:

- Condition-specific QOL questionnaires for women with pelvic floor disorders
- The role of transperineal ultrasound (TPUS) imaging in women with pelvic floor disorders
- The evaluation of a rectocele plication in women with posterior compartment prolapse
- The contribution of a perineal body repair in women with posterior compartment prolapse
- The role of a rectopexy concomitant with a sacrocolpopexy in women with pelvic organ prolapse
- The evaluation of a rectocele plication in comparison to a defect-specific repair in women with posterior compartment prolapse

1.6 OUTLINE OF THESIS

Chapter 1 provides the background to the study, as well as a description of the problem statement, objectives and an outline of the thesis.

Chapter 2 presents a literature review in support of the proposed study.

Chapter 3 contains a description of operational definitions, measuring techniques and the population.

Chapter 4 investigates the validation of three condition-specific quality-of-life health questionnaires in the South African population for the languages of Sesotho and Afrikaans.

Chapter 5 examines the role of a 2-dimensional transperineal ultrasound assessment in women with pelvic floor disorders and the integration of this imaging modality in clinical decision making.

Chapters 6 reviews surgical treatment options for women with posterior compartment prolapse.

Chapter 7 evaluates the effect of the randomized addition of a rectopexy to a sacrocolpopexy in women with advanced general pelvic organ prolapse.

Chapter 8 describes the clinical outcomes after a rectocele plication for women with posterior compartment prolapse.

Chapter 9 evaluates the role of reconstructing the perineal body at the time of a posterior compartment repair

Chapter 10 investigates the outcomes after random allocation of women with symptomatic posterior compartment prolapse to undergo either a rectocele plication or a defect-specific repair.

Chapter 11 provides conclusions and recommendations.

CHAPTER 2

RECTOCELE: LITERATURE OVERVIEW AND POSITIONING OF STUDY AIMS

2.1 INTRODUCTION

The female pelvic floor is a complex anatomical structure whose purpose is integrally related to bladder, bowel and sexual function. Consequently, the effects of pelvic floor weakness frequently manifest as dysfunction in any or all of these areas. POP refers to the downward displacement of structures associated with the anterior, apical or posterior vaginal compartments (Bernard T Haylen et al. 2016). It is a prevalent condition, especially in multiparous females, and requires surgical reconstruction in up to 20% of women in their lifetime (Wu, Matthews, et al. 2014).

Disorders of the posterior pelvic floor include a wide range of afflictions which may present with pelvic floor dysfunction and commonly disturb defecatory function. Normal defecatory function is the complex result of anatomic and physiological interactions (Sultan et al. 2016). This is an integral element of a dynamic female pelvic floor and its functionality is dependent on a normal anatomical environment (DeLancey 2016).

Gynecologists traditionally described a rectocele as a herniation of the anterior rectal wall of the rectum outside its normal confines, such that it causes protrusion of the posterior vaginal wall and/or the perineum. Coloproctologists on the other hand recognized this abnormality via rectal examination – often without regard to vaginal prolapse – and also identified posterior rectoceles that involves the posterior rectal

wall (MA Kahn 1998). Recent work from the International Urogynecology Association (IUGA) and the International Continence Society (ICS) has resulted in the publication of terminology papers to standardize the description of POP and anorectal dysfunction (Bernard T Haylen et al. 2016)(Sultan et al. 2016). Posterior vaginal wall prolapse is defined as the observation of descent of the posterior vaginal wall, often resulting in protrusion of the rectum into the vagina. A rectocele is defined as a bulge in the posterior vaginal wall which is associated with herniation of the anterior wall of the rectum. The anterior rectal wall can furthermore result in a perineal bulge, in which case it would be defined as a perineocele (Sultan et al. 2016).

2.2 EVIDENCE-BASED MEDICINE

Evidence-based medicine has contributed significantly to the understanding of pelvic floor function and dysfunction. In 1926 women were advised to adopt a “kangaroo walk” for a period of one month after delivery to prevent POP (Lynch FW 1926). We have fortunately moved on from this approach.

Contemporary clinical challenges exist in regards to the evidence-based management of women with rectoceles for several reasons. Firstly, much of the surgical management and outcomes presented in gynecologic literature is summarized together with concomitant procedures such as hysterectomy, cystocele repair, and levatorplasty (Karram & Maher 2013). Until relatively recently, most of this literature also did not take into account the clinical relevance or pathophysiological basis of associated defecatory disorders. There is secondly still ongoing controversy concerning the anatomical and embryological importance (or even existence) of the rectovaginal septum (RVS) as well as its involvement in the pathogenesis of middle

and low rectoceles (Zbar et al. 2003)(Kleeman et al. 2005)(Stecco et al. 2005)(Milley & Nichols 1969). These reasons challenge the finer differentiation of evidence and when combined with individual characteristics, it results in the need to make management decisions beyond the basic classification of levels of evidence.

2.3 EPIDEMIOLOGY

2.3.1 PELVIC ORGAN PROLAPSE IN GENERAL

The prevalence of POP ranges between 12-84% worldwide among parous women. Significant variation exists among the specific populations studied and the definition used in determining prevalence (Wu, Matthews, et al. 2014)(Walker & Gunasekera 2011)(de Araujo et al. 2009)(Chuenchompoonut et al. 2005)(Garshasbi et al. 2006)(Scherf et al. 2002). There is no epidemiological data for the South African female population in this regard. It is furthermore difficult to assume a predictive model based on published data due to the ethnic diversity of this population. Genetic factors and specifically collagen composition contribute significant risk and is currently the probable explanation for the variation in prevalence of anatomic defects documented in different ethnic groups (Lince et al. 2012)(Kudish et al. 2011)(Buchsbaum et al. 2006)(Söderberg et al. 2004)(Mattox & Bhatia 1996)(Bump 1993). Additional factors contributing to the epidemiological profile of POP is the present increase in life expectancy and prevalence of obesity in modern societies (Quiroz et al. 2012)(Halverson & Boller 2010). There is furthermore documented ethnic differences in the knowledge of pelvic floor dysfunction and this is reflected in the subsequent care seeking behaviour among women from developing nations (Rizk 2008). This underlines the inherent selection bias in estimates based on hospital data and factors

such as convenience of consultation, provider gender preference, access to health care facilities, expectations from health care, language proficiency, incurred service cost, and perceptions of medical encounter that all influence the estimation of epidemiological data (Rizk 2009)(El-Azab & Shaaban 2010) (Shah et al. 2008).

The natural history of POP after menopause showed that the progression rate for stage 1 POP was 13.5 per 100-women years and that the annual regression rate was 22 per 100-women years (Handa et al. 2004). POP furthermore mostly become symptomatic only once it reaches the level of the hymen, equivalent to an ICS pelvic organ prolapse quantification (POP-Q) stage ≥ 2 (Ellerkmann et al. 2001). Recent literature have questioned both the value of identifying stages 0 and 1 POP, as well as the correlation of POP-Q stage 2 measurement with the presence of clinical symptoms of pelvic floor dysfunction (Dietz & Mann 2014). POP is however not a condition that occurs exclusively in parous women as a recent survey by Durnea et al. found. In this survey of nearly 1500 nulliparous women in Ireland, they documented bothersome pelvic floor dysfunction among 37% of the participants (Durnea et al. 2014). This disparity in epidemiological data and the particulars raised, affirms the complexity of PFD beyond a simplistic determination of clinically observed POP severity.

2.3.2 POSTERIOR COMPARTMENT PROLAPSE

Posterior compartment (vaginal wall) prolapse includes those of rectocele, enterocele and a perineocele. An enterocele will mostly, but not exclusively, occur after a hysterectomy (Sultan et al. 2016). There is however more to the posterior compartment that needs to be kept in mind in women presenting with associated

defecatory dysfunction (Pescatori et al. 2006). Rectoceles and enteroceles have been described in 40% of asymptomatic parous women (Burrows et al. 2004) and this combinatined defects are also more prevalent in obese women (Hausammann et al. 2009). In a report by Kenton et al. using pelvic floor fluoroscopy in women presenting with posterior POP, they identified rectoceles in 82% and enteroceles in 71% of their population (Kenton et al. 1999). This is in agreement with the often-observed co-existence of these disorders in women presenting with posterior compartment POP.

2.3.3 RECTOCELE

The true prevalence of rectoceles reveal a similarly limited evidence base. In the Women's Health Initiative, 41% of women aged 50-79 years showed some amount of POP. This included a cystocele in 34%, uterine prolapse in 14% and a rectocele in 19% (Hendrix et al. 2002). Handa et al. calculated the prevalence of a rectocele in 12.9-18.6% of women and they estimated the annual incidence to be 5.7 cases per 100-women years (Handa et al. 2004). POP is believed to be less prevalent among women of black ethnicity. The lower prevalence that has been recorded for POP in general among ethnic black women have been challenged by a publication performed among Nigerian women that identified a rectocele in 11.4% of women over the age of 40 years, which is similar to those reported in other populations (Okonkwo et al. 2003). Pelvic floor imaging among Ugandan nulliparous women have additionally questioned the assumption that black ethnicity is a protective factor against the development of POP (Shek et al. 2016). Other authors have questioned the true accuracy and the variation in pelvic floor disorders described among different ethnic groups without

taking into account the existence of barriers to healthcare (Dunivan et al. 2014)(Rizk 2008).

A rectocele is defined as a posterior vaginal bulge according to the current IUGA/ICS terminology for anorectal dysfunction (Sultan et al. 2016) and the severity described according to the POP-Q system (Bump et al. 1996), but defecography studies have illustrated the presence of small to moderate size rectoceles in up to 20-81% of women, some of whom were asymptomatic nulliparous volunteers and others who had defecatory disorders (Greenberg et al. 2001)(Healy et al. 1997)(Siproudhis et al. 1992)(Shorvon et al. 1989). These would not have been classified as rectoceles if the official terminology alone was used. Pelvic floor imaging have identified rectoceles in 39% of women recruited form a urogynecology outpatient department (Steensma & Dietz 2004). This divergence has resulted in uncertainty of the true prevalence of rectoceles and in the identification of what a clinically significant rectocele entails.

Olsen et al., in a commonly cited publication, identified the presence of rectoceles in 76% of women with POP who required surgical intervention (Olsen et al. 1997). Reviews of surgical registries report that a posterior compartment repair is performed in 40-85% of cases of POP reconstruction (Olsen et al. 1997)(Karram & Maher 2013)(Richardson et al. 2012)(Pollak & Davila 2003). Rectocele severity is strongly associated with the severity of prolapse in the other vaginal compartment (Mourtialon et al. 2013), but isolated rectoceles however appear to be more uncommon and have been reported in only about 7% of women presenting for surgical repair of POP (Kudish & Iglesia 2010).

The natural history of rectoceles lacks in-depth evaluation, but a common assumption is that it will increase in size over time depending on the underlying risk factors (Goh et al. 2002).

2.4 RESOURCE LIMITED HEALTHCARE ENVIRONMENT

2.4.1 THE SOUTH AFRICAN SCENARIO

POP is not limited by socio-economic affluence and afflicts women worldwide (Gunasekera et al. 2007). The demand for healthcare resources worldwide will always exceed supply (Kluge 2007)(Mitton & Donaldson 2004). Low and middle income countries find it even more challenging to deliver universal access to healthcare and a lack of financial support discourages the individual from accessing healthcare services (Mills 2014). The main aim in these countries is to primarily reduce mortality. South Africa can be classified as a middle income country where there is a clear divide in access to healthcare between the small percentage of insured individuals accessing private healthcare and the majority of the population whom are dependent on an underfunded public healthcare system as was mentioned in Chapter 1 (Ataguba et al. 2014)(Mayosi et al. 2012)(Coovadia et al. 2009). Limited resources denote human resources (healthcare workers), access to diagnostic equipment and availability of medical and surgical consumables. The lack of these elements are all compounded by bureaucratic inefficiency (Mills 2014)(Mayosi et al. 2012) and the ever diminishing resources are confronted by an ever increasing volume of patients needing access to these resources (Amoako-sakyi & Amonoo-kuofi 2015) (Evans et al. 2015).

South Africa is one of many developing countries that produces only a tiny fraction of the world's health research literature. Clinical research in South Africa in recent times

have experienced a persistent decline in public funding. The health departments of provincial governments are primarily funded for basic service delivery and mostly overspend their annual budgets in an endeavor to reach this mandate with limited or no budget allocation for research (Coovadia et al. 2009)(Siegfried et al. 2010). When funding is made available, it is mostly allocated to research directed towards communicable diseases.

The realities of patient circumstances in resource limited settings include barriers to potential therapeutic interventions and the ability to comply with these interventions. Factors such as poor nutrition, unemployment, limited access to transportation and population-specific social norms contribute significantly to an individual's management plan (Kim et al. 2013).

The urogynecology unit at Universitas Academic Hospital (UAH) sees approximately 870 patients with pelvic floor disorders per year. It is a tertiary referral unit in a teaching hospital that serves a geographic area covering 43% of the country. The drainage area includes the Northern Cape Province, the Free State Province, the northern parts of the Eastern Cape Province as well as the southern parts of the North West Province. Reconstructive surgery is performed on approximately 230 patients per year. The dedicated staff consists of a registrar rotating in this unit for three months at a time, two consultants and a pelvic floor physiotherapist. Diagnostic equipment consists of two 2-dimensional (2D) ultrasound machines and urodynamic equipment enabling the performance of cystometry. The catheters used for cystometry are however mostly not available and results in limitations to this service.

2.4.2 INNOVATION IN A RESOURCE LIMITED ENVIRONMENT

Recommended assessments of individuals with defecatory disorders in a well-resourced healthcare environment includes the following: anorectal manometry, surface electromyography, balloon expulsion testing, endo-anal ultrasound, evacuation proctography, scintigraphic defecography, barium enema or colonoscopy screening, colonic transit studies, dynamic magnetic resonance imaging and biochemistry testing (Podzemny et al. 2015). The clinical value of detailed anorectal testing at large has not been clearly demonstrated and it is accepted to be reasonable to plan therapeutic interventions after a detailed clinical assessment, especially if there is an element of imaging involved to evaluate for concomitant disorders (Lam & Felt-Bersma 2013).

Conservative treatment for women with defecatory disorders in association with a rectocele is always recommended prior to a surgical intervention in any healthcare setting (Brown & Grimes 2016). Additional recommendation such as biofeedback therapy and dietary changes are often not attainable in limited resource settings due to the practicalities of accessing this service and the ability to financially comply with it (Mills 2014).

It is therefore a constant strive to deliver outcomes on par with international standards, but with limited access to special investigations and diagnostic equipment (Tran & Ravaud 2016). Frugal innovation describes this endeavor. It encompasses the heterogeneous activities which aim to provide functionally effective solutions with minimal use of resources to regularly encountered problems. These innovations frequently arise in low-resource settings when usual solutions are too expensive or not available. In these constrained environments people work with what they have, using

affordable but effective tools, processes and techniques to solve their problems (Tran & Ravaud 2016). This approach in low resource environments does not necessarily imply an inferior quality of service or management and the idea of “reverse innovation”, i.e. the flow of ideas from a lower to a higher income setting, is increasingly gathering consideration and has led to fruitful partnerships between developed and developing countries (Syed et al. 2012).

2.5 CLINICAL APPROACH TO THE EVALUTION OF A RECTOCELE

2.5.1 POSTERIOR COMPARTMENT AND RECTAL ANATOMY

It is essential to briefly discuss the relevant anatomy as it relates to the posterior compartment and rectum prior to proceeding to the clinical assessment of a rectocele.

2.5.1.1 VAGINAL SUPPORT

Vaginal support is on three levels as described by DeLancey (DeLancey 1992). The vaginal apex is supported by the cardinal-uterosacral ligament complex. The midvagina is laterally supported by the endopelvic fascia originating from the arcus tendinous fascia pelvis (ATFP) and the lateral posterior vagina is attached to the levator plate. The distal posterior vagina is attached to the perineal body and supported by the levator ani muscle and perineum. The perineal membrane is directly below the pelvic diaphragm. It is laterally attached to the ischiopubic rami and medially to the distal third of the vagina and posteriorly to the perineal body (Arakawa et al. 2004)

Some authors consider the cervix as the superior central tendon and the perineum as the inferior central tendon of support (Petros & Inoue 2013). The levator ani muscle is divided into four parts. Three of these are named for the component of pubic bone from which they originate: pubococcygeus, iliococcygeus, and ischiococcygeus. The fourth, the puborectalis, arises from the posterior symphysis pubis and loops around the recto-anal flexure, intermingling its fibers with the external anal sphincter (EAS) (Stoker 2009). Contraction of the levator ani compresses the vagina in an anterior direction and relieves load bearing. The distal vagina however does not benefit from the levator contraction and this is likely why there is a clear layer of dense connective tissue to provide protection at this level (DeLancey 1999).

2.5.1.2 RECTOVAGINAL SEPTUM

Numerous synonyms have been used to describe the layer(s) between the posterior vagina and rectum. These included Denonvillier's fascia, rectogenital septum, rectovaginal septum (RVS), perirectal fascia, prerectal fascia, and vaginal fascia among others (MA Kahn 1998).

The distal one-third of the posterior vaginal wall fuses with the aponeurosis of the levator ani muscle from the perineal body along a line called the arcus tendinous rectovaginalis. This line converges with the ATFP approximately halfway between the pubic symphysis and the ischial spine (Leffler et al. 2001). The anterior wall of the rectum and the distal posterior vaginal wall are fused for the lower approximately 3-4 centimeter (DeLancey 1999). This was confirmed in live dissections where the mean longitudinal length of the perineal body was found to be 4.5 (3.5-5.5) centimeter and it accounted for 50% of the posterior vaginal support (Wagenlehner et al. 2013).

There has been long-standing debate concerning the existence and integrity of the RVS and the rectovaginal fascia (RVF). Initial adult and fetal cadaveric dissections by Uhlenluth et al. described this septum and this was later affirmed by Richardson (Uhlenluth et al. 1948)(AC Richardson 1993). Fritsch et al. also identified this fascia which consisted mainly of collagenous fibers without any smooth muscle cells and which is most evident caudally in the vagina (Fritsch et al. 2012). This is essentially in agreement with the work of DeLancey and others which confirms only distal fusion of the posterior vaginal wall with that of the perineal membrane (DeLancey 1999)(Ludwikowski et al. 2002). Histological studies have noted that what has previously been termed fascia is actually vaginal muscularis in both the anterior and posterior compartments and fascia could not be identified as a separate histologic layer from the vaginal muscularis (Farrell et al. 2001). The fascial support of the mid- and proximal vagina is primarily lateral with very few fibres crossing the midline and it is in close proximity to the longitudinal muscle fibers of the rectum (Corton 2005)(Leffler et al. 2001). Histological assessment of the posterior mid-vaginal wall specifically, noted the following layers from the lumen of the vagina to the lumen of the rectum: the vaginal epithelium, the lamina propria of the vagina, the fibromuscular wall of the vagina (smooth muscle cells, elastin and type II collagen), the adventitia, the outer muscular wall of the rectum, the inner muscular wall of the rectum, the lamina propria of the rectum and the rectal mucosa (Kleeman et al. 2005). It is the fibromuscular wall of the vagina and adventitia that comprise the layer often referred to as the RVS or RVF. The separation of these layers from the lamina propria of the vagina is what many surgeons find in the operating theater and describe to be plicating. It is this layer that can be easily found in the distal one third of the vagina as this is where the rectum and vagina are densely fused. Proximal to this, there is

increased adipose tissue in the adventitial layer which guides dissection so that there does not appear to be a “fascial layer” left to plicate more proximally (Grimes & Lukacz 2012).

The posterior vaginal support is thus suggested to be multifaceted and reliant upon the endopelvic fascia, levator ani muscle, and perineal membrane. Distally the perineal membrane fibers are effectively horizontal and it becomes parasagittal in the midvagina, connecting the vaginal channel to the pelvic diaphragm (DeLancey 1999).

2.5.1.3 RECTAL ANATOMY

The rectum itself is approximately 12 centimetres long and has three lateral curves, the rectal valves of Houston, often two on the left and one on the right. The rectal wall comprises of colonic epithelium, lamina propria, muscularis mucosae, submucosa and the muscularis propria. The latter concerns an outer longitudinal layer and an inner circular layer. The inner circular layer thickens at the anorectal junction, forming the internal anal sphincter (IAS). The longitudinal layer continues as the longitudinal layer of the anal sphincter. The ampullary portion of the rectum rests on the pelvic diaphragm. At this level, the rectum turns backwards and downwards at about a 90-degree angle at the anorectal junction. In women, the rectum is relatively anterior to the upper vagina and uterus. Lateral condensations of the endopelvic fascia give lateral support to form the lateral rectal ligaments (or pillars). The lateral ligaments course from the posterolateral pelvic wall at the level of the third sacral vertebra to the rectum. The ligaments have a divergent spiral course, being posterior at the rectosigmoid junction and anterolateral at the lower third of the rectum. Within these ligaments run the posterior portion of the inferior hypogastric nerve, which supplies the

rectum in its anterolateral wall and the middle rectal vessels. The nerve supply to the rectum is via the autonomic system from the superior hypogastric nerve (sympathetic) and from the inferior rectal nerve (parasympathetic / motor). The inferior hypogastric nerve (S2-4) gives sensory supply and helps to distinguish between flatus and feces (Stoker & Wallner 2008)(Sultan et al. 1993)(Hsu et al. 2008)(DeLancey 2008)(Park et al. 2010). The posterior rectum is fixed to the sacrum by Waldeyer's fascia (Arakawa et al. 2004)

2.5.1.4 ANAL ANATOMY

The anal canal makes up the most distal part of the posterior compartment. The canal is 4–6 cm (average 5 cm) in length and the lining of the anal canal changes along the length of the canal. In its upper part is colonic-type mucosa arranged into 6–10 vertical folds, called the anal columns, which are separated by grooves. The mucosa has muscularis mucosae at this level. At the caudal end of each anal column is a fold, the anal valve, with the opening of submucosal anal glands just above this. This is adjacent to the dentate line which has autonomic nerve supply above it and somatic nerve supply (inferior rectal nerve) below it as well as a portosystemic venous connection (Rociu et al. 2000)(Beets-Tan et al. 2001). The IAS is a smooth muscle sphincter which is the continuation of the circular layer of the muscularis propria of the rectum. The IAS is important in maintaining anal sphincter rest pressure and is approximately 2–3 mm thick. With age, the IAS increases in thickness in both sexes. It does not extend to the lower edge of the external anal sphincter (EAS), but ends approximately 1 cm above this level. The lower muscular part of the anal sphincter therefore only constitutes external sphincter (Rociu et al. 2000)(Beets-Tan et al. 2001).

The inter-sphincteric space is a thin fat-containing space with variable thickness: it may be hard to discern in some and easily visible in others. The space is between the IAS and the outer striated muscles (external sphincter and puborectalis). The inter-sphincteric space contains the longitudinal layer (also named longitudinal muscle), which is the continuation of the smooth muscle longitudinal layer of the rectum. The longitudinal layer receives contributions from the levator ani, particularly the puboanalis (Gladman et al. 2005). The EAS is approximately 2.7 cm high, but is anteriorly shorter in women (approximately 1.5 cm). The external sphincter has a thickness of 4 mm and extends approximately 1 cm beyond the IAS. The EAS has posterior fibres continuous with the anococcygeal ligament. Some of the anterior fibres decussate into the superficial transverse perineal muscles and perineal body. The deep part of the EAS is intimately related to the puborectalis (Rociu et al. 2000)

2.5.2 PHYSIOLOGY OF DEFECATION AND CONTINENCE

During normal defection, stool enters the rectum from the sigmoid colon and is detected by stretch receptors in the pelvic floor or rectal wall. In this way, the urge to defecate is produced. The anal sampling reflex detects the difference between stool and flatus by allowing the contents of the rectum to come into contact with the more sensitive anal canal lining by relaxing the IAS (the recto-anal inhibitory reflex). Distension sensation receptors are located in the mucosa and muscular wall. The muscular receptors are more sensitive to the intensity of distension. Continence at this time is preserved because there is simultaneous contraction of the EAS. If defecation is not convenient, contraction of the EAS and puborectalis propels the stool proximally into the sigmoid colon, the IAS regains its resting tone, and defecation is deferred.

Continence is additionally maintained by the levator ani muscles. These muscles are comprised of a unique type of striated muscles that contain a majority of type I (slow twitch) muscle fibers, maintaining a constant resting tone over time. Each muscle group also contains a smaller proportion of type II (fast twitch) fibers, permitting them to respond quickly during sudden increases in intra-abdominal pressures (Gosling & Emmanuel 2014). Contraction of the pelvic diaphragm closes the genital hiatus and provides a horizontal levator plate on which the pelvic viscera lie. This also pulls the distal vagina and anorectal junction toward the pubic symphysis and creates a near 90° angle between the anal and rectal canals, referred to as the anorectal angle (ARA) which is a supplementary addition to the continence mechanism (PH Gordon 2001). Fecal continence is furthermore dependent on the complex interaction of rectal motility, compliance, capacity and sensation (Davis & Kumar 2005)

2.5.3 PATHOGENESIS OF A RECTOCELE

2.5.3.1 TYPES OF RECTOCELE

There is no universally accepted descriptive system for rectoceles. DeLancey described three types of posterior compartment prolapse: 1- distal failure in the perineal body, 2 - failure of the levator ani muscles to close the genital hiatus, and 3 - failure that is more proximal with the loss of upward suspension of the posterior wall by the uterosacral ligaments (DeLancey 1999).

Rectoceles have also been described to occur at three levels: low, middle and high. Low and middle rectoceles are generally believed to be associated with childbirth trauma and concomitant anal sphincter effects can co-exist. It is assumed to originate in response to disruption of the rectovaginal attachment to the perineal membrane

(Abendstein et al. 2008). Pudendal neuropathy is prevalent after vaginal childbirth (MA Kahn 1998). Neurophysiologic studies have furthermore demonstrated that pudendal neuropathy is associated with excessive perineal decent which can often be detected in patients with low rectoceles (Ho et al. 1998)(Lien et al. 2005). Excessive perineal descent has also been associated with displacement of the levator plate as a result of levator ani dysfunction (Beco 2008)(Dietz et al. 2016)(Rostaminia et al. 2015). With the emergence of evidence obtained from imaging, the importance of perineal support has been emphasized. Perineal descent was shown to be the factor most strongly associated with rectoceles in nulliparous women (Dietz & Clarke 2005). Steensma et al. similarly concluded that the loss of perineal support, exposure of the posterior vaginal wall and levator hiatus enlargement were the more important factors in the pathogenesis of rectoceles, rather than RVS defects (Steensma & Dietz 2004).

Mid rectoceles are thought to be due to overstretching of the rectovaginal endopelvic connective tissue or attenuation of this fascia. DeLancey postulated that levator ani dysfunction – either due to avulsion or underactivity – places considerable stress at the mid-vaginal level and this, with associated perineal membrane disruption, leads to the formation of rectoceles. Beck et al. explains this observation further in that the levator plate extends from the pubic bone to the sacrum/coccyx and provides support for the change in vaginal axis from vertical to horizontal along the mid vagina. Further assistance from the levator ani provides constant tone and maintains the urogenital hiatus size. A rectocele typically develops in the background of levator dysfunction at or below the levator plate and along the vertical vaginal plane, resulting in anterior displacement of the rectal wall (Beck & Allen 2010). This disturbance in the support mechanism, resulting in anterior displacement of the rectal wall with subsequent

increased forces exerted on the rectal muscularis, is thought to lead to a gradual increase in the rectocele size over time.

High rectoceles which protrude into the proximal vagina on the other hand are considered to be due to level 1 defects (DeLancey 1999). They have been observed to frequently be associated with other disorders such as enteroceles (Davis & Kumar 2005).

Further light is shed on the pathogenesis of rectoceles when one look at the occurrence thereof in males, in whom it is rarely seen. The limited space between the prostate and the urogenital diaphragm (perineal membrane) prevents the development of a rectocele. It has however been described after prostatectomy and the pathogenesis is due to the creation of a potential space, which, in individuals with constipation and straining, allows herniation of the anterior rectal wall (Cavallo et al. 1991).

2.5.3.2 RECTAL WALL CHANGES

Sarles et al. noted that the horizontal fibers of the circular muscle of the rectum become spread apart in rectoceles and transanal rectocele repairs developed partially in recognition of the fact that a vaginal repair might not correct a ballooning anterior rectal wall (Sarles et al. 1989). This muscular thinning of the anterior rectal wall has subsequently been confirmed by other authors (Regadas et al. 2007)(Frøkjær et al. 2005). In addition, histological studies of the rectal wall in women known with obstructed defecation have confirmed that the biomechanical qualities were significantly different between the anterior and posterior part of the rectal wall as a result of this anterior displacement. The anterior wall was found to be less elastic and

more fragile than the posterior wall (Bruninieks et al. 2013). The extent of damage to the RVF or anterior rectal wall is likely to be variable and may be one of the factors that determine whether a rectocele causes symptoms and the extent of these symptoms (DH Nichols 1991)(Marks 1967). Marks describes this process which occurs over time even further. He states that when a rectocele develops, there is thinning of the posterior vaginal wall; and, since the adjacent anterior rectal wall has greater distensibility, it, too, is stretched. Because of the dehiscence that forms in the vaginal fibromuscularis layer, a pocket of rectal mucosa protrudes into it. The rectocele may not become symptomatic until the fourth or fifth decade of life for by that time a gradual change in the connective tissue of the body has occurred which brings relaxation of all supporting structures (Marks & Goldman 2012).

2.5.3.3 OBSTETRIC EVENTS

Vaginal childbirth is frequently cited as a significant contributing factor in the development of rectoceles. Nichols blamed separation of the rectal fascia, bulbocavernosus muscle and levator fascia from the perineal body during birth as the main reason for the development of low rectoceles (DH Nichols 1991). The contributing effect of childbirth was confirmed in an ultrasound study which evaluated primigravidae antenatally as well as postpartum. Defects in the RVS were seen in 3% of these women antenatally and in 15% postpartum. Those with antenatal defects all showed deepening of the rectocele depth postpartum (Dietz & Steensma 2006). A similar study recently reported matching finings of 4% and 16% respectively (Guzmán Rojas et al. 2015). This observed effect is likely to be a combination of maternal and fetal factors and not a simplistic model of fascial injury. Maternal android pelvic shape

is known to be associated with occipito-posterior fetal positions, which is acknowledged to be associated with prolonged labour and has a subsequent increased risk for posterior compartment disorders (Tillack et al. 2015).

The complexity of the pathogenesis of a rectocele is however highlighted by its finding in 12-80% of nulliparous women (Dietz & Clarke 2005)(Lukacz et al. 2006)(Buchsbaum et al. 2006)(Shorvon et al. 1989). This confirms that although obstetric events are a probable reason fot the development of this condition, it is unlikely to be as important a cause as is the case for other types of POP.

2.5.3.4 CHRONIC STRAINING

Straining on its own is unlikely to result in a rectocele in the absence of underlying levator ani, endopelvic fascial or pudendal nerve injury or dysfunction. The condition of anismus illustrates this. In these patients, straining occurs against a contracted puborectalis and EAS with resultant attenuation of the rectovaginal septum over time only (Johansson et al. 1992). Surgical procedures such as the Burch colposuspension lead to opening up of the genital hiatus and therefore increases the risk of posterior POP. When straining at defecation is added to this disturbance, it may potentially be exaggerated by causing further pelvic floor descent and the chance for a traction neuropathy to develop (Infantino & Lauretta 2013). In support of the neuropathy argument, it has been proposed that vaginal support defects are largely the result of denervation injuries due to overstretching or compression of the pudendal nerve. Conceptually, this results from any acute protraction disorder of labor or the effect of chronic traction such as with longstanding constipation (Beevors et al. 1991). The prolonged straining may well likewise cause a weakness in the rectovaginal septum

as high intrarectal pressures of up to 390 centimeter H_20 have been demonstrated during straining (Halligan 2008). The magnitude of this pressure needs to be appreciated within comparative context, as the mean vaginal pressure during coughing is approximately 96 centimeter H_20 and during Valsalva it is approximately 79 centimeter H_20(Mouritsen et al. 2007).

Lastly, one needs to recognize force distribution in the posterior compartment. Coughing or straining evokes a reflex puborectalis contraction which leads to a high-pressure gradient in the vagina. This, in the presence of an intact RVS, is one of the mechanisms of protection against prolapse. The intact RVS also protects the posterior compartment against high intrarectal pressure gradients. Shafik et al. investigated the hypothesis that a weak bulbocavernosus muscle and puborectalis muscle share in the origin of a rectocele by changing the rectovaginal pressure gradient. In the healthy volunteers in there study, the rectal and vaginal pressures showed a significant increase on coughing or straining, with no significant difference between the rectal or vaginal pressures. In the women with a rectocele, they demonstrated a difference in the rectovaginal pressure gradient, showing a significant increase in the rectal against the vaginal pressure, particularly on coughing or straining. They suggest that this is an additional factor in the pathogenesis of rectocele (Shafik et al. 2003) and this is in keeping with the views of DeLancey (DeLancey 1999) in regards to lower posterior vaginal support

2.5.4 SYMPTOMS OF A RECTOCELE

2.5.4.1 GENERAL SYMPTOMS

There is much discussion in regards to the specific symptoms of a rectocele. This is due to rectoceles frequently co-existing with other pelvic floor disorders, rectoceles arising in the background of underlying pelvic floor dysfunction, the complexity of attributing cause to defecatory disorders and the presence of smaller rectoceles in asymptomatic women. Some authors believe that up to 80% of women with rectoceles are generally asymptomatic (Greenberg et al. 2001). This is however dependent on the assumption of symptoms related to the presence of a rectocele.

Symptoms associated with a rectocele include the sensation of a vaginal bulge, constipation, incomplete emptying of the rectum often requiring digitation to evacuate, fecal/flatal incontinence, rectal pain, rectal bleeding, sexual dysfunction and lower back pain (Goh et al. 2002)(Nieminen et al. 2004) . In general, only weak-to-moderate correlation exists between severity or stage of prolapse and the presence of specific symptoms such as bulging, heaviness, and voiding dysfunction and especially for bowel symptoms (Siproudhis et al. 1992). In studies of the relation between bowel dysfunction in general and presence and severity of prolapse, researchers have reported either a weak correlation between posterior vaginal wall support and specific anorectal symptoms or no link at all (Jelovsek et al. 2007). However, when assessment of posterior prolapse is defined as a dichotomous variable (presence versus absence of prolapse), there appears to be a better correlation between posterior compartment prolapse and specific obstructed defecation symptoms (ODS) (Erekson et al. 2010).

It has been known for a long time that it is difficult to correlate rectocele defect size with symptoms (Capps 1975)(Burrows et al. 2004)(Ting et al. 1992). Yoshioka et al. studied this association in 3 groups of women (1 = 22 pts with symptomatic rectocele, 2 = 15 pts with asymptomatic rectocele, and 3 = 14 pts with no rectocele). They utilised

anorectal physiology to study this. No significant difference was found between resting anal pressure (2 cm from anal verge), maximum pelvic floor contraction and attempted defecation. No significant difference was present at 6 cm rectal pressures, nor for rectal sensation measures, rectal compliance or for perineal descent. The only ssignificant difference was found in pelvic floor descent. The median descent in the first two groups were 4.3 cm compared to 2.5 cm in group 3. The singificant finding in their study was therefore that the pelvic floor significantly descends in patients with rectocele compared with control subjects (Yoshioka et al. 1991). This is in keeping with the observations that Dietz and Steensma reported by means of pelvic floor ultrasound imaging.

2.5.4.2 VAGINAL PROLAPSE SYMPTOMS

The sensation of pelvic pressure, the feeling of something falling or bulging out of the vagina, symptoms worsened by standing up and eased by lying down and lower abdominal pain are all more frequent in women with POP and similarly observed for those with rectoceles (Murthy et al. 1996)(Senagore et al. 2014)(Adjoussou et al. 2014). Most studies show that symptoms of POP correlate with a threshold of the leading edge of the prolapse at or beyond the hymen (Tan et al. 2015)(Bradley et al. 2007)(Swift et al. 2003).

2.5.4.3 DEFECATORY SYMPTOMS

2.5.4.3.1 DIGITATION

The defecatory symptom that arises most consistently with respect to posterior vaginal prolapse is the need to splint the vagina or perineum to defecate (Burrows et al. 2004) This is indicative of defecatory outlet obstruction. The specific symptom of splinting may occur in 18–25% of women, straining in 27%, and incomplete evacuation in 26% of women (Whitcomb et al. 2009)(Hall et al. 2014). Associated perineal pressure and a sensation of incomplete bowel emptying can lead to a cycle of increasing pelvic force due to more straining at defecation, worsening of the rectocele bulge and further deterioration in rectal emptying which is often associated with hemorrhoids (Beck & Allen 2010). Siproudhis et al. evaluated 468 women to explore the association between rectoceles and digitation to defecate. They noted that digitation occurred significantly in patients with large rectocele (59% vs. 30%), rectal prolapse (41% vs. 38%), anismus (53% vs. 36%) and higher anal resting pressures (53 ± 24 vs. 44 ± 23 mmHg). They concluded that vaginal digitations were generally associated with large rectoceles (Siproudhis et al. 2008). Carter et al. found that full evacuation of rectoceles was more common in small rectoceles (79% vs. 24%, p=0.0001), and no evacuation was more common in large rectoceles (37% vs. 0, p =0.01), but that rectal hyposensitivity and anismus were not related to the size of the rectocele (Carter & Gabel 2012)

The symptoms of a rectocele in correlation with the presence of a rectocele during transperineal ultrasound examination was the topic of description in a study by Dietz et al. A rectocele was clinically diagnosed in 64% of their cohort and clinical staging correlated with the ultrasound findings. The significantly associated symptoms in these women, were those of incomplete bowel emptying and digitation and less so were dyschezia, fecal incontinence (FI) and

chronic constipation (Dietz & Korda 2005). These data provide evidence that posterior compartment prolapse is associated with the ODS of splinting, especially in women with rectoceles of POP-Q stage ≥ 2.

2.5.4.3.2 OBSTRUCTED DEFECATION

ODS, or rectal-emptying difficulties, is frequently associated with anatomical abnormalities and/or an inability to relax the pelvic floor at attempted rectal emptying. Common anatomical abnormalities observed in women with ODS include rectocele, rectal intussusception, and enterocele and these must all be considered in the clinical assessment of these patients (Mellgren 2011)(van Dam et al. 1996). Pathophysiological mechanisms for ODS include mechanical outlet obstruction (intussusception or enterocele), dissipation of force vector (rectocele, descending perineum, and rectal prolapse), impaired rectal sensation (megarectum/rectal hyposensitivity), functional outlet obstruction secondary to inefficient inhibition of the internal anal sphincter (short segment Hirschprung's, Chagas, and hereditary internal sphincter myopathy) and inefficient relaxation of the striated pelvic floor muscles (multiple sclerosis, spinal cord lesions, and puborectalis syndrome) (Gurland & Zutshi 2010). The often-associated presence of perineal descent contributes to the difficulty to evacuate. The perineum bulges upon straining, reflecting a lack of pelvic floor support for the rectum and perirectal structures. This occurs because the anterior rectal wall protrudes into the anal canal, particularly when straining to defecate. The protrusive mucosa may act as a plug of the anal canal and prevents transit of the stool. Patients with descending perineum syndrome

strain endlessly to defecate but the rectum empties incompletely. This inability to empty leads to a constant feeling of rectal fullness and more straining, which leads to progressive denervation of the EAS and puborectalis muscles, and in time to FI (D'Amico & Angriman 2000) .

2.5.4.3.3 CONSTIPATION

Constipation per se is generally not due to a rectocele itself, although its presence has been documented in up to 75% of women with a rectocele (Mollen et al. 2000). Constipation in the setting of pelvic floor dysfunction is called functional constipation and refers to defecatory difficulty occurring in at least a quarter of bowel movements (Berman et al. 2005). Symptoms such as hard and/or infrequent stools are perhaps more suggestive of normal or slow transit constipation rather than POP related defecatory disorders. As even normal subjects may struggle to expel small hard pellets, difficulty in evacuation of soft, formed, or more so, liquid stools is more suggestive of an evacuation disorder (Bharucha & Wald 2010).

In the literature, constipation is defined as the need to strain at stool for more than 25% of the number of bowel movements or a stool frequency of less than three times per week, or both. Most patients with ODS seem to fulfill this definition of constipation because of excessive straining and not because of infrequent defecation (Drossman & Dumitrascu 2006). Rectoceles can be a cause or consequence of chronic constipation with excessive straining and it may be associated with defecatory dysfunction, rectal mucosal intussusception, or excessive perineal descent. Whether it is a cause or an effect of these changes remains unclear, but it is apparent that there is a strong association

between these entities (Schey et al. 2012)(Pescatori et al. 2007). Other bowel related symptoms described in relation to a rectocele are rectal pain in 12–70% of patients and rectal bleeding (mostly due to associated hemorrhoids) in 20–60% of cases (Zbar et al. 2003)(Arnold et al. 1990).

2.5.4.3.4 ANAL INCONTINENCE

A rectocele is not just associated with symptoms of evacuation difficulty, but also with anal incontinence (AI), and often specifically with fecal soiling (Felt-Bersma et al. 2008)(Tjandra et al. 1999). The possible mechanisms underlying this symptom are occult recto-anal intussusception, complete rectal prolapse, physiologic dysfunction, and IAS or EAS injury or atrophy (Pucciani et al. 1996). Yet again, a rectocele alone is unlikely to cause AI, unless it is associated with altered rectal sensation as a result of pudendal neuropathy and/or a sphincter defect as was evident by the finding of abnormal pudendal nerve terminal motor latency in 94% of anally incontinent women with a rectocele (Ayabaca et al. 2002).

2.5.4.4 URINARY SYMPTOMS

Many surgeons do not report on urinary symptoms, and especially not in those patients with posterior dominant prolapse undergoing repair of the posterior compartment in the absence of spinal cord lesions.

The associations between urinary symptoms and defecatory disorders were described in an elegant study by Cameron, et al. This was a secondary analysis of an initial

telephonic survey for defecatory disorders. They observed nocturia in 1.8%, urgency in 47.6%, and a sensation of incomplete voiding in 55.6% of their study population. There was no real difference in daytime frequency or dysuria. They could however not identify the underlying pathophysiological mechanism for these observations (Cameron et al. 2010). Nguyen et al. found that posterior vaginal retraction resulted in significant changes in urodynamic indices, but that it also unmasked stress urinary incontinence (SUI) in 54% of their small series (n=22) (Nguyen et al. 2007). A questionnaire based evaluation noted significant improvement in urinary incontinence (UI) after a defect-specific posterior repair. This significance was specifically for women in which the fascial defect was identified superiorly. The authors did however not describe the type of UI that was found to be improved (Glavind & Christiansen 2016). These reports suggest a potential obstructive effect that posterior compartment prolapse might have on urinary flow. Finco et al. on the other hand could not find any difference in urodynamic parameters between women with isolated posterior compartment prolapse opting for surgery in comparison to those declining it (Finco et al. 2007). They used a QOL questionnaire to explore this association. They were unable to differentiate between specific urinary symptoms or type of UI in their study. The association was yet again mostly observed in those patients with a superior fascial defect.

Obstructed voiding symptoms or voiding difficulty is otherwise frequently overlooked in urogynecology literature in favour of UI or overactive bladder (OAB). Constantini et al. documented obstructive voiding in 24% of their urogynecology population (Costantini et al. 2003). The only other significant reference to an association between posterior compartment prolapse and voiding abnormality was in a study from Haylen et al.(Haylen et al. 2007). The aim of their study was to determine the prevalence and

associations of voiding difficulty using a definition of urine flow rate under 10th centile of the Liverpool Nomograms and/or residual urine volume more than 30 ml. They studied 592 women referred to an urogynecology unit. The prevalence of voiding difficulty was 39% and it was the third most common urodynamic diagnosis after urodynamic stress incontinence (72%) and POP (61%) and ahead of overactive bladder (13%). They observed that voiding difficulty significantly increased in prevalence with age and increasing grades of all types of POP.

2.5.4.5 SEXUAL SYMPTOMS

There are several facets that need to be considered when contemplating the possible association between sexual symptoms and rectoceles. For one, there is no linear relationship between the existence of vaginal defects and the presence or severity of sexual symptoms. Furthermore, symptoms that is perceived to be due to POP can be from other causes altogether (Nusbaum et al. 2000). Sexual dysfunction is additionally prevalent in the general adult female population and increases with age (Knoepp et al. 2010). Rectoceles are simlarly prevalent in women with pelvic floor disorders and approximately 50% of parous women suffers with pelvic floor disorders (Wu, Vaughan, et al. 2014). This makes the specific association between rectoceles and sexual dysfunction challenging to explore beyond the mere description of presence of prolapse and sexual dysfunction (Athanasiou et al. 2012). Sexual complaints described in women with rectoceles include vaginal laxity or looseness (Lefevre & Davila 2008). Women with increasing degrees of prolapse develop progressive enlargement of the genital hiatus, which is a likely associated factor (Delancey & Hurd 1998). Sexual dysfunction is therefore not acknowledged to be pathognomonic of a

rectocele. The importance of considering sexual function does however become much more relevant when a surgical intervention is required which may alter the vaginal anatomy.

2.5.5 CLINICAL ASSESSMENT

A thorough clinical examination requires no specialised equipment and is required in all women who present with POP, irrespective of the healthcare environment in which these individuals are seen. This needs to include a digital rectal examination (DRE), particularly when posterior compartment prolapse is suspected. Posterior compartment prolapse is described in the POP-Q system through the measurement of points Ap and Bp. There is however concern that points Ap and Bp of the POP-Q may not demonstrate or describe the full extent of a posterior defect that exists between the rectum and vagina. When it comes to evacuation disorders, a rectocele is often just the tip of the iceberg. There are numerous other disorders that one should be on the lookout for that can give rise to these symptoms. Conditions that can co-exist includes rectoceles and occult intussusception, or a rectocele and non-relaxing puborectalis muscle. The clinician's ability to correctly identify and diagnose all pathologies that are present will lead to optimization of management and subsequent clinical outcomes. (Pescatori et al. 2006). A defect in the POP-Q system is therefore that it only accounts for vaginal displacement, but does not incorporate evaluation of the underlying rectum itself.

A recent study revealed that of those with normal POP-Q posterior points, 19% had a rectocele diagnosed by digital rectal exam (Zoorob et al. 2012). The importance of the

DRE was however realised 100 years prior to this publication when Fothergill stated that a rectocele is recognized clinically by passing a finger through the anal canal and observing its tip emerges at the vaginal outlet covered by rectal wall and vaginal wall (Fothergill WE 1912). A standardised DRE was described by Crane et al. (Crane et al. 2014). A concern with their method is that the DRE was performed at rest and not during Valsalva as is the norm for evaluating POP. This might lead to an underestimation of the full extent of the rectocele and possibly underestimate associated co-morbidities such as intussusception and anismus. They found that the POP-Q generally underdiagnosed rectoceles when compared to a standardised DRE.

A thorough clinical examination has good sensitivity in the detection of rectoceles. Greenberg et al. found that 8% of rectoceles were undetected at clinical examination compared to 4% undetected at defecography (Greenberg et al. 2001). Kahn and DeLancey have described the development of an enlarging rectocele and noticed that it will widen the levator hiatus and increase vaginal caliber, i.e. it will enlarge laterally and then cranially (Kahn et al. 2005)(Delancey & Hurd 1998).

Dietz et al. also looked at refining the posterior compartment POP-Q measurements to be more reflective of the presence of symptoms. They identified a POP-Q point Bp measurement of – 0.5 cm as the optimal cut-off value for predicting prolapse symptoms. They suggested that the ICS POP-Q staging system requires revision and that prolapse of the anterior and posterior vaginal wall of < -1 should probably be regarded as normal (Dietz & Mann 2014). The incorporation of a DRE furthermore allows for the evaluation of puborectalis dyssynergia. In the DRE, dyssynergia can be identified by two or more of the following features: impaired perineal descent, paradoxical anal contraction, or impaired push effort. This clinical examination

technique has shown a good correlation with anorectal manometry and balloon expulsion tests (Tantiphlachiva et al. 2010).

When the patient bears down as if to defecate, the examiner should perceive relaxation of the sphincter together with perineal descent. If not perceived, this suggests functional pelvic outlet obstruction or dyssynergic defecation (Maglinte et al. 2011). Other aspects to evaluate and document clinically includes: patulous anus, stool presence, straining at stool, fissures, neoplasms, prolapsing hemorrhoids, anal stenosis, scars, anal sphincter tone, skin irritation, rectal prolapse, perineal descent, rectal intussusception and enterocele (Kelvin et al. 1994). Widening of the genital hiatus and perineal decent can be measured by placing a ruler along the posterior vaginal wall at the level of the ischial tuberosities. Descent is measured as the distance the perineal body moves on straining and is abnormal when the perineum is greater than or equal to 2 cm below the level of the ischial tuberosities (Cundiff & Fenner 2004). Additionally, an enterocele may be appreciated on rectovaginal exam as bowel seen herniating into the vagina demonstrating a “double bubble” or eliciting a palpable cough impulse (Kleeman & Karram 2008). An accurate clinical assessment is of vital importance to allow for optimal management planning. This is of particular importance in women for whom surgery are planned, for it has been shown that the sensitivity and positive predictive value of clinical evaluation compared to evaluation in the operating room was less than 40% (Bernard T. Haylen et al. 2016)(Burrows et al. 2003). Specific rectovaginal fascial defects cannot be reliably identified pre-operatively and these mostly require intra-operative confirmation (Miklos et al. 1998).

2.6 SUMMARY

It is apparent that POP is prevalent worldwide and increasing in number in line with the improvement in female life expectancy. Isolated posterior compartment prolapse is less commonly encountered, but needs to be considered in any woman who presents with pelvic floor disorders. South Africa is a resource limited country and the evaluation of these women needs an innovative approach in regards to diagnostic workup and definitive treatment. Recommended conservative treatment modalities are often not feasible in this healthcare environment. The symptoms associated with a rectocele are not limited to the size of the defect, nor are they limited to defecatory disorders. There is therefore a dearth of information on the assessment, management and outcomes of such women in a healthcare environment with limited resources.

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CHAPTER 3

METHODOLOGY

3.1 INTRODUCTION

In this chapter the methodologies used in this research will be presented. This will include the different research components and statistical analyses that make up the collective that describes the evaluation and management of a rectocele in the South African healthcare environment.

The techniques used in the evaluation of the participants will be discussed and elaborated on. Specific methodologies pertaining to each research project are additionally incorporated in the prepared manuscripts included in the respective chapters of this thesis.

The applicable terminology will be briefly defined, but the official and standardized IUGA/ICS terminology used in respect to pelvic floor disorders are those that the researcher primarily used throughout the trials performed and for all of the participants (Bernard T Haylen et al. 2016) (Sultan et al. 2016).

3.2 STUDY DESIGN

A variety of study designs are incorporated in the different components of this project and this is illustrated in Figure 2.

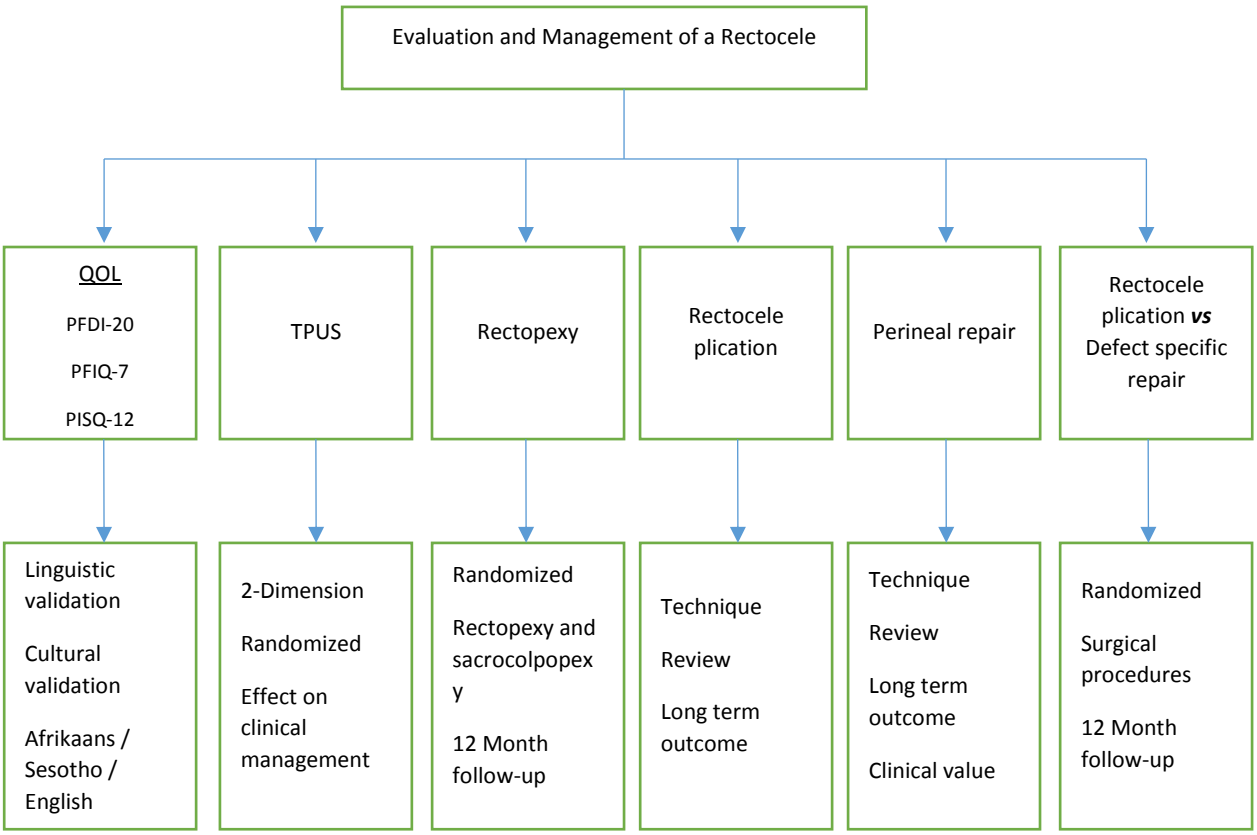


Figure 2: Framework to illustrate research components in the evaluation and management of a rectocele.

3.3 METHODOLOGY: VALIDATION OF CONDITION-SPECIFIC QUALITY OF LIFE QUESTIONNAIRES (Addendum 1)

The objective of this study was to translate and validate the Pelvic Floor Distress Inventory-20 (PFDI-20), Pelvic Floor Impact Questionnaire-7 (PFIQ-7) and the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire-12 (PISQ-12) in Afrikaans and Sesotho to serve the needs of the population that is encountered in daily clinical practice. In the Free State, Sesotho is spoken by 64% and Afrikaans by 13% of the

population. The original English versions were additionally adapted and validated for the local population.

3.3.1 RATIONALE

The PFDI-20, PFIQ-7, and PISQ-12 questionnaires are condition-specific and measures objectively and in a structured fashion the influence of symptoms on an individual's QOL. The original questionnaires were however developed in a specific culture and language and its psychometric properties can hence not be assumed to be valid in different cultures and language groups. These questionnaires therefore required to be psychometrically validated in regards to its reliability, validity, responsiveness and interpretability in a defined group of women.

3.3.2 PSYCHOMETRIC PROPERTIES

The psychometric measurement properties that were assessed included the fields of acceptability, reliability, validity, responsiveness and interpretability.

Acceptability is a measure that looked at how well the questionnaires were completed. Recording of missing data is an accurate reflection of the acceptability of an instrument (Strauss et al. 2006).

Internal consistency is a measure of the reliability of the instrument and evaluates the interrelatedness among the items in a questionnaire. It is expressed by Cronbach's alpha value. The value was determined for the specific scale scores in a questionnaire as well as the overall summary score. The sub-scales aim to measure a single concept related to PFD by using multiple items. A high Cronbach's alpha value indicates good

correlation between the items evaluated. If the value is above 0.60 then it is considered that the scale demonstrates acceptable internal consistency (Henson 2001).

Reliability evaluates the degree to which a questionnaire will produce the same result if administered again, or the “test-retest” concept. It is also a measure of the degree to which a questionnaire can reflect a true change. It is assessed through the intraclass correlation coefficient (ICC). Values ≥ 0.70 are considered to reflect adequate reliability (Bland & Altman 1986). This was evaluated by means of a repeated administration of the questionnaires after one week.

Content validity is the degree to which a questionnaire reflects reality. There are a number of different facets to validity. Content validity is the degree to which the content of a questionnaire is an adequate reflection of the construct to be measured. Important aspects are whether all items are relevant for the construct, aim, and target population and if no important items are missing (comprehensiveness).

Internal validity is the degree to which questions within an instrument agree with each other, i.e., that a subject will respond to similar questions in a similar way. It also affects the likelihood of producing false positives and false negatives.

External validity on the other hand is the ability to make generalizations about a population beyond that of the sample tested. Sensitivity reflects the degree to which the instrument can identify a true positive, e.g., accurately identify a person who does have the condition and specificity is similar to sensitivity, it being the degree to which the instrument can identify a true negative, e.g., correctly identify the people who do not have the disease. Sensitivity and specificity are another side of the coin from internal validity. The determination of specific cut-off values can be utilised to discriminate those affected by the disorder to those unaffected.

Statistical validity is related to internal validity, and assesses whether the differences in the questionnaire results between patient groups can appropriately be subjected to statistical tests of significance.

Construct validity relates to the relationships between the questionnaire and underlying theories. A common method of obtaining some indication of the construct validity of a questionnaire is to examine its ability to differentiate between different patient groups, i.e. women with pelvic floor disorders compared to those not known with pelvic floor disorders. The concept of construct validity was evaluated through the participation of a control group. The ideal control group is a random population based selection of women demographically matching the study group. This was however not possible or practical in this study design and clinical environment. We therefore selected the control group as that of women referred to a gynaecology outpatient clinic for reasons other than PFD. There still remains the likelihood that even amongst these, there will be women with some element of PFD, but this should reflect the prevalence of the condition in the population in general and are therefore deemed to be representative of a control group.

Responsiveness measures change in questionnaires. There are three main aspects to the measurement of change: differentiating between those who change a lot and those who change little, the identification of factors which are associated with a good outcome and inferring treatment effects from group differences. Treatment effects can be assessed by examining pre- and post-treatment differences between the intervention and control group by means of unpaired t-tests or repeated measures of analysis of variance. As additional evidence, patients' perceptions of change can also be measured and relationships between reported change and difference in quality of life scores can be examined. Effect sizes are also commonly used. Responsiveness

can be assessed in all patients who received any treatment during follow-up. The linear relationship of the mean change in measure scores between the baseline and the 6-month follow-up was evaluated by means of the patient global impression of improvement (PGI-I) scale (Srikrishna et al. 2010)(Terwee et al. 2009) (Addendum 2). The PGI-I response were dichotomized to allow for analysis. Patients reporting themselves to be “very much better”, “much better”, or “a little better” were classified as improved. Patients reporting themselves to be “no change”, “a little worse”, “much worse” or “very much worse” were classified as not improved. This outcome was evaluated at the 6 month follow up for this was a time when some form of clinical treatment or intervention would have been given to the patient and the clinical response could therefore be determined.

Item response rate was calculated as the number or percentage of respondents who had completed all the items in the total instrument as well as in the subscales. A figure of ≥ 90% is considered satisfactory (Strauss et al. 2006).

3.3.3 LINGUISTIC AND CULTURAL VALIDATION

Linguistic adaptation:

The original questionnaires were translated into Sesotho by 3 Sesotho speaking persons. This included 2 clinicians with experience in the field of PFD and 1 clinician with general gynecology experience. They were identified by the principal researcher. The original questionnaires were translated into Afrikaans by 3 Afrikaans speaking persons. This included 2 clinicians with experience in the field of PFD and 1 clinician with general gynaecology experience. They were identified by the principal researcher. The translated versions were then back translated to English by a 3rd clinician, not

involved previously, and who was a native speaker of Sesotho and Afrikaans in the case of each questionnaire as referred to above. A panel consisting of the principal researcher and 2 experienced clinicians representing the different linguistic versions met and discussed the translated questionnaires and compared it in meaning and aim to the original versions. Any contentious aspects related to the translated versions were discussed and resolved at this combined meeting. The result was a consensus questionnaire in each of the languages prepared for the next step in the process.

Cultural adaptation:

Linguistic equivalence does not equal cultural equivalence for health related QOL questionnaires. The translators used in the linguistic translations were issued with the following specific directives to ensure that the translated versions were culturally representative for Sesotho and Afrikaans speaking persons:

1. The topic of the question should not be changed.
2. If the question is in a particular context, then that context should be retained.
3. The number of response categories and the underlying metric of the response categories should remain the same.

Any contentious aspects related to the translated versions were discussed and resolved at a combined meeting. The result was a consensus questionnaire in each of the languages prepared for the next step in the process.

Validation

The panel agreed upon versions of the Sesotho, Afrikaans and English questionnaires were then tested in face-face individual interviews in 10 patients from the urogynecology clinic at Universitas Academic Hospital (UAH) by the principal researcher and an experienced Sesotho speaking nursing sister working in the clinic.

This process aimed to determine whether the wording of the questionnaire was understood in the same way by everyone who completed it. Patient feedback and comments were integrated and final versions of the questionnaires were then prepared for use in the formal psychometric testing phase (Addenda 3-5).

3.3.4 POPULATION AND SCHEDULE

The study population consisted of women seen at the urogynecology outpatient department of UAH. The control group consisted of women seen at the general gynecology outpatient department of Pelonomi Regional Hospital (PRH) and who were not referred due to pelvic floor disorders. The inclusion criteria were age over 18 years, not pregnant, able to read/write and understand the target language (English/Sesotho/Afrikaans) and known with POP/UI/FI (study population). The exclusion criteria were those with vulvodynia, painful bladder syndrome, chronic pelvic pain (> 6 months) or chronic regional pain syndromes (e.g. fibromyalgia).

A standard data form was completed for all consenting participants. There were three rounds of questionnaire completion for the study group and two rounds for the control group. The first round was at the time of enrollment and included the capturing of baseline information. The second round was one week later by means of telephonic administration of the questionnaires. This was opted for in view of the limited resources for patients traveling to and from the healthcare facilities and the near universal access to cellphones in this population. The telephonic questionnaire was administered by either the principal researcher or the allocated Sesotho speaking registrar in the Urogynecology unit. The third round of completion in the study group happened at the

3-month post-operative follow-up visit or at the 6-month conservative treatment follow-up visit.

3.4 METHODOLOGY: THE INFUENCE OF TRANSPERINEAL ULTRASOUND ON CLINICAL DECISION MAKING IN WOMEN WITH PELVIC ORGN PROLAPSE

Ultrasound imaging of the pelvic floor allows the clinician to evaluate all three vaginal compartments (anterior, apical, and posterior) simultaneously. This is a non-invasive, well described and well tolerated modality which produces objective information of the pelvic anatomy (Dietz 2004). When combined with the clinical evaluation, this allows the clinician to potentially make a more informed decision on the appropriate management for the individual woman. The purpose of this study was to determine whether the integration of 2D TPUS findings with that of the clinical assessment had an influence on the clinical management of women presenting with POP.

3.4.1 RATIONALE

The primary objective was to determine if and to what extent the use of 2D TPUS in women with POP adds to the final clinical management plan. Additional objectives were to determine if there was a difference in the impact of TPUS when the patient was initially assessed by a consultant compared to a registrar and to determine if a TPUS differs in its ability to contribute to management decisions in relation to the predominantly affected vaginal compartment (i.e. anterior, apical or posterior).

3.4.2 POPULATION AND STUDY SCHEDULE

This was a prospective randomized trial. The population consisted of eligible women seen at the urogynecology outpatient department who verbally consented to the study protocol. Participants were seen by either an urogynecology consultant or a senior registrar rotating in the unit after being randomised to “consultant” or “registrar”. They were clinically evaluated in the standard manner and this included a detailed clinical history and clinical and pelvic examination. The clinician then compiled a problem list and formulated a management plan for the individual woman. Once this was completed, the participant was seen by another urogynecology consultant who performed the 2D TPUS. The second consultant was blinded to the clinical findings and history of the individual. Once the ultrasound was completed and documented, the clinical case was discussed between the two clinicians who saw the specific patient and all findings were considered. A final decision was then made on the appropriate management for the individual woman by the clinician who initially saw her. The relevant clinical as well as ultrasound findings were captured for statistical analysis (Addenda 6-7).

3.5 METHODOLOGY: RECTOPEXY AT THE TIME OF AN ABDOMINAL SACROCOLPOPEXY

Sacrocolpopexy is the acknowledged gold standard procedure for women with generalised POP where there is invariably a loss of apical support (Maher et al. 2013). The operative technique for sacrocolpopexy can however vary significantly. An extensive variant of sacrocolpopexy has been performed for the last 15 years at UAH where it is often combined with a rectopexy. The specific contribution of the rectopexy

in regard to the objective and subjective clinical outcomes has never been prospectively evaluated.

3.5.1 RATIONALE

With the extensive sacrocolpopexy, known as a perineo-colpo-sacrosuspension (PCSS), mesh was placed on both sides of the vagina. Anteriorly, it extended from the distal urethra to the sacrum and posteriorly from the perineal body to the sacrum. In addition, the rectum was mobilized, elevated and suspended to the mesh (ventral mesh rectopexy). The success of this operation has been reported on before (Cronjé 2004)(Cronjé & de Beer 2008a). Of importance was an observed reduction in ODS from 40 to 15%. It was however not evident whether this improvement in ODS was due to the sacrocolpopexy alone or to the addition of a rectopexy. The primary objective of this study was to evaluate the effect of rectopexy during abdominal sacrocolpopexy with regards to the relief of mainly ODS and posterior compartment prolapse. Secondary outcomes were the assessment of subjective improvement, complications and operative parameters associated with these procedures.

3.5.2 POPULATION AND STUDY SCHEDULE

This was a randomized controlled trial in a referral urogynecology unit among women with generalised POP and who have been recommended for an abdominal sacrocolpopexy. Exclusion criteria were women younger than 18 years, those not consenting to randomisation, women without a prior hysterectomy, those in need of any other additional vaginal mesh procedure, individuals who had previous vaginal

mesh repair for POP, women with contra-indications for the use of mesh and ethnic black patients.

With an expected improvement of ODS from 40 to 15% with rectopexy, compared to 40 to 30% without rectopexy, the sample size was calculated to be 134 cases per group (alpha 0.05, beta 0.2). For recurrent posterior compartment prolapse, a similar improvement was expected. An interim analysis was scheduled after enrolment of the first 50 participants with a minimum follow-up period of 12 months.

Randomization was based on a schedule provided by the Department of Biostatistics of the University of the Free State. A consecutively numbered sealed envelope was selected and opened by the theatre scrub sister to indicate randomization. Variation was limited by the small number of surgeons (two) which ensured that the same procedure was followed. Bias was limited by blinding of the patient as well as the post-operative assessor to group allocation and furthermore through structured and objective post-operative evaluations (Addendum 8).

3.6 METHODOLOGY: REVIEW OF CLINICAL OUTCOMES AFTER A RECTOCELE PLICATION

A specific and novel type of posterior repair has been performed at the urogynecology unit of UAH for the past approximately 9 years. This procedure was named a rectocele plication and consists of a transvaginal approach to enable repair of a rectocele. An electronic database was introduced in the Urogynecology unit in 2010 and this allowed for accurate capture of clinical information. The primary objective of this study was to assess the clinical outcomes in the medium to long term after a rectocele plication.

3.6.1 RATIONALE

Many surgical techniques have been described to repair a rectocele. These include abdominal, vaginal, perineal and transanal techniques and will be further elaborated on in Chapter 6. A rectocele plication is a novel surgical technique with observed good clinical outcomes, but a procedure that has never been formally assessed. The primary purpose of this review was to identify women who underwent an isolated rectocele plication procedure and evaluate their objective and subjective outcomes over the medium to long term. This would allow one to objectively describe such outcomes, to identify areas of possible concern and to point the way for future research.

3.6.2 POPULATION

The eligible population consisted of women identified in the electronic database of the urogynecology unit at UAH. All those who underwent a rectocele plication were identified in the database. The women who had concomitant repairs in other vaginal compartments, those where any mesh were used and where there were less than 12 months' follow-up data, were then eliminated from this review. This was done in order to limit the variables which could influence the accuracy of the clinical findings in regards to this specific technique and pathology. The relevant data were retrieved and coded for statistical purposes (Addendum 9).

Data were collected from those who had their surgical procedure performed in the period January 2010 to December 2015. The qualitative metrics were compared and analyzed with the Chi-square and Fisher's exact tests and the continuous variables with the student-t test with statistical significance set at a value of $p < 0.05$. Patients

with incomplete data were excluded from the final reporting as were those that were lost to follow up.

3.7 METHODOLOGY: THE EFFECT OF A PERINEAL BODY REPAIR IN COMBINATION WITH A POSTERIOR VAGINAL REPAIR

A deficient or descending perineal body is often associated with a rectocele as has been described in Chapter 2. A perineal repair would often be performed at the time of a posterior repair in the urogynecology unit at UAH. An electronic database was introduced in the urogynecology unit in 2010 and this allowed for accurate capture of clinical information. The primary objective of this study was to evaluate the specific benefit which a perineal body repair added in women who underwent a posterior vaginal repair for a rectocele.

3.7.1 RATIONALE

A perineal repair or perineorrhaphy is frequently performed in women deemed to have a perineal abnormality (DH Nichols 1991). The diagnosis of an abnormal perineum is however not defined, nor is the surgical procedure for perineal repair. A standardised technique of perineal repair is followed in the urogynecology unit at UAH. The primary purpose of this review was to identify women who received a perineal repair concomitant with a rectocele plication procedure and to describe the potential benefit that this procedure added. This would allow one to prospectively identify those women who might benefit form this procedure, to identify areas of possible concern and to point the way for future research.

3.7.2 POPULATION

The eligible population consisted of women identified in the electronic database of the urogynecology unit at UAH. All those who underwent a posterior vaginal repair were identified in the database. The women who had concomitant repairs in other vaginal compartments, those where any mesh were used and where there were less than 12 months' follow-up data, were then eliminated from this review. The population identified were then sub-analyzed in those who had a rectocele plication without a perineal body repair and those who had a perineal repair added to their posterior vaginal repairs. The relevant data were retrieved and coded for statistical purposes (Addendum 9).

Data were collected from those who had their surgical procedure performed in the period January 2010 to December 2015. The qualitative metrics were compared and analyzed with the Chi-square and Fisher's exact tests and the continuous variables with the student-t test with statistical significance set at a value of $p < 0.05$. Patients with incomplete data were excluded from the final reporting as were those that were lost to follow up.

3.8 METHODOLOY: RECTOCELE PLICATION COMPARED TO A DEFECT-SPECIFIC REPAIR FOR THE CORRECTION OF A RECTOCELE

Many procedures have been described for the repair of a rectocele. These include vaginal approaches, transanal and transperineal procedures, native tissue repairs, graft (synthetic and biological) augmented repairs, laparoscopic and laparotomy approaches. The surgical procedures will be discussed in more detail in Chapter 6. Gynecologists tend to approach the repair of a rectocele via the vaginal route and

colorectal surgeons favour the transanal approach. The primary aim from a gynecologic perspective has traditionally been to cure the bulge in the posterior vagina and improve sexual function and from a colorectal perspective to cure the associated defecatory disorder (Pollak & Davila 2003). There is currently no clear evidence or specific clinical indications to select one type of procedure over the other (Cundiff et al. 2000). The primary aim of this study was to compare two surgical procedures for the repair of women with symptomatic rectoceles. These procedures were a rectocele plication and a defect-specific rectocele repair.

3.8.1 RATIONALE

A current internationally accepted standard for repair of a rectocele is the RVS defect-specific (site-specific) posterior repair. This has become popular after the previously used posterior colporrhaphy resulted in an increased rate of dyspareunia post-operatively and was subsequently abandoned in general. The defect-specific repair is a native tissue repair which has its focus on identifying discrete defects in the RVS and repairing each of these defects individually. This procedure is based on the theory of Richardson who described the presence of breaks in the RVS with the result of a rectocele pushing through these breaks and presenting as the typical bulge in the posterior vaginal wall (Richardson 1993). He described five types of posterior compartment prolapse based on five discrete breaks in the rectovaginal septum that lead to loss of support and subsequent bulge including: 1—low transverse, 2—midline vertical, 3—lateral, 4—L-shaped, and 5—U-shaped. The most common type according to him was a transverse defect above the perineal body attachment leading

to a low rectocele.The overall success rate for this repair is approximately 80% based on the published literature (Cundiff et al. 1998).

There are currently no publications with respect to a vaginal approach for the correction of a rectocele where the surgery is primarily focused on the anterior rectal wall. The rectocele plication provides a philosophical unification between the traditional gynecologic and colorectal approaches to repairing a rectocele. Rectocele plication however has the additional advantage of addressing vaginal and perineal abnormalities which cannot be simultaneously addressed with the transanal approaches (Boccasanta et al. 2001).

This study evaluated whether a rectocele plication was not inferior to a defect-specific posterior repair in women with symptomatic rectoceles. It evaluated the anatomic as well as the functional outcomes in these patients over a period of 12 months after the date of surgery. The hypothesis was that a rectocele plication would be at least as effective as a defect-specific repair in regards to the anatomical outcome, but might possibly result in superior functional outcomes due to the type of repair performed.

The secondary objectives were to assess the symptoms associated with a rectocele, the ultrasound characteristics of a rectocele as evaluated with transperineal ultrasound, the rectal sensitivity profile pre-and post-operatively, the uroflow profile pre- and post-operatively, the operative parameters and post-operative morbidity between the two procedures, the overall patient satisfaction and factors associated with failed symptomatic or anatomical cure.

3.8.2 POPULATION AND STUDY SCHEDULE

The study was designed as a non-inferiority randomized controlled trial in the setting of a urogynecology unit at UAH. Inclusion criteria were age > 18 years, the ability to provide informed consent, the presence of a symptomatic rectocele with failed medical or conservative management and the ability to understand the implications of the study. Exclusion criteria were women who had an asymptomatic rectocele that was a co-incidental clinical finding, those with previous prolapse surgery where mesh were used, women who had a previous surgical repair of a rectocele, those who were using full anticoagulant therapy, women with chronic pelvic or lower abdominal pain or fibromyalgia, those with undiagnosed rectal bleeding and those unable to provide informed consent or understand the implications of the study.

The sample size calculation was for a non-inferiority randomized clinical trial with a binary outcome. An alpha significance level of 5% and power of 80% was specified. The expected percentage of success in the control group was 80% based on the published literature. The expected percentage of success in the study group was 90% based on clinical impression in the urogynecology unit. A non-inferiority limit of 15% was deemed to be of clinical significance. The non-inferiority limit of 15% was based on the expected difference in anatomical outcome of 10% between the two procedures. The transanal procedures described in the literature for the correction of rectocele generally have a lesser anatomical success rate (approximately 75%) compared to those performed vaginally (approximately 80%). The functional outcomes however show improvement in both the transanal and vaginal categories for anatomical success rates of 75% and above. It was based on this information that a non-inferiority limit of 15% from the expected anatomical outcome of 90% for the new surgical procedure was deemed clinically appropriate. The sample size calculation

based on the above specifications was n=50 for the total group or n=25 patients per group and therefore at least 25 patients would be recruited per group. An expected loss to follow-up of 5% was projected and was based on previous experience in this research environment.

Randomization was based on a randomization list provided by a biostatistician. Randomization took place in theatre and allocation was determined via the opening of sequentially numbered sealed envelopes by the theatre scrub sister. The patients were blinded to group allocation as were the clinicians performing the post-operative clinical evaluations. The groups were evaluated similarly at baseline and after surgery at 8 weeks, 6 months and 12 months. Variation was limited through a single surgeon, with experience of at least 50 procedures of each technique, performing the operations. The information collected consisted of a history, clinical examination including POP-Q staging of prolapse, validated condition-specific QOL questionnaires (PFDI-20, PFIQ-7, PISQ-12), patient impression of improvement score (PGI-I), 2-dimensional TPUS imaging, free uroflowmetry ad rectal balloon sensitivity testing (Addenda 10-11). The choice of investigations were deliberately limited to be accommodating in a resource limited environment.

The data were analyzed by an appropriately qualified biostatistician using SAS Version 9.4 (Cary, NC, USA). Normally distributed continuous data were expressed as means and standard deviations, not-normally distributed data as medians and percentiles, and categorical data as frequencies and percentages. Univariate analyses were performed using Student's t test for normally distributed continuous variables, the Mann-Whitney or Kruskal-Wallis test for continuous data that is not normally distributed and the Chi-square or Fisher's exact tests for categorical variables. Statistical significance was noted for a one-sided p value of less than 0.05.

3.9 OPERATIONAL DEFINITIONS AND TECHNIQUE DESCRIPTION

3.9.1 TERMINOLOGY

Methods, definitions and units conform to the standards jointly recommended by the IUGA and the ICS in the papers on pelvic organ prolapse and anorectal dysfunction, except where specifically noted otherwise (Bernard T Haylen et al. 2016)(Sultan et al. 2016).

3.9.1.1 POSTERIOR COMPARTMENT PROLAPSE

This is the observation of descent of the posterior vaginal wall. Commonly, this would represent rectal protrusion into the vagina (rectocele). Higher stage posterior vaginal wall prolapse after prior hysterectomy would generally involve some vaginal vault descent and possible enterocele formation.

3.9.1.2 RECTOCELE

This is a bulge in the posterior vaginal wall associated with herniation of the anterior wall of the rectum. It needs to be distinguished from an enterocele which is a bulge of the upper wall of the vagina associated with herniation of the peritoneal sac and loops of small bowel and a perineocele which is a bulge in the perineum associated with herniation of the anterior wall of the rectum.

3.9.1.3 PERINEAL BODY

This is the anatomical area from the posterior margin of the hymen to the mid-anal opening and is measured during the POP-Q examination as well. The perineal body can descent during a Valsalva maneuver and perineal body descent was clinically diagnosed when there was ≥ 2cm descent of the perineum as determined with the ischial tuberosities as a reference point (Cundiff & Fenner 2004).

3.9.1.4 POP-Q

A standardized clinical examination system initially described by Bump et al. (Bump et al. 1996). The hymen is the fixed point of reference used throughout the POP-Q system of quantitative prolapse description. The anatomic position of the six defined points (two on the anterior vaginal wall, two in the superior vagina, and two on the posterior vaginal wall) for measurement is expressed in centimeters (cm) proximal to the hymen (negative number) or cm distal to the hymen (positive number) with the plane of the hymen being defined as zero (0). All points are measured during a maximal Valsalva maneuver (except total vaginal length).

The anterior vaginal wall is measured through *point Aa* (A point located in the midline of the anterior vaginal wall three cm proximal to the external urethral meatus and can range relative to the hymen from −3 to +3cm) and *point Ba* (A point that represents the most distal position of any part of the upper anterior vaginal wall from the vaginal cuff or anterior vaginal fornix to point Aa. By definition, point Ba is at −3 cm in the absence of prolapse and would have a positive value equal to the position of the cuff (point C) in women with total uterine prolapse or post-hysterectomy vaginal eversion.

The superior vaginal measurements reflect the most proximal locations of the normally positioned lower reproductive tract. It is measured through *point C* (A point that represents either the most distal edge of the cervix or the leading edge of the vaginal cuff (hysterectomy scar) after total hysterectomy) and *point D* (A point that represents the location of the posterior fornix in a woman who still has a cervix. Point D is omitted in the absence of the cervix)

The posterior vaginal wall is measured through *point Ap* (A point located in the midline of the posterior vaginal wall three cm proximal to the hymen and can range from – 3 to + 3cm) and *point Bp* (A point that represents the most distal position of any part of the upper posterior vaginal wall from the vaginal cuff or posterior vaginal fornix to point Ap. By definition, point Bp is at −3 cm in the absence of prolapse and would have a positive value equal to the position of the cuff in a woman with total post-hysterectomy vaginal eversion).

The genital hiatus (*GH*) is measured from the middle of the external urethral meatus to the posterior margin of the hymen.

The total vaginal length (*TVL*) is the length of the vagina (cm) from the posterior fornix to the hymen when point C or D is reduced to its full normal position.

The perineal body (*PB*) is measured from the posterior margin of the hymen to the mid-anal opening.

Prolapse severity is staged from 0-4. Stage 2 prolapse is assigned when any of the measurements in the three vaginal compartment lies within 1 cm either side of the hymenal margin.

3.9.1.5 LEVATOR AVULSION

Levator avulsion is the disconnection of the muscle from its insertion on the inferior pubic ramus and the pelvic sidewall, whereas tears may occur in any part of the muscle. Avulsion is a common consequence of overstretching of the levator ani during the second stage of labor and it was detected by clinical palpation. The clinician uses his index finger placed lateral of the urethral meatus and against the inferior pubic ramus while asking the patient to perform a pelvic floor contraction. Avulsion was diagnosed if an area of deficiency was identified or the bare pubic ramus palpated medial to the muscular contraction.

3.9.1.6 VAGINAL BULGE

Vaginal bulge is the complaint of a “bulge”, lump or “something coming down” or “falling out” through the vaginal introitus. The patient may state she can either feel the bulge by direct palpation or see it.

3.9.1.7 OBSTRUCTED DEFECATION

ODS was defined as the complaint of incomplete evacuation of fecal contents from the rectum due to physical blockage of the fecal stream during defecation attempts. It includes symptoms such as straining to defecate, sensation of blockage, digitation, and splinting. The term ODS (outlet obstruction) encompasses all pelvic floor dysfunctions, which are responsible for an incomplete evacuation of fecal contents from the rectum, straining at stool and vaginal digitations. Straining to defecate was defined as the complaint of the need to make an intensive effort (by abdominal

straining or Valsalva) to either initiate, maintain or improve defecation. The sensation of anorectal blockage was defined as a complaint suggestive of anorectal obstruction. Splinting and/or digitation was defined as the need to digitally replace the prolapse or to otherwise apply manual pressure, e.g., to the vagina, perineum or perianal area (splinting), or rectally (digitation) to assist defecation.

3.9.1.8 ANAL INCONTINENCE

AI is the symptom of involuntary loss of feces or flatus. This included fecal as well as flatus incontinence, but also that of passive fecal leakage which is the involuntary soiling without sensation or difficulty wiping clean the anus after defecation.

3.9.1.9 OBSTRUCTED VOIDING

This included the symptom of a slow stream, i.e. a urinary stream perceived as slower compared to previous performance (particularly prior to the development of POP) or in comparison with others. It also referred to the patient having to make an intensive effort (by abdominal straining, Valsalva or suprapubic pressure) to either initiate, maintain or improve the urinary stream as well as position-dependent micturition where the individual has to assume specific positions to be able to micturate spontaneously or to improve bladder emptying e.g., leaning forwards or backwards on the toilet seat or voiding in the semi-standing position.

3.9.1.10 OVERACTIVE BLADDER (DRY)

This was defined as the presence of irritative lower urinary tract symptoms such as urgency, frequency and nocturia. The essential symptom required to document this was however that of urinary urgency, i.e. the sudden, compelling desire to pass urine which is difficult to defer in the absence of underlying bladder disorders such as infection, neoplasia or inflammatory conditions.

3.9.1.11 OVERACTIVE BLADDER (WET)

This was defined as the presence of irritative lower urinary tract symptoms such as urgency, frequency and nocturia, accompanied by the associated involuntary leakage of urine. The essential symptoms required to document this was that of urinary urge incontinence (UUI), i.e. the sudden, compelling desire to pass urine that resulted in the involuntary leaking of urine in the absence of underlying bladder disorders such as infection, neoplasia or inflammatory conditions.

3.9.1.12 RECURRENT URINARY TRACT INFECTION

Recurrent urinary tract infection (RUTI) was a diagnosis by clinical history assisted by the results of diagnostic tests. It involved the determination of the occurrence of at least three symptomatic and medically diagnosed urinary tract infections (UTI) over the previous 12 months.

3.9.1.13 SEXUAL DYSFUNCTION

This was documented as being present when an individual confirmed abnormal function and/or difficulty with sexual intercourse. This included dyspareunia, i.e. the complaint of persistent or recurrent pain or discomfort associated with attempted or complete vaginal penetration, obstructed intercourse, when vaginal penetration is impeded due to narrowing or a bulge, vaginal laxity and complaints of loss or decrease of sexual desire.

3.9.1.14 PYRAMID SIGN

This was the finding during a standard digital rectal examination and indicative of a rectocele. The clinician's index finger was inserted per rectum while the patient was asked to perform a Valsalva maneuver. The index finger was directed anteriorly and a rectocele was identified through the finger filling the rectovaginal hollow that was present. The distance from the apex of the defect to the posterior fourchette was expressed in centimeters.

3.9.1.15 PROCEDURE TIME

The procedure time was recorded in minutes from the time of initial surgical incision – in the case of abdominal procedures – or the injection of a hydrodissection – in the case of vaginal procedures – until the completion of the last closing suture.

3.9.1.16 OPERATIVE BLOOD LOSS

This was calculated as the total blood lost during a surgical procedure. The calculation was performed through the weighing of surgical swabs used, the determination of blood volume in the aperture pouch during vaginal surgery and the volume of blood in the suction canister. These values were added to provide the operative blood loss. The weight of the swabs in gram was directly converted to milliliter to allow for this calculation.

3.9.1.17 DINDO SURGICAL COMPLICATION GRADING

The Clavien-Dindo system for the classification of surgical complications was used in all patients (Clavien et al. 2009). This system grades surgical complications in a standard and reproducible manner from 1 to 5. For statistical purposes a Grade 0 was introduced to convey the absence of surgical complications.

Grade 1: Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic and radiological interventions. Acceptable therapeutic regimens are: drugs such as anti-emetics, antipyretics, analgesics, diuretics and electrolytes, and physiotherapy. This grade also includes wound infections opened at the bedside.

Grade 2: Complications requiring pharmacological treatment with drugs other than those allowed for grade I complications. Blood transfusions and total parenteral nutrition are also included.

Grade 3: Complications requiring surgical, endoscopic or radiological intervention. This can be subdivided into Grade 3-a (Intervention not under general anesthesia) and Grade 3-b (Intervention under general anesthesia).

Grade 4: Life-threatening complication (including CNS complications: brain hemorrhage, ischemic stroke, subarachnoid bleeding, but excluding transient ischemic attacks) requiring intensive care unit management. This can be subdivided into Grade 4-a (Single organ dysfunction (including dialysis)) and Grade 4-b (Multi-organ dysfunction)

Grade 5: Death of a patient.

3.9.1.18 HOSPITAL STAY

Hospital stay was defined as the number of days that the patient spent in hospital as a result of the specific surgical intervention. This was calculated from the day of surgery (day one) until the day of discharge from hospital. The day of discharge was expressed as one hospital day, irrespective of the time of day when the actual discharged occurred.

3.9.1.19 REPEAT OPERATION

This was any repeat surgery in the same site/compartment for symptomatic POP recurrence.

3.9.1.20 OPERATION FOR COMPLICATIONS

This was any surgical procedure for complications e.g., mesh exposure, pain, infection or hemorrhage.

3.9.1.21 DIFFERENT OPERATION

This was defined as primary surgery in a different (new) site/compartment for POP.

3.9.2 QUESTIONNAIRES

The purpose of the questionnaires were to provide additional objective information on condition-specific symptoms at time intervals which span the periods from baseline assessment to post-interventional evaluations. There are many health-related questionnaires that can be used in women with pelvic floor disorders. The questionnaires used in this research were all selected on the basis of them having been internationally validated and being self-administered. The selected questionnaires had to place no additional demand on the limited resource of healthcare workers, nor be cumbersome to complete for the patients. The questionnaires selected fulfilled all of these criteria.

3.9.2.1 UNIVERSITAS HOSPITAL UROGYNECOLOGY QOL QUESTIONNAIRE

The QOL assessment and scoring were initially based on a locally used abbreviated pelvic floor questionnaire compiled from internationally validated questionnaires and consisting of 10 questions (3 on impact on quality of life, 3 on urinary distress impact,

3 on colorectal impact and 1 on sexual function impact). Each question could be scored from 1-5, with the 5 carrying the most weight and a higher score thus reflecting less dysfunction.

3.9.2.2 PFDI-20 (Addendum 3)

The PFDI-20 is a condition-specific short form questionnaire (Barber et al. 2005). It consists of 20 questions, divided into three scales: The Pelvic Organ Prolapse Distress Inventory-6 (POPDI-6), the Colorectal-Anal Distress Inventory-8 (CRADI-8) and the Urinary Distress Inventory-6 (UDI-6). Each question, if answered yes, can be scored from 1-4. A higher score indicated more bother. The scale scores were calculated by obtaining the mean value of all of the answered items within the corresponding scale (possible value 0 to 4) and then multiplying it by 25 to obtain the scale score (range 0 to 100). Missing items were dealt with by using the mean from answered items only. The overall PFDI-20 summary score was calculated by adding the scores from the 3 scales together to obtain the summary score (range 0 to 300). The questionnaire was administered in the language of choice of the individual, i.e. Sesotho, Afrikaans or English.

3.9.2.3 PFIQ-7 (Addendum 4)

The PFIQ-7 is a condition-specific short form questionnaire which measures the impact of pelvic floor disorders on the individual's quality of life (Barber et al. 2005). It consists of 7 questions for each of three scales: The Urinary Impact Questionnaire-7 (UIQ-7), the Colorectal-Anal Impact Questionnaire-7 (CRAIQ-7) and the Pelvic Organ Prolapse Impact Questionnaire-7 (POPIQ-7). Each question could be scored from 0-

3 with a higher score indicating more bother. The scale scores were calculated by obtaining the mean value for all of the answered items within the corresponding scale (possible value 0 to 3) and then multiplying by (100/3) to obtain the scale score (range 0 to 100). Missing items were dealt with by using the mean from answered items only. The overall PFIQ-7 summary score was calculated by adding the scores from the 3 scales together to obtain the summary score (range 0 to 300). The questionnaire was administered in the language of choice of the individual, i.e. Sesotho, Afrikaans or English.

3.9.2.4 PISQ-12 (Addendum 5)

The PISQ-12 is a condition-specific short form questionnaire which evaluates the impact of pelvic floor disorders on sexual function (Rogers et al. 2003). The PISQ-12 consists of 12 questions on sexual function. Questions 1-4 deals with behavioral and emotive factors, questions 5-9 with physical factors and questions 10-12 with partner related factors. Each question can be scored from 0-4 and the overall score is a numeric value out of 48. A higher score was indicative of less sexual dysfunction. The questionnaire was administered in the language of choice of the individual, i.e. Sesotho, Afrikaans or English

3.9.2.5 PGI-I (Addendum 2)

The PGI-I is a scale that reflect the individual's perception of improvement. It is recommended to be used in conjunction with the condition-specific QOL questionnaires and provides an accurate reflection of improvement when completed by the same individual over time. The PGI-I have been validate in women with pelvic

floor disorders (Srikrishna et al. 2010). It can be scored from 1-7 with a one defined as “very much better” to a seven defined as “very much worse”. The PGI-I was dichotomized into “improved” for scores 1-3 and “not improved” for scores 4-7 to allow for statistical analysis.

3.9.2.6 NUMERICAL PAIN SCALE (Addendum 11)

The numerical pain scale was used in the evaluation of pain in the acute post-operative period as well as during follow-up visits. It is a validated scale, numerically ranging from 0-10 (Hjermstad et al. 2011). A score of 0 indicates “no pain” and a score of 10 the “worst possible pain”. It was, similar to the other questionnaires, a self-administered tool.

3.9.3 DIAGNOSTIC PROCEDURES

3.9.3.1 2D TRANSPERINEAL ULTRASOUND

A conventional convex abdominal transducer with frequencies between 4 to 6 MHz was used to provide 2D imaging of the pelvic floor (Bernard T Haylen et al. 2016). The patient was asked to have a comfortable, but not full, bladder prior to the examination, but to empty her bowels if possible. Examination occurred in a private cubicle and the patient remained covered with a sheet from abdomen to feet. The ultrasound machine used was a Philips HD11XE. TPUS was performed with the patient placed in the dorsal lithotomy position, with the hips flexed and abducted. No rectal or vaginal contrast medium was used. Perineal ultrasound provided sagittal, coronal and oblique sectional imaging, with the mid-sagittal plane being the most commonly used as this gave an

overall assessment of all anatomical structures (bladder, urethra, vaginal walls, anal canal, rectum and puborectalis muscle) between the posterior surface of the symphysis pubis (SP) and the posterior part of the levator ani (LA). The imaging was performed at rest, during maximal Valsalva maneuver and on pelvic floor muscle contraction (PFMC). The access to the mid-sagittal plane allowed the following evaluations at baseline and during follow-up visits:

- Levator hiatus at rest (mm)
- Levator hiatus during contraction (mm)
- Levator hiatus during Valsalva (mm)
- Urethrovesical junction (UVJ) at rest (mm)
- UVJ during Valsalva (mm)
- Anterior prolapse – during Valsalva and measured in relation to the inferior border of the SP (mm)
- Uterine prolapse - during Valsalva and measured in relation to the inferior border of the SP (mm)
- Vault prolapse - during Valsalva and measured in relation to the inferior border of the SP (mm)
- Enterocele prolapse during Valsalva and measured in relation to the inferior border of the SP (mm)
- Rectocele depth – measured during Valsalva from the height of the defect perpendicular to a line drawn along the expected anterior rectal wall contour (mm)
- Rectocele width – measured at Valsalva as the width of the defect along the expected anterior rectal wall contour (mm)

- Rectovaginal septum – identified as an echogenic line anterior to the anterior rectal wall and described in regards to whether it appeared intact or not. In cases where it was deemed not to be intact, the length of the defect was measured (mm)
- Rectal intussusception – evaluated during Valsalva as invagination of the rectal wall into the rectal lumen or into the anal canal
- Rectal ampulla at rest measured in relation to the inferior margin of the SP (mm)
- Rectal ampulla during Valsalva measured in relation to the inferior margin of the SP (mm)
- Distance from the rectocele to the UVJ during Valsalva (mm)
- Distance from the rectocele to the mid-urethra during Valsalva (mm)
- Distance from the rectocele to the distal urethra during Valsalva (mm)
- Perineal position at rest in relation to the inferior margin of the SP (mm)
- Perineal position during Valsalva in relation to the inferior margin of the SP (mm)

3.9.3.2 FREE UROFLOWMETRY

This investigation was performed at the baseline and post-operative visits as part of the randomized trial for vaginal repair of rectoceles. The urodynamic test mostly used in the urogynecology literature is the cystometrogram. We opted for free uroflowmetry alone for two reasons. Firstly, we were specifically concerned with the flow pattern in women with a rectocele as the hypothesis was that the observed improvement in urinary symptoms after repair of a rectocele could be due to the relief of an outflow obstruction. Secondly, the catheters and equipment used for cystometry are frequently

not available in our healthcare environment due to financial restrictions. The use of uroflowmetry was thus a pragmatic decision based on the environment in which we deliver healthcare service.

Uroflow was performed with the patient experiencing a moderately full bladder. The patient was asked to empty her bowels prior to the evaluation if the presence of stool was sensed. Uroflow was measured with the use of digitally recorded uroflowmetry as was the standard clinical practice in the urogynecology unit, using a MMS Solar Silver system (Medical Measurement Systems B.V., Netherlands). The patient was seated on a commode and the beaker positioned under the funnel of the commode and placed on a spinning disk flowmeter. Privacy was ensured and the patient was asked to void spontaneously at her own leisure. The clinician entered the room once voiding was completed. The following variables were captured: average flow (ml/sec), peak flow rate (ml/sec), time to maximum flow rate (sec), voiding time (sec), flow time (sec), volume voided (ml) and stream (this was classified as continuous or intermittent based on the flow curve graph).

3.9.3.3 DIGITAL RECTAL EXAMINATION

In the absence of any anorectal manometry equipment, we made use of a standardized digital rectal examination (DRE) and scoring system to evaluate anorectal function (Orkin et al. 2010). The DRE and scoring requires a rectal examination of the patient. The patient was positioned in the supine position with her hips moderately flexed. This scoring system made use of an analog scale in increments of 0 to 5. The evaluation was performed and scored during rest and during anal sphincter contraction. A resting and squeeze score of 3 was considered normal.

A resting score of 5 indicated very high pressures and a tight anal canal, whereas a score of 0 indicated an open or patulous anal canal at rest with separation of the buttocks. A squeeze score of 5 indicated a very strong squeeze, almost painful to the examiner, while a score of 0 indicated no discernable increase in pressure from rest with maximal patient effort. During DRE, the clinician assigned these values to resting pressure (RP) and to maximal squeezing pressure (SP). These were documented at the initial evaluation as well as with each follow-up visit. The DRE scoring was as follows:

Resting Score:

0 = No discernable tone at rest, an open or patulous anal canal

1 = Very low tone

2 = Mildly decreased tone

3 = Normal

4 = Elevated tone, snug

5 = Very high tone, a tight anal canal, difficult to insert a finger

Squeeze Score:

0 = No discernable increase in tone with squeezing effort

1 = Slight increase

2 = Fair increase but below normal

3 = Normal

4 = Strong squeeze

5 = Very strong squeeze, to the point of being painful to the examiner

3.9.3.4 RECTAL BALLOON SENSITIVITY TESTING

This assessed rectal sensation to distension. Rectal sensation to distension is most commonly assessed by manually inflating an intrarectal domestic balloon at a rate of approximately 5 ml/s. The following variables were assessed: The volume which elicits the first sensation of balloon expansion (typical normal range 12–25 ml), the volume where the individual experienced an urge to defecate (typical normal range 35–65 ml), and the maximal tolerated volume (typical normal range 120– 300 ml). The normal ranges for the latter two sensations are highly variable due to the lack of consensus on measurement technique, especially in regards to the nature and speed of inflation of the balloon. The pressure required to elicit these sensations can also be measured using specific electro-mechanical equipment, which might be more reproducible. However, even with these instruments, the published ranges vary widely: typically, distension volumes 1.5 to 3 times are published for thresholds with a barostat compared to manual balloon inflation. Distension sensitivity testing is of proven value in patients with fecal incontinence to help with biofeedback training by normalization of the initial sensation sensory thresholds. It also aids in identifying visceral hypersensitivity, poor rectal compliance, or rectal irritability if maximal tolerated volumes are low. The manual balloon technique was opted for in the resource limited setting where there was no access to more specialized equipment and to make it feasible as a long-term evaluation option in this environment.

The procedure was done during the session of the transperineal ultrasound. The patient was asked to empty her rectum prior to the procedure and she was positioned

in the dorsal supine position with her hips flexed comfortably. The balloon was composed of a Foley's catheter with the cut-off index finger of a latex examination glove securely attached to its tip to provide a waterproof seal. This Fr-12 Foley's catheter was inserted with the tip 7 cm past the anal verge. Sterile water at body temperature was then used to fill the catheter with the balloon to a maximum volume of 300 ml. The catheter was filled at a constant rate of 20 ml/minute. In addition to the variables mentioned above, we evaluated the volume if and when a urinary voiding desire occurred. The TPUS examination was performed after completion of this test.

3.9.3.5 POSTVOID RESIDUAL URINE VOLUME

The volume of urine left in the bladder at the completion of micturition was calculated by means of TPUS measurement. This was done immediately after the patient voided to prevent filling of the bladder. The postvoid residual volume (PVR) was determined at baseline and during the follow-up visits in the randomized trial of vaginal rectocele repair. The formula used with TPUS in the sagittal plane was height x depth x 5.6 (Dietz, et al. 2012).

3.9.4 SURGICAL TECHNIQUES

3.9.4.1 SACROCOLPOPEXY

The technique for this sacrocolpopexy is based on the work of Cronje (Cronjé 2004)(Cronjé & de Beer 2008).

A laparotomy was performed, usually by a lower transverse abdominal incision. The vaginal vault was identified and the vesicovaginal plane was dissected to the level of

the urethrovesical junction. The peritoneum medially to the rectum was subsequently incised, from the sacral promontory down to the bottom of the pouch of Douglas. Care was taken not to injure the lateral rectal ligament which contained the inferior hypogastric nerve supplying the rectum, which could add significant post-operative morbidity. At the same time the rectum was separated from the vagina along the rectovaginal space. The surface over S1–2 was exposed and the branches of the superior hypogastric nerve moved left laterally. Vaginally, a small midline anterior incision was made and the vesicovaginal space dissected. This was continued until it joined with the plane of abdominal dissection. A rectangular (15 x 4cm) strip of Type 1 polypropylene mesh (Ultrapro, Johnson & Johnson) was inserted from the vaginal incision into the abdominal cavity. This was subsequently anchored with nylon 2/0 sutures either side of the distal urethra and the vaginal epithelium was closed. The next step was a midline posterior vaginal incision and dissection of the rectovaginal space until the abdominal dissection plane was reached. At this stage a rectocele repair and/or a perineal body repair could be performed at the discretion of the surgeon. A second rectangular strip of mesh, similar to that used in the anterior compartment, was inserted from the vagina into the abdominal cavity. It was anchored approximately 2 cm proximal to the perineum with two polydiaxonone 2/0 sutures and the vaginal epithelium was closed. The two strips of mesh were then attached to the vault with two polydiaxonone 0 sutures. A rectopexy was performed next in those women randomized to it (See 3.9.4.2). The strips of mesh were attached to the anterior longitudinal ligament at the level of the S1 vertebra with minimal tension applied to the vault of the vagina. The posterior peritoneum was closed with a polydiaxonone 2/0 suture to allow for extraperitoneal positioning of the mesh. An acriflavine impregnated vaginal pack was inserted and removed after 24 hours.

3.9.4.2 RECTOPEXY

A ventral mesh rectopexy was performed according to the Orr-Loygue technique (Portier et al. 2006) with the specific aim of avoiding injury to the hypogastric nerve supply to the rectum. The sacrocolpopexy was performed as mentioned in the preceding section. The presacral space was opened with blunt dissection and the rectum was mobilised in a caudal direction along its medial aspect to the level of the levator ani muscle. The rectum was then elevated and attached along its antero-ventral wall to the mesh used for the sacrocolpopexy with a continuous polypropylene 2/0 suture. The posterior peritoneum was closed as mentioned above.

3.9.4.3 RECTOCELE PLICATION

The patient was positioned in a modified lithotomy position after induction of anesthesia and a single dose of prophylactic intravenous antibiotic (2g Cefoxitin). The surgical area was cleaned and sterile draping performed. A transurethral catheter was inserted. A mixture of 1:200 000 Adrenaline in Saline was used for hydrodissection and injected in the rectovaginal space. A midline posterior vaginal incision was made and a full thickness vaginal wall dissection from the underlying anterior rectal wall was performed. This dissection was continued cranially to one centimeter superior of the apex of the rectocele and caudally to the level of the perineum. Lateral dissection was performed to the level of the insertion of the puborectalis portion of levator ani, with care not to transect the muscle fibers. The index finger of the surgeon was placed in the rectum and the anterior rectal wall put under tension. Rectocele plication sutures consisting of polydiaxonone 2/0 was inserted in a zig-zag manner under digital

guidance of the rectal finger into the rectal muscularis, starting cranially at the apex of the defect and continuing caudally to the level of the perineum. These longitudinal sutures were spaced approximately one centimeter apart from right to left and four separate sutures were generally inserted and individually tied after placement of the final one. In cases where there were thought to be excess vaginal epithelium, this was trimmed in a conservative fashion. Hemostasis was monitored for and ensured. The vaginal epithelium was closed with a running interlocking polyglycolic acid 2/0 suture. An acriflavine impregnated vaginal pack was inserted at the end of the procedure and removed after 24 hours. All patients received a stool softener for four weeks after surgery.

3.9.4.4 PERINEAL BODY REPAIR

This was mostly performed in conjunction with a posterior vaginal repair. The surgeon inserted his finger in the distal anorectum after the posterior repair was completed. The lateral spaces were opened on both sides of the rectum with sharp dissection and the EAS was dissected laterally, i.e. the intersphincteric space was entered. We have observed that the perineal body disruption often occured in the midline and that it appears to include a portion of the EAS. Care was taken not to inadvertently cause an anal mucosal laceration. The surgeon removed his finger on completion of this dissection. A Bonney's forceps was positioned vertically alongside the anorectum to protect it at the time of suture placement. Three polydioxanone 0 sutures were then inserted. The first suture was inserted in the EAS, distal to the puborectalis muscle, from the patient's left to right. The second suture, placed in a similar way, included the EAS just distal to the first suture. The third suture incorporated the superficial EAS and

bulbospongiosus muscle at the level of reattachment to the perineal body. The sutures were then individually tied, resulting in an end-end approximation of the sphincter. A rectal examination was once more performed to ensure no mucosal injury occurred during suture placement. The last layer incorporated closure of the vaginal epithelium and superficial transverse perineal muscles with the use of a polyglycolic acid 2/0 running suture. An acriflavine impregnated vaginal pack was inserted and removed the next morning. All patients received a stool softener for four weeks after surgery.

3.9.4.5 DEFECT-SPECIFIC POSTERIOR REPAIR

The patient was positioned in a modified lithotomy position after induction of anesthesia and a single dose of prophylactic intravenous antibiotic (2g Cefoxitin). The surgical area was cleaned and sterile draping performed. A transurethral catheter was inserted. A mixture of 1:200 000 Adrenaline in Saline was used for hydrodissection and injected in the rectovaginal space. A midline posterior vaginal incision was made and the vaginal epithelium was dissected off the fibromuscular portion so that the rectovaginal fascia was left anterior of the anterior rectal wall. Dissection was continued cranially to one centimeter superior of the apex of the rectocele and caudally to the level of the perineum. Lateral dissection was to the level of the insertion of the puborectalis portion of levator ani, with care taken not to injure the muscle fibers, and to the lateral attachment of the fascia at the arcus tendinous levator ani. Discrete rectovaginal fascial breaks were identified. When not clearly visible, an index finger placed in the rectum helped to define the defects and identify the fascial margins. Each defect was individually repaired with running polydiaxonone 2/0 sutures to ensure an intact rectovaginal fascia. Transverse apical defects were attached to the pubocervical

fascia, or in women who have had a prior hysterectomy, to the vaginal vault with incorporation of the uterosacral ligaments in this attachment. In cases where there were thought to be excess vaginal epithelium, this was trimmed in a conservative fashion. Hemostasis was monitored for and ensured. The vaginal epithelium was closed with a running interlocking polyglycolic acid 2/0 suture. An acriflavine impregnated vaginal pack was inserted at the end of the procedure and removed after 24 hours.

3.10 SUMMARY

This research project will consist of numerous individual research components which are all part of the collective objective of describing the evaluation and management of a rectocele in a resource limited healthcare environment.

The evaluation is contained within the methodologies for the validation of condition-specific QOL questionnaires for the specific population in which this research occurs as well as the integration of 2D TPUS findings in the development of clinical management strategies for these women.

The management is contained within the methodologies of a randomized controlled trial of a rectopexy at the time of a sacrocolpopexy, the description of a rectocele plication procedure and retrospective review of its clinical outcomes, the description of a perineal body repair in combination with a rectocele plication and review of its clinical outcomes and a randomized trial of a transvaginal repair of a rectocele though either a rectocele plication of a defect-specific repair.

All these components will be approached within the confines of the limited resources available in this research setting and thus be reflective of a pragmatic research

approach. This is a feature that will allow the evaluation and management of these women to be continued in a similar fashion after completion of the research.

CHAPTER 4

QUALITY OF LIFE QUESTIONNAIRES

4.1 INTRODUCTION

Pelvic floor disorders often have a detrimental effect on the affected individual's QOL (Schimpf et al. 2009). This manifests as symptoms of PFD. Symptoms are defined as any morbid phenomenon or departure from the normal in structure, function or sensation, experienced by the woman and indicative of disease or a health problem. Symptoms are either volunteered by, or elicited from the woman (Bernard T Haylen et al. 2016). The dilemma with this approach is the inherent variation in the nature of history-taking among clinicians (Teutsch 2003)(Duffy et al. 2004). A detailed history however remains the cornerstone in the assessment of pelvic floor disorders (Dwyer 2004)(Riss & Kargl 2011).

Condition-specific health related QOL questionnaires can be used to assess an individual's overall sense of wellbeing and how it relates to the specific condition and the subsequent treatment (Chopra & Kamal 2012). In recent medical literature, there has been an emphasis on incorporating QOL measures in outcome reporting. The importance of condition-specific questionnaires is evident when one studies the contemporary literature. It demonstrates a decrease in the use of generic QOL questionnaires and a significant increase in condition-specific QOL questionnaires (Garratt et al. 2002). These patient-reported outcomes can be used as primary endpoints in women presenting with pelvic floor disorders, for an improvement in QOL or level of bother should be the aim of any treatment initiated in this group of women. It is essential in research and clinical practice that the severity of these conditions are

properly assessed and recorded. Furthermore, the extent of the impact on QOL varies among individuals and the presence or absence of symptoms alone cannot fully reflect severity (Gil et al. 2009).

Numerous QOL questionnaires have been developed to evaluate potential pelvic floor related disorders (Table 1). This include those for UI, defecatory dysfunction, sexual dysfunction and some general pelvic floor QOL instruments (Omotosho & Rogers 2009)(Avery et al. 2007)(Steele et al. 2015)(Izumi 2014)(Gil et al. 2009)(Schimpf et al. 2009)(Barber 2007).

Table 1: Pelvic floor quality of life questionnaires

Urinary dysfunction	**Defecatory dysfunction**	**Sexual dysfunction**	**General POP**
International Consultation on Incontinence Questionnaire (ICIQ)	Defecation Distress Inventory (DDI)	Pelvic organ prolapse / urinary incontinence questionnaire (PISQ-12)	King's Health questionnaire (KHQ)
Bristol Female Lower Urinary Tract Symptoms Questionnaire-Short Form (BFLUTS-SF)	Incontinence impact questionnaire (IIQ)	Pelvic organ prolapse / urinary incontinence questionnaire – IUGA revised (PISQ-IR)	Short Form Health Survey (SF-36)
Stress and Urge Incontinence and Quality of Life Questionnaire (SUIQQ)	Constipation-Related Quality of Life (CRQOL)	Golombok Rust Inventory of Sexual Satisfaction (GRISS)	Gastrointestinal QOL questionnaire
Urogenital Distress Inventory (UDI)	Modified Wexner questionnaire	Brief Index of Sexual Functioning—Women (BISF-W)	Pelvic floor distress inventory (PFDI-20)

Incontinence Severity Index (ISI)	The Obstructed Defecation Syndrome (ODS) Questionnaire	McCoy Female Sexuality Questionnaire (MFSQ)	Pelvic floor impact questionnaire (PFIQ-7)
Incontinence QOL questionnaire (I-QoL)	Cleveland Clinic Incontinence Score (CCIS)	Female Sexual Function Index (FSFI)	EuroQol EQ-5D
Stress-related leak, Emptying ability, Anatomy, Protection, Inhibition, Quality of life, Mobility and Mental status Incontinence Classification System (SEAPI-QMM)	Knowles–Eccersley–Scott-Symptom (KESS)	Sexual Behavior Inventory (SBI)	Australian pelvic floor questionnaire
Incontinence Impact Questionnaire (IIQ)	Patient-Assessment of Constipation Symptoms	BFLUTS sex	
Urinary Incontinence Severity Score (UISS)	Patient Assessment of Constipation Symptoms (PACS)	Psychosocial Adjustment to Illness Scale (PAIS)	
Quality of Life questionnaire for urinary incontinence (CONTILIFE)	Chinese Constipation Questionnaire	Multidimensional Sexuality Questionnaire (MSQ)	
Sandvik Incontinence Severity Index (ISS)	Fecal Incontinence Severity Index (FISI)	Derogatis Interview for Sexual Functioning (DISF)	
Medical, Epidemiological and Social Aspects of Aging (MESA)	Fecal Incontinence Quality of Life Scale (FIQOL)	Changes in Sexual Functioning Questionnaire (CSFQ)	
Overactive bladder quality of life (OAB-q)	Chronic idiopathic constipation index (CICI)	The Sexual Interaction Inventory	

The selection of a specific questionnaire therefore requires some form of justification. Psychometric properties need to be evaluated in the original design of the considered questionnaires and this include those of validity, reliability and responsiveness. Two grades of recommendation have been established for QOL questionnaires (Donovan et al. 2002). This includes grade A - highly recommended, which is reserved for established measures with documented, rigorous validity, reliability and responsiveness in several clinical studies and grade B - recommended, which is the grade recommended for measures with some validity, reliability and an indication of responsiveness, or for which only validity and reliability but not responsiveness have been established with rigor in several clinical studies.

4.2 THE OBJECTIVE USE OF QUESTIONNAIRES

Health related QOL questionnaires has the ability to provide an objective, structured evaluation of patient perceived symptoms over time and is complimentary to the history taken by the clinician. The evolution of health care has required clinicians to evaluate the impact of interventions on their patients' well-being more critically. Prior clinical interventions focused primarily on anatomical endpoints. These outcomes frequently were tenuously linked to patient benefit. The current emphasis is on patient-oriented outcomes, including health related QOL. This shift in emphasis is not limited to pelvic floor disorders. Internal medicine literature now frequently describe the effects of therapies on health related QOL (Eisen et al. 1999) and a review of ophthalmology literature found that in nearly all of the studies identified, the QOL estimates of patients differed significantly from those of clinicians. Clinicians generally underestimated the impact of the condition on patients' QOL (Stein 2004).

The concept of rating an individual's QOL and symptom bother was vividly illustrated in the pediatric literature. One would expect that a parent would be able to accurately rate their child's health related QOL. The traditional assumption in pediatrics – both clinical and research – that parents can answer for their children is mostly not challenged. The child is often seen as an unreliable respondent, lacking the linguistic skills to understand and respond to questionnaires. A review by Eiser et al., however found that there was great agreement for observable, i.e. physical functioning, but significantly less for emotional and social functioning. This was found irrespective of whether a parent or a healthcare worker acted as proxy in the completion of questionnaires. The only accurate measure of determining QOL was to use validated questionnaires which the affected child were able to complete him/herself. (Eiser & Morse 2001).

This concept was initially reported on in the urogynecology literature by Rodriguez et al. (Rodríguez et al. 2003). They investigated the relationship between physician-assessed QOL parameters obtained from patient interview and patients' self-report of QOL using a validated questionnaire and found poor concordance between the physician and patient responses. Overall, the physicians underestimated the patient's degree of bother by 25% to 37%.

Srikrishna et al. examined the accuracy of physician's determination of bothersomeness of POP symptoms (Srikrishna et al. 2008). They studied the prolapse quality of life questionnaire (P-QOL) completed by firstly the patient and subsequently by the physician, blinded to the patient's questionnaire. They found overall poor correlation (Kappa values) between the physician and patient responses. The agreement was particularly poor in all questions related to emotional distress, sleep

and energy caused by prolapse symptoms. The physician underestimated the bothersomeness of the symptoms.

The importance of subjectivity should additionally not be underestimated in the post-operative period. Physicians have been found to be over-optimistic when interpreting patient symptoms after pelvic floor surgery (Black et al. 1997). This supports an objective instrument to evaluate and report on anatomic and functional treatment outcomes.

4.3 THE INFLUENCE OF QUESTIONNAIRES ON HEALTHCARE COST

Patient reported QOL may carry even more weight in a limited resource healthcare environment. Cost-effectiveness analysis traditionally focused on identifying when treatments are cost-effective based on their average benefits and costs in the population. However, there may be considerable value in identifying when treatments are cost-effective for individual patients given their preferences or other personal attributes. Basu et al. reviewed a theoretical framework to assess the potential value of identifying cost-effective treatment protocols for individual patients given their preferences and compared this to the traditional model of population or condition based guidelines. They concluded that the financial value of individualizing care can be far greater than the value of improved decision making at the group level (Basu & Meltzer). Benning et al. showed that customized care leads to higher utility and lower costs than standardized programs in oncology and this was particularly evident when preferences for health care programs were heterogeneous (Benning et al.). The potential cost-benefit of individualized care has not been evaluated for pelvic floor disorders. It does seem plausible that appropriately planned individualized treatment

based on clinical findings in combination with patient reported bother would result in superior outcomes. This is likely to translate into healthcare cost savings.

4.4 THE USE OF QUESTIONNAIRES FOR PELVIC FLOOR DISORDERS

Pelvic floor disorders are multidimensional in nature. There is therefore no simplified measure to define treatment success. The standardisation for the measurement of POP, the POP-Q, and the use of condition-specific QOL questionnaires have however provided a more accurate and reproducible platform to describe success or failure. The recommendation from all relevant bodies is that outcome reporting should include a variety of standardised anatomic and functional measurements in women with pelvic floor disorders (Barber & Maher 2013).

A recent review by Chapple et al. highlighted the limitation of traditional outcome measures (Chapple et al. 2016). They showed the inadequate value of bladder diaries in evaluating outcomes in women with OAB when compared to patient-reported outcome measures. They however noted that QOL questionnaires have their own limitations. This exist in regards to the psychometric properties related to the population in which it is being utilised, recall period recommendations, and the amount of weight that it should carry in the integration with other measures for clinical management and subsequent clinical outcomes. The variation in reporting of bladder outcomes after POP surgery was summarized by Baessler et al and reflected the sentiments shared by Chapple et al. in regards to traditional outcome reporting (Baessler & Maher 2013).

The data on sexual function after POP surgery are also conflicting. This is in part a reflection of the complexity of sexual health which has been defined by the WHO as

“a state of physical, emotional, mental and social wellbeing in relation to sexuality”. The majority of reports observed that sexual function stayed the same or improved as long as the levator muscle is not plicated during the surgical repair. Sexual function is a domain which has often been found lacking in reported clinical outcomes of pelvic floor disorders, and specifically surgical outcomes. The determination of sexual function has also been varied and has consisted of history, generic QOL measurements and condition-specific QOL questionnaires (Dietz & Maher 2013). It is even the case with RCTs, which, although including sexual outcomes in their reporting, often has described it as a secondary outcome measurement and was subsequently underpowered to detect differences in sexual outcomes. Women with pelvic floor disorders have been shown to have poorer sexual function as reported by QOL questionnaires, have less frequent sexual activity, are more likely to restrict sexual activity for fear of incontinence, has decreased sexual excitement and difficulty in achieving orgasm during intercourse compared to women without these conditions (Rantell et al. 2016). Posterior colporrhaphy, particularly levator plication, is associated with postoperative dyspareunia. Consequently, older studies report alarmingly high rates of dyspareunia as well as apareunia following posterior repair (MA Kahn 1998). The modern approaches, such as site-specific repair of rectoceles, have a much lower reported risk of dyspareunia (Porter et al. 1999).

Defecatory disorders are frequently encountered not only in patients with rectoceles, but also as part of a wider pelvic floor dysfunction. There are numerous questionnaires that have been developed for defecatory disorders. The same criteria apply when selecting an individual questionnaire (Izumi 2014). Of importance in defecatory outcome evaluation is the use of terminology. It is essential that the terminology used

is specifically defined in order to allow for the evaluation of comparative outcomes (Barber 2007).

4.5 THE INTERPRETATION OF IMPROVEMENT

The change in mean scores derived from health related QOL assessment instruments may give statistically significant results, but the clinical interpretation of the meaning of small numerical differences remain uncertain.

What is considered to be important by patients may depend on a number of factors, many of which may be specific to that individual. For example, the importance of maintaining a given level of physical or social activity may vary between individuals; therefore, the importance, or significance, of changes in levels of these activities may be different for different individuals. Similarly, while one individual may consider some hair loss after chemotherapy very bothersome, another individual may consider the same degree of hair loss as being insignificant. The so-called "subjective significance" of improvement as determined by the individuals themselves is clinically more relevant than a statistically calculated significant change for a study group or population at large

4.6 SUMMARY

The application of patient assessed measures of health outcome has become increasingly important to the evaluation of health care. Condition-specific QOL instruments focus on aspects of health that are related to a particular area of disease and are therefore more likely to fulfil the requirements for treatment planning and outcome evaluation. The use of individualized measures to plan treatment additionally

allows patients to include different aspect of their lives which might have been influenced by the specific pelvic floor disorder. Clinicians on the other hand have been found across various disciplines to be inclined to underestimate the bothersomeness of a patient's symptoms.

There were four essential criteria identified for questionnaire selection in our healthcare environment. The questionnaires had to be highly recommended, evaluate both symptom distress and QOL, not consist of too many questions and be self-administered. The PFDI-20, PFIQ-7 and PISQ-12 questionnaires met all these criteria. The healthcare environment in which these questionnaires are used, entails a large volume of patients and limited healthcare workers and these were the motivation for the second and third criteria. The three questionnaires in combination provided a thorough assessment of all relevant aspects of PFD and its impact on QOL.

The methodology followed for the psychometric validation of these questionnaires have been referred to in Chapter 3 and is furthermore contained within the methodology sections of the following articles.

4.7 SUBMITTED ARTICLE: VALIDATION OF THE PFDI-20 AND PFIQ-7 QUESTIONNAIRES (ADDENDUM 12)

Validation of the PFDI-20 and PFIQ-7 quality of life questionnaires in the African languages of Afrikaans and Sesotho

Abstract

Introduction: Self-administered quality of life (QOL) questionnaires provide objective evaluation of an individual's symptoms. The Pelvic Floor Distress Inventory-20 (PFDI-20) and the Pelvic Floor Impact Questionnaire-7 (PFIQ-7) are condition-specific short form questionnaires. The aim of this study was to validate these questionnaires in South African women for the languages of Afrikaans and Sesotho.

Methods: Patients with pelvic floor disorders completed the questionnaires at baseline, one week later and after 6 months. A control group of women not known with pelvic floor disorders completed the questionnaires at baseline and one week later. Psychometric properties tested were internal consistency, reliability, construct validity and responsiveness.

Results: 100 Control and 100 study participants in each language group completed the scheduled rounds. Internal consistency, as measured by the Cronbach alpha value, was good for the PFDI-20 (0.71-0.89) and the PFIQ-7 (0.81-0.89) for both the Afrikaans and Sesotho patients. The test-retest reliability showed very good intraclass correlation coefficients of 0.89-0.99 across all scales of both questionnaires and in

both language groups. The construct validity was confirmed as was the responsiveness to treatment for both questionnaires.

Conclusion: The Afrikaans and Sesotho versions of the PFDI-20 and PFIQ-7 are reliable and valid instruments that can be used in women with pelvic floor disorders in South Africa.

Keywords: Africa, pelvic floor dysfunction, quality of life, questionnaires, validation

Introduction

Pelvic floor dysfunction (PFD) largely manifests as a variety of symptoms which can have a potentially detrimental effect on a woman's quality of life (QOL). The aim of any treatment plan for such an individual is the restoration of function. The objective and standardized assessment of symptoms are of vital importance to jointly guide the planning of treatment and the evaluation of functional outcomes. This assessment can be achieved with the use of condition-specific health-related QOL questionnaires (1). The Pelvic Floor Distress Inventory-20 (PFDI-20) and the Pelvic Floor Impact Questionnaire-7 (PFIQ-7) are validated short form questionnaires that measure symptom severity and impact on QOL (2). These questionnaires have been linguistically and culturally validated in diverse languages and cultures (3)(4)(5)(6)(7)(8)(9)(10)(11)(12). This process additionally allows for international comparison of symptom severity and response to treatment. It has however never been validated in any African language or culture. The cultural and linguistic validation of these questionnaires were performed in South African women for the Afrikaans and Sesotho languages.

Materials and methods

This research was performed at a referral urogynecology unit in Universitas Academic Hospital as well as at a general gynecology outpatient clinic in Pelonomi Hospital, Bloemfontein, South Africa. The research was approved by the local ethics committee (HSREC 51/2016). The PFDI-20 measures symptom severity and consists of three scales: the pelvic organ prolapse distress inventory-6 (POPDI-6), the colorectal-anal distress inventory-8 (CRADI-8) and the urinary distress inventory-6 (UDI-6). Each item in a specific scale can be scored form 0-4 and the scale score is calculated as a percentage. The PFDI-20 score is the sum of the scale scores out of 300. The PFIQ-7 measures symptom impact on QOL and also consists of three scales: the urinary impact questionnaire-7 (UIQ-7), the colorectal-anal impact questionnaire-7 (CRAIQ-7) and the pelvic organ prolapse impact questionnaire-7 (POPIQ-7). Each item in these scales can be score from 0-3 and the scale score is calculated as a percentage. The PFIQ-7 score is the sum of the scale scores out of 300. A higher score in each of these questionnaires indicated more symptom bother.

Linguistic and cultural validation

The questionnaires were translated into Afrikaans and Sesotho by means of three forward translations by clinicians and backward translation by a native speaker not involved in the forward translation (13)(14). They were then tested on a sample of ten women with pelvic floor dysfunction during which they completed the questionnaires and were interviewed afterwards. The content were not altered, but the layout and approach to administration of the questionnaires were restructured and finalized based on these interviews.

Study design and population

Women were eligible to be included if they were over the age of 18 years, did not suffer from any chronic pain syndrome and were literate in the language evaluated. The study group consisted of women referred to the Urogynecology unit with complaints of PFD. The control group consisted of women seen at a general gynecology outpatient clinic who were not referred due to PFD. The sample size was determined by the number of items in the questionnaire. We selected a minimum of five participant per item (15). The PFDI-20 had the most items and the aim was thus to recruit 100 study and 100 control participants per language group. Definitions used for pelvic organ prolapse (POP), urinary incontinence (UI) and anal incontinence (AI) were according to the International Urogynecological Association (IUGA)/International Continence Society (ICS) report on terminology (16). AI was noted as present if the symptom of either fecal and/or flatus incontinence was asserted at baseline data completion.

Participants completed both questionnaires at the baseline visit and one week later. The study group also completed the questionnaires 6 months later to allow for the evaluation of intervention. The completion of the questionnaires after one week was by means of telephonic administration (17). The desired modality is self-completion by the patient. This was however the only feasible option to permit for test-retest assessment in this population due to the vast referral area, cost of transport, lack of internet facilities and lack of an effective postal service. Any treatment were deferred during this week to avoid test-retest changes related to clinical improvement. The study group completed the patient global impression of improvement (PGI-I) in the third round (18). The PGI-I was dichotomized into “improved” for scores 1-3 and “not improved” for scores 4-7.

Measurement properties

The psychometric domains of reliability, validity and responsiveness were assessed for each questionnaire as recommended in the consensus-based standards for the selection of health measurement instruments (COSMIN) checklist (19).

Internal consistency was assessed by Cronbach's alpha value for the extent to which the individual scale items measure the same concept. Acceptable values range from 0.70 to 0.95 (20).

Test-retest reliability was assessed by the completion of the questionnaires one week apart. This time period is considered long enough to prevent recall bias, but short enough for any relevant clinical changes to occur. It is calculated as the intraclass correlation coefficient (ICC) between the baseline and second round of completion and is performed for all individual scales as well as for the summary scores. Values ≥ 0.70 were considered to reflect adequate reliability (21). Measurement error was expressed as the calculated limits of agreement (LOA) and summarized as the mean change of scores during the test-retest period and was a reflection of the random error of scores not attributable to true clinical changes (22).

Construct validity assesses the validity of the questionnaires to measure the given construct, i.e. PFD (21). We hypothesized the following: The women with symptoms of POP will score higher in the POPDI-6 and POPIQ-7 scales than those without. The women with symptoms of UI will score higher in the UDI-6 and UIQ-7 scales than those without. The women with symptoms of AI will score higher in the CRADI-8 and CRAIQ-7 scales than those without. Construct validity was considered adequate when at least 75% of these hypotheses were confirmed (23)(21).

Responsiveness in the context of a questionnaire can be defined as the outcome that can be achieved when the instrument is designed in such a way that it is cognisant of

and respond appropriately to the clinical result experienced by the individual. Responsiveness therefore measures the ability of the questionnaires to detect change that occurs as a result of treatment. This was assessed during the third round in the study population. The relationship of the mean change in scores and the PGI-I's dichotomized classification were summarized. The baseline scores were also compared to the third round scores using the paired t-test and in this case a value of $p < 0.05$ was considered significant of improvement. The standardised response mean (SRM) was used to evaluate whether the questionnaires were responsive to change at the group-level in each of the languages. The changes in mean values were calculated and 95% confidence intervals were constructed by assuming a normal distribution (24)(25). A number of statistical tests have been described to evaluate responsiveness. The SRM is however considered appropriate when evaluating responsiveness in single group pre- and post-intervention as was the case in this population (26)(27).The difference in mean PFDI-20 and PFIQ-7 scores between those classifying themselves as "improved" compared to "not improved" via the PGI-I were used to define a cut-off value indicative of improvement.

The remainder of results were summarized categorically by frequencies and percentages. The Chi-square and Fischer's exact tests were used for investigating univariate associations and the unpaired t-test for continuous variables. Statistical significance was set at a p-value < 0.05

Results

The eligible study population consisted of 213 (64.5%) women out of a possible 330 women for the Afrikaans and Sesotho questionnaire validation. Of these 208 (97.6%) (104 in each language group) consented to participate in the three rounds and 200

(96.1%) completed the required questionnaires at the specified time points. For the control group, 206 (89.2%) women (103 in each language group) out of 231 approached, consented to participate and completed data were available for 200 (97.1%) of these. The baseline characteristics are summarized in Table 1. The mean age of the study groups were higher (p <0.0001) for both languages. There was a significant difference (p <0.0001) in pelvic floor symptoms between the study and control groups for both languages and the majority of participants in the study groups experienced more than one symptom.

Table 1 Baseline characteristics and questionnaire scores of participants

Metric	**Afrikaans Study (n=100)**	**Afrikaans Control (n=100)**	**P value**	**Sesotho Study (n=100)**	**Sesotho Control (n=100)**	**P value**
Age (years)	59.94 ± 9.75	48.76 ± 13.38	<0.0001*	56.42 ± 11.77	46.45 ± 11.75	<0.0001*
Education						
Primary school	26 (26)	6 (6)	0.0002*	44 (44)	47 (47)	0.3089
Secondary	55 (55)	48 (48)	0.3960	48 (48)	29 (29)	0.0087*
Grade 12	15 (15)	40 (40)	0.0001*	7 (7)	21 (21)	0.0072*
Higher education	4 (4)	6 (6)	0.7475	1 (1)	3(3)	0.6212
Parity	3 (0-6)	3 (1-5)	0.1615	4 (0-8)	3 (1-7)	0.0009*
POP	88 (88)	13 (13)	<0.0001*	92 (92)	19 (19)	<0.0001*
UI	68 (68)	12 (12)	<0.0001*	53 (53)	9 (9)	<0.0001*
AI	34 (34)	6 (6)	<0.0001*	46 (46)	8 (8)	<0.0001*
Symptoms per patient						
0	0 (0)	81 (81)	<0.0001*	0 (0)	74 (74)	<0.0001*
1	35 (35)	9 (9)	<0.0001*	45 (45)	17 (17)	<0.0001*
2	40 (40)	8 (8)	<0.0001*	19 (19)	8 (8)	<0.0001*
3	25 (25)	2 (2)	<0.0001*	36 (36)	1 (1)	<0.0001*

PFDI-20 (0-300)	131.8 ± 59.2	16.1 ± 22.3	<0.0001*	124.9 ± 55.2	26.8 ± 26.7	<0.0001*
POPDI-6(0-100)	52.1 ± 23.2	6.8 ± 12.7	<0.0001*	54.7 ± 21.8	13.2 ± 14.3	<0.0001*
Missing	7 (1.16)	12 (2.00)	0.3554	6 (1.00)	2 (0.33)	0.2874
CRADI-8 (0-100)	32.2 ± 25.2	4.4 ± 6.9	<0.0001*	31.7 ± 21.8	6.4 ± 10.2	1.0000
Missing	8 (1.00)	8 (1.00)	1.0000	7 (0.87)	7 (0.87)	1.0000
UDI-6 (0-100)	45.2 ± 27.8	4.8 ±7.3	<0.0001*	36.0 ± 24.9	7.1 ± 9.7	<0.0001*
Missing	9 (1.50)	4 (0.67)	0.2642	9 (1.50)	5 (0.83)	0.6608
PFIQ-7 (0-300)	115.5 ± 61.6	13.2 ± 15.1	<0.0001*	116.1 ± 62.4	13.8 ± 16.5	<0.0001*
UIQ-7 (0-100)	44.2 ± 29.1	4.7 ± 5.8	<0.0001*	39.8 ± 27.8	5.7 ± 6.6	<0.0001*
Missing	10 (1.43)	13 (1.86)	0.6746	13 (1.86)	22 (3.14)	0.1691
CRAIQ-7 (0-100)	25.9 ± 26.2	2.9 ± 4.9	<0.0001*	30.2 ± 26.5	3.3 ± 5.5	<0.0001*
Missing	11 (1.57)	10 (1.43)	0.8261	11 (1.57)	18 (2.57)	0.2608
POPIQ-7 (0-100)	45.4 ± 27.9	5.1 ± 7.9	<0.0001*	46.1 ± 25.6	4.8 ± 8.0	<0.0001*
Missing	7 (1.00)	10 (1.43)	0.6266	9 (1.28)	12 (1.71)	0.6608

Data summarized as mean ± standard deviation, n (%), or median and (range). Unpaired t-test for means, Mann-Whitney U test for medians and Fisher's and Chi-square tests for numerical data. *P value ≤ 0.05.

Internal consistency

The PFDI-20 demonstrated good internal consistency with Cronbach alpha values of 0.89 and 0.84 in the Afrikaans study and control groups and acceptable consistency among the Sesotho study (0.71) and control (0.75) groups. The PFIQ-7 demonstrated good consistency (0.88) in the Afrikaans study group, but poor consistency (0.54) in the control group. A similar pattern was found among the Sesotho study (0.81) and control (0.64) participants.

Reliability

The test-retest intraclass correlation for both participant groups in both languages ranged from 0.89 to 0.99 and confirmed very good reliability. It also confirmed that it was feasible and reliable to perform a telephonic follow-up with these questionnaires in the population studied.

Table 2: Internal consistency and reproducibility

	Internal consistency				**Test-retest reliability**			
QOL	**Afrikaans Study (n=20)**	**Afrikaans Control (n=10)**	**Sotho Study (n=20)**	**Sotho Control (n=10)**	**Afrikaans Study (n=100)**	**Afrikaans Control (n=100)**	**Sotho Study (n=100)**	**Sotho Control (n=100)**
PFDI-20	0.89	0.83	0.71	0.75	0.97	0.99	0.97	0.98
POPDI-6	0.80	0.91	0.43	0.43	0.95	0.99	0.99	0.98
CRADI-8	0.89	0.59	0.85	0.61	0.99	0.99	0.98	0.97
UDI-6	0.79	0.78	0.71	0.61	0.99	0.98	0.98	0.95
PFIQ-7	0.88	0.54	0.81	0.64	0.99	0.93	0.98	0.97
POPIQ-7	0.86	0.27	0.70	0.45	0.99	0.97	0.98	0.96
CRAIQ-7	0.97	0.40	0.79	0.31	0.99	0.90	0.96	0.95
UIQ-7	0.93	0.47	0.81	0.52	0.99	0.89	0.98	0.92

Cronbach alpha for internal consistency. Intraclass correlation coefficient for test-retest reliability.

Measurement error

The LOA are summarized in table 3 for the different language groups. The overall magnitude of the measurement error was calculated by dividing the LOA by the range of all measures. The measurement error was 8.8% for the PFDI-20 and 3.2-8.4% for the PFIQ-7 among the study participants in both groups. This confirmed low measurement error in both language groups.

Table 3: Limits of agreement (LOA)

QOL	Afrikaans Study (n=100)	MME (%)	Afrikaans Control (n=100)	MME (%)	Sotho Study (n=100)	MME (%)	Sotho Control (n=100)	MME (%)
PFDI-20	-29.6 to 23.5	8.8	-4.1 to 3.2	1.2	-28.9 to 24.2	8.8	-8.6 to 6.6	5.1
POPDI-6	-14.5 to 14.0	14.2	-3.4 to 2.8	3.1	-5.7 to 5.4	5.5	-5.6 to 4.3	4.9
CRADI-8	-3.3 to 3.3	3.3	-1.8 to 1.5	1.6	-9.1 to 8.2	8.6	-4.8 to 4.3	4.5
UDI-6	-6.4 to 5.1	6.4	-2.7 to 2.7	2.7	-8.1 to 9.6	8.8	-5.9 to 5.8	5.8
PFIQ-7	-10.5 to 8.7	3.2	-12.9 to 8.2	3.5	-27.5 to 22.9	8.4	-7.6 to 8.3	2.6
POPIQ-7	-6.1 to 5.3	5.7	-4.2 to 3.4	3.8	-11.1 to 8.8	9.9	-3.9 to 4.3	4.1
CRAIQ-7	-5.2 to 4.8	5.0	-4.8 to 3.1	3.9	-11.6 to 8.9	10.2	-3.7 to 3.1	3.4
UIQ-7	-4.9 to 4.3	4.6	-5.4 to 4.2	4.8	-13.2 to 13.8	13.5	-4.7 to 5.6	5.1

MME = overall magnitude of measurement error (%)

Construct validity

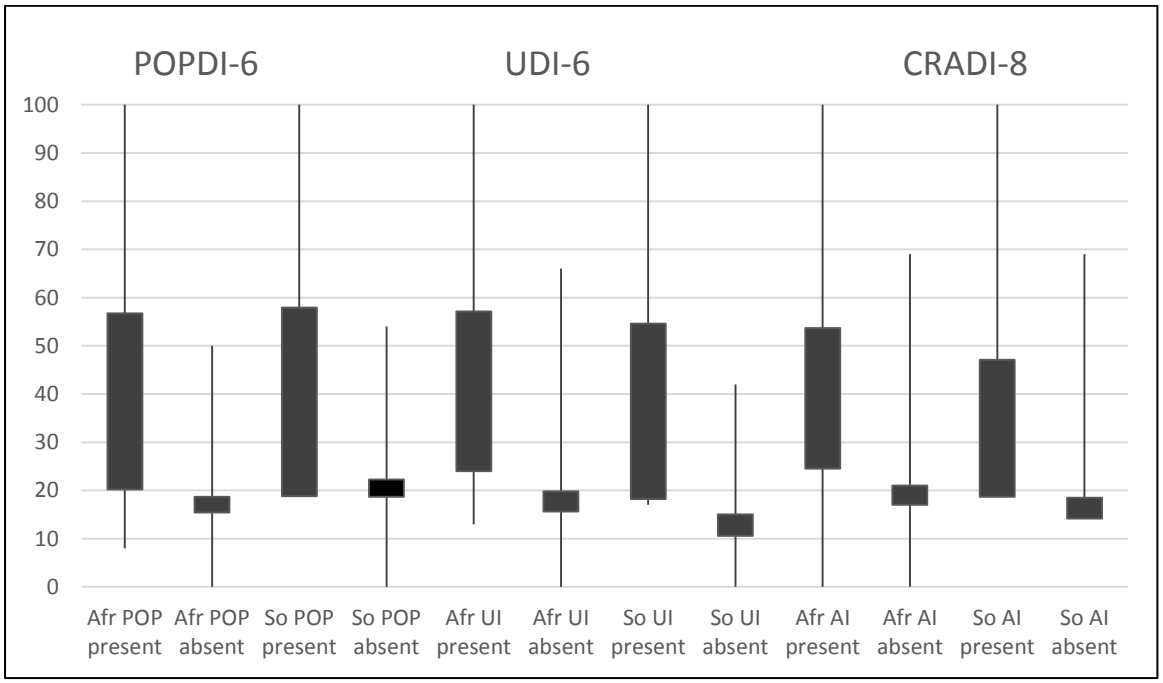
Figures 1 and 2 illustrate the construct validity. The Afrikaans subgroup with POP reported higher mean scores for the POPDI-6 (56.7 ± 20.2) and POPIQ-7 scales (50.2 ± 26.0) than those without (18.7 ± 15.4 and 10.4 ± 13.7 respectively), ($p < 0.0001$). The Sesotho subgroup with POP reported higher mean scores for the POPDI-6 (57.8 ± 18.8) and POPIQ-7 scales (48.4 ± 24.9) than those without (18.7 ± 22.3 and 20.2 ± 18.4 respectively), ($p < 0.0001$).

The Afrikaans subgroup with UI reported higher mean scores for the UDI-6 (57.1 ± 24.0) and UIQ-7 scales (52.6 ± 27.7) than those without (19.8 ± 15.6 and 26.3 ± 23.8 respectively), ($p < 0.0001$). The Sesotho subgroup with UI reported higher mean scores for the UDI-6 (54.6 ± 18.2) and UIQ-7 scales (51.7 ± 25.0) than those without (15.0 ± 10.7 and 26.3 ± 24.7 respectively), ($p < 0.0001$).

The Afrikaans subgroup with AI reported higher mean scores for the CRADI-6 (53.7 ± 24.5) and CRAIQ-7 scales (41.1 ± 29.9) than those without (21.1 ± 17.2 and 18.2 ± 20.2 respectively), ($p < 0.0001$). The Sesotho subgroup with AI reported higher mean scores for the CRADI-6 (47.1 ± 18.7) and CRAIQ-7 scales (40.9 ± 25.8) than those without (18.5 ± 14.2 and 21.0 ± 23.7 respectively), ($p < 0.0001$).

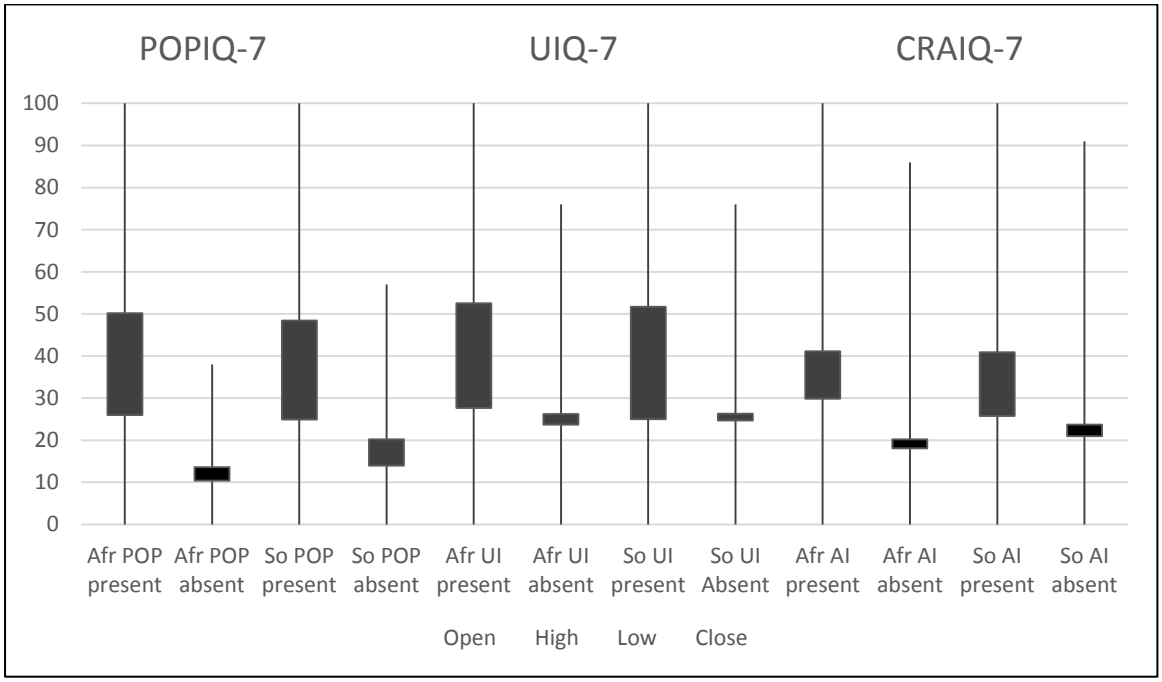
These findings supported the specified hypotheses for POP, UI and AI.

Figure 1: PFDI-20 scales.



Afr POP = Afrikaans POP. So POP = Sesotho POP. Afr UI = Afrikaans UI. So UI = Sesotho UI. Afr AI = Afrikaans AI. So AI = Sesotho AI. Box = mean and standard deviation. Whisker = minimum and maximum scores. N=100 for each variable.

Figure 2: PFIQ-7 scales



Afr POP = Afrikaans POP. So POP = Sesotho POP. Afr UI = Afrikaans UI. So UI = Sesotho UI. Afr AI = Afrikaans AI. So AI = Sesotho AI. Box = mean and standard deviation. Whisker = minimum and maximum scores. N=100 for each variable.

Responsiveness

The 3rd round of completion was after an average period of 5.2 months. One hundred participants in each language group completed the 3rd round of questionnaires (table 3). There was a significant improvement in scores across all domains and this was evident in both language groups.

Table 4: Responsiveness

Questionnaire	**Afrikaans (n=100)**		**P-value**	**Sesotho (n=100)**		**P-value**
	Mean	**95% CI**		**Mean**	**95% CI**	
PFDI-20	-94.5 ± 63.6	-107.1, -81.9	<0.0001*	-94.7 ± 63.4	-107.3, -82.2	<0.0001*
POPDI-6	-37.4 ± 25.3	-42.4, -32.4	<0.0001*	-44.2 ± 26.8	-49.5, -38.9	<0.0001*
CRADI-8	-22.3 ± 23.4	-26.9, -17.6	<0.0001*	-22.3 ± 19.8	-26.2, -18.3	<0.0001*
UDI-6	-32.3 ± 27.4	-37.7, -26.8	<0.0001*	-25.8 ± 26.3	-31.0, -20.6	<0.0001*

PFIQ-7	-87.6 ± 64.5	-100.4, -74.8	<0.0001*	-87.1 ± 66.6	-100.3, -73.9	<0.0001*
POPIQ-7	-33.6 ± 31.8	-39.9, -27.3	<0.0001*	-37.5 ± 28.6	-43.1, -31.8	<0.0001*
CRAIQ-7	-19.6 ± 24.0	-24.3, -14.8	<0.0001*	-21.2 ± 25.1	-26.2, -16.2	<0.0001*
UIQ-7	-32.6 ± 29.1	-38.4, -26.8	<0.0001*	-28.3 ± 29.2	-34.0, -22.5	<0.0001*

Data presented as change in mean (± standard deviation) and 95% confidence intervals. * P-value < 0.05

The PGI-I results showed improvement in the Afrikaans group in 79% and in 81% among the Sesotho participants. Comparing the summary scores of the questionnaires, the cut-off score to distinguish the improved population form those who were classified as not improved could be determined. This score for the PFDI-20 was <35 and for the PFIQ-7 it was < 24 in the Afrikaans group. Among the Sesotho participants, the PFDI-20 cut-off score was < 31 and the PFIQ-7 score < 30.

Discussion

The objective of this study was to validate the PFDI-20 and PFIQ-7 in South African women for the Afrikaans and Sesotho languages. The psychometric properties of reliability, validity and responsiveness affirmed the validated nature of these questionnaires in this population.

The original PFDI and PFIQ showed very good internal consistency with alpha values of 0.88 and 0.97 respectively. This agreement was confirmed with the development of the short form versions of these questionnaires (2). Overall Cronbach alpha values between 0.71-0.89 for the PFDI-20 and 0.81-0.88 for the PFIQ-7 were calculated in the two language groups. Similar alpha values were documented in the Spanish,

Turkish, Japanese, Chinese, Hebrew, Dutch and Swedish versions of the PFDI-20 and PFIQ-7 questionnaires. (4) (9)(5)(7)(10)(3)(8).

A telephonic interview as described by Geller et al. was used for the second round (17). This was a potential concern in regards to its effect on reliability. The calculated ICC values were 0.89-0.99 in this population by means of telephonic administration. These ICC values were not inferior to those documented in the validation of these questionnaires elsewhere (3)(8)(5). The high correlation could be explained by the fact that the patient had completed the questionnaires herself the week before and was thus familiar with the questions being asked telephonically. This might not have been the case if the questionnaires were primarily administered telephonically.

Responsiveness is an essential element to assess any intervention. This is of particular importance in urogynecology where the primary aim of an intervention is mostly to improve the individual's QOL (28)(29). The PGI-I was utilized as the gold standard to allow for evaluation of response to intervention. The responsiveness was statistically significant across all scales ($P < 0.0001$) in this population for both languages. A similar degree of responsiveness has been shown in the validation of these questionnaires in Turkish and Dutch populations (9)(3). Responsiveness was however not evaluated in the majority of PFDI-20 and PFIQ-7 validation studies (30)(5)(4)(6)(8)(10). The initial validation of these short form questionnaires found the PFDI-20 to be more responsive (2). This was not observed in this population and there is no apparent explanation for this finding at present.

There were some limitations to this study. The internal consistency was evaluated on a smaller sample of women and the Cronbach alpha value might be altered if a larger sample were analyzed. The second round of completion were conducted

telephonically and although the format was structured, it was not possible to ensure this for all interviews. It additionally introduces a modality that was not specifically validated in this population. The statistical results were however reassuring in regards to the test-retest reliability. The education level of both language groups were generally limited and we had to verbally explain and demonstrate to the majority of patients the process of filling in and scoring symptom severity for the questionnaires. This was in addition to having redesigned the questionnaires after the pilot phase to permit ease of completion. This results in a more labour intensive process and furthermore emphasize the importance of short form questionnaires in an environment with limited human resources, such as South Africa. Longer questionnaires would very likely not have been practically feasible in our environment and possibly result in high rates of incomplete questionnaires, which subsequently limits its clinical worth. Pelvic floor symptom screening was not repeated in the third round and only the PGI-I was used to calculate responsiveness of the questionnaires. This lack of additional clinical information had the potential of influencing the evaluation of responsiveness and consequently the determination of improvement or deterioration of function. This method was selected as a feasible approach in order to allow for a comparable analysis between the study and control groups.

The strengths of this study are the use of an adequate sample size based on the items evaluated in the questionnaires for both the study and the control groups. The methodological design of this study was according to the recommendations of the COSMIN initiative in order to ensure adequate evaluation of the different psychometric measurement properties for these questionnaires. This is especially important for the validation of patient-reported health outcomes. The control group allowed us insight into the score distribution in women who have not been identified with pelvic floor

dysfunction. It revealed the importance of public education in regards to symptoms of pelvic floor dysfunction. This was particularly observed among the Sesotho speaking women, where an unexpectedly high number of women (26%) with symptoms of PFD were identified. This was in contrast to an expected low prevalence of this condition amongst ethnic black African women, based on observations in the referral urogynecology unit. The role of the questionnaires as a routine screening tool should hence be further explored in this population to allow for the identification of PFD and appropriate referral and management. It also points out the lack of robust epidemiological data that exists for PFD among South African and African women.

Conclusion

The validation of the PFDI-20 and PFIQ-7 in South African women for Afrikaans and Sesotho languages has revealed appropriate psychometric properties to permit its use in clinical practice. Practical guidance for the administration of these questionnaires have been recognized in this population and healthcare setting. A much higher than expected prevalence of pelvic floor dysfunction among Sesotho speaking women was observed and this requires further investigation.

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4.8 SUBMITTED ARTICLE: VALIDATION OF THE PISQ-12 QUESTIONNAIRE (ADDENDUM 13)

Validation of a sexual function quality of life questionnaire in the African languages of Afrikaans and Sesotho

Abstract

Introduction: The Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire-12 (PISQ-12) is a condition-specific quality of life (QOL) instrument. The objective of this study was to validate this questionnaire in South African women for the languages of Afrikaans and Sesotho.

Methods: Patients with pelvic floor disorders completed the questionnaires at baseline, one week later and after 6 months. A control group of women not known with pelvic floor disorders completed the questionnaires at baseline and one week later. Psychometric properties tested were internal consistency, reliability, construct validity and responsiveness.

Results: 100 Control and 100 study participants in each language group completed the scheduled rounds. Internal consistency, as measured by the Cronbach alpha value, was very good (0.83-0.84) for both the Afrikaans and Sesotho patient groups. The test-retest reliability showed very good intraclass correlation coefficients of 0.98-0.99 in both language groups. The construct validity was confirmed as was the responsiveness to treatment for both questionnaires.

Conclusions: The Afrikaans and Sesotho versions of the PISQ-12 are reliable and valid instruments that can be used in women with sexual dysfunction associated with pelvic floor disorders in South Africa

Keywords: Africa, PISQ-12, quality of life, questionnaire, sexual dysfunction, validation

Introduction

Pelvic organ prolapse (POP) is a prevalent condition and requires surgical correction in up to 1 in 5 women in their lifetime (Wu et al. 2014). Urinary, bowel and sexual dysfunction often accompanies POP and is a reflection of a larger pelvic floor disorder (2). Female sexual dysfunction (SD) is underestimated in women seen for routine gynecological evaluation and often not specifically explored by the attending clinician (3)(4). It is particularly more prevalent in those with pelvic floor disorders, such as POP, urinary incontinence (UI) and anal incontinence (AI) and detrimentally affects these women's quality of life (QOL) (5)(6)(7). Female sexual function is however complex and evaluations should include physical, emotional and psychological factors. Validated, condition-specific QOL health questionnaires allow for a structured and objective evaluation which is repeatable over time and allows for the consideration of therapeutic interventions.

The Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire-12 (PISQ-12) is a short form condition-specific questionnaire and is the validated short form of the PISQ-31 (8). It has been validated in other cultures and languages (9)(10)(11)(12)(13)(14)(15). A more recent measure of sexual function, the Pelvic Organ Prolapse/Incontinence Sexual Questionnaire, IUGA-Revised (PISQ-IR) has

been developed to evaluate both sexually active and inactive women (16). The foundation of this questionnaire was the PISQ-12. It is a much more comprehensive sexual questionnaire, but that asset is a limitation in a resource limited environment. There is limited epidemiological data for female SD in South Africa (17). There is furthermore no validated female sexual function questionnaire available for South African women to the best of our knowledge. The aim of this research was to translate and psychometrically validate the PISQ-12 for the South African languages of Afrikaans and Sesotho.

Materials and methods

This research was performed at a referral Urogynecology unit in Universitas Academic Hospital as well as at a general gynecology outpatient clinic in Pelonomi Regional Hospital, Bloemfontein, South Africa. The research was approved by the local ethics committee (HSREC 51/2016). The PISQ-12 consists of 12 questions on sexual function. Questions 1-4 deals with behavioral and emotive factors, questions 5-9 with physical factors and questions 10-12 with partner related factors. Each question can be scored from 0-4 and the overall score is a numeric value out of 48. A higher score indicates less symptom bother.

Linguistic and cultural validation

The questionnaire was translated into Afrikaans and Sesotho by means of three forward translations by clinicians and backward translation by a native speaker not involved in the forward translation (18)(19). It was then tested on a sample of ten women with pelvic floor dysfunction (PFD) during which they completed the questionnaire and were interviewed afterwards. Based on feedback received, the

content was subsequently altered to identify those women not sexually active and without a partner. The layout and approach to administration of the questionnaire was also restructured and finalized based on these interviews.

Study design and population

Women were eligible to be included if they were over the age of 18 years, did not suffer from any chronic pain syndrome and were literate in the language evaluated. The study group consisted of women referred to the Urogynecology unit due to PFD. The control group consisted of women seen at a general gynecology outpatient clinic who were not referred due to PFD. The sample size for validation of a questionnaire is determined by the number of items in the questionnaire. The recommended calculation is 5-10 participants per item (20). We set out to recruit 200 women in each language group (100 study participants and 100 control participants). Definitions used for POP, UI, AI and SD symptoms were according to the International Urogynecological Association (IUGA)/International Continence Society (ICS) report on terminology (21). SD was affirmed in the data collection if the participant reported sexual difficulty during sexual activity over the preceding six months.

Participants completed the PISQ-12 at the baseline visit and one week later. The study group additionally completed the questionnaire 6 months later to allow for the evaluation of sexual function after intervention. The completion of the questionnaire after one week was by means of telephonic administration (22). The preferred modality for this questionnaire is self-administration. This was however the only feasible option to permit for test-retest reliability in this population due to the vast referral area, cost of transport, lack of internet facilities and lack of an effective postal service. Any treatment was deferred during this week to avoid test-retest changes related to clinical

improvement. The study group completed the patient global impression of improvement (PGI-I) scale in the third round (23). The PGI-I was dichotomized into “improved” for responses 1-3 and “not improved” for responses 4-7.

Measurement properties

The psychometric domains of reliability, validity and responsiveness were assessed for each questionnaire as recommended in the consensus-based standards for the selection of health measurement instruments (COSMIN) checklist (24).

Internal consistency was assessed by Cronbach’s alpha for the extent to which the individual scale items measure the same concept. Acceptable values range from 0.70 to 0.95 (25). Internal consistency was evaluated in 20 cases and 10 controls in each language group.

Test-retest reliability was assessed by the completion of the questionnaires one week apart. This time period is considered long enough to prevent recall bias, but short enough for any relevant clinical changes to occur. It is calculated as the intraclass correlation coefficient (ICC) between the baseline and second round of completion and is performed for all individual scales as well as for the summary scores. Values ≥ 0.70 were considered to reflect adequate reliability (26). Measurement error was expressed as the calculated limits of agreement (LOA) and summarized as the mean change of scores during the test-retest period and is a reflection of the random error of scores not attributable to true clinical changes (27).

Construct validity assesses the validity of the questionnaires to measure the given construct, i.e. sexual dysfunction in women with pelvic floor dysfunction (26). We hypothesized the following: The women with SD would score lower in the PISQ-12

questionnaire than those without. Construct validity was considered adequate when the hypothesis was confirmed in at least 75% of the population studied (28)(26).

Responsiveness in the context of a questionnaire can be defined as the outcome that can be achieved when the instrument is designed in such a way that it is cognisant of and respond appropriately to the clinical result experienced by the individual. Responsiveness therefore measures the ability of the questionnaire to detect change that occurs as a result of treatment. This was assessed at the third round in the study population. The relationship of the mean change in scores and the PGI-I's dichotomized classification were summarized. The baseline scores were also compared to the third round scores using the paired t-test and in this case a value of $p < 0.05$ was considered significant of improvement. The standardised response mean (SRM) was used to evaluate whether the questionnaires were responsive to change at the group-level in each of the languages. The changes in mean values were calculated and 95% confidence intervals were constructed by assuming a normal distribution (29)(30). A number of statistical tests have been described to evaluate responsiveness. The SRM is however considered appropriate when evaluating responsiveness in a single group pre- and post-intervention as was the case in this population (31)(32).

The remainder of results were summarized categorically by frequencies and percentages. The Chi-square and Fischer's exact tests were used for investigating univariate associations and the unpaired t-test for continuous variables. Statistical significance was set at a p-value < 0.05

Results

The eligible study population consisted of 213 (64.5%) women out of a possible 330 women for the Afrikaans and Sesotho questionnaire validation. Of these 208 (97.6%) (104 in each language group) consented to participate in the three rounds and 200 (96.1%) completed the required questionnaires at the specified time points. For the control group, 206 (89.2%) women (103 in each language group) out of 231 approached consented to participate and completed data was available for 200 (97.1%) of these. The baseline characteristics are summarized in Table 1. The mean age of the study groups were higher (p <0.0001) for both languages. There was a significant difference (p <0.0001) in pelvic floor symptoms between the study and control groups for both languages and the majority of participants in the study groups experienced more than one symptom. In the Afrikaans population, 23 (23%) of study participants and 13 (13%) of control participants were not sexually active due to the absence of a partner. In the Sesotho population, this was documented in 19 (19%) of the study participants and in 5 (5%) of the control participants.

Table 1 Baseline characteristics and questionnaire score of participants

Metric	**Afrikaans study group (n=100)**	**Afrikaans control group (n=100)**	**P value**	**Sesotho study group (n=100)**	**Sesotho control group (n=100)**	**P value**
Age (years)	59.94 ±9.75	48.76 ±13.38	<0.0001*	56.42 ±11.77	46.45 ±11.75	<0.0001*
Education						
Primary school	26 (26)	6 (6)	0.0002*	44 (44)	47 (47)	0.3089
Secondary	55 (55)	48 (48)	0.3960	48 (48)	29 (29)	0.0087*
Grade 12	15 (15)	40 (40)	0.0001*	7 (7)	21 (21)	0.0072*
Higher education	4 (4)	6 (6)	0.7475	1 (1)	3(3)	0.6212
Parity	3 (0-6)	3 (1-5)	0.1615	4 (0-8)	3 (1-7)	0.0009*

POP	88 (88)	13 (13)	<0.0001*	92 (92)	19 (19)	<0.0001*
UI	68 (68)	12 (12)	<0.0001*	53 (53)	9 (9)	<0.0001*
AI	34 (34)	6 (6)	<0.0001*	46 (46)	8 (8)	<0.0001*
Symptoms per patient						
0	0 (0)	81 (81)	<0.0001*	0 (0)	74 (74)	<0.0001*
1	35 (35)	9 (9)	<0.0001*	45 (45)	17 (17)	<0.0001*
2	40 (40)	8 (8)	<0.0001*	19 (19)	8 (8)	<0.0001*
3	25 (25)	2 (2)	<0.0001*	36 (36)	1 (1)	<0.0001*
Sexual						
Dysfunction	53 (68.83)	17 (19.54)	<0.0001*	51 (62.96)	23 (24.21)	<0.0001*
Not active/partner	23 (23)	13 (13)	0.0967	19 (19)	5 (5)	0.0039*
PISQ-12 (0-48)	24.9 ± 7.9	35.1 ± 6.3	<0.0001*	24.6 ± 8.1	35.4 ± 6.2	<0.0001*
Missing	12 (1.00)	13 (1.08)	0.8407	15 (1.25)	23 (1.91)	0.2524

Data summarized as mean ± standard deviation, n (%), or median and (range). Unpaired t-test for means, Mann-Whitney U test for medians and Fisher's and Chi-square tests for numerical data. *P value < 0.05.

Internal consistency

The PISQ-12 demonstrated very good to excellent overall internal consistency with Cronbach alpha values of 0.83 to 0.84 in the study groups and 0.77 to 0.92 in the control groups. The behavioral and emotive domain (questions 1-4) showed moderate to good consistency in the study groups (0.63-0.79) and good to very good consistency in the control groups (0.71-0.83). The physical domain (question 5-9) showed very good consistency for the study groups (0.80-0.83) and good consistency for the control groups (0.73-0.76). The partner related domain showed moderate to good consistency in the study groups (0.63-0.71) and moderate to very good consistency in the control groups (0.62-0.87). This domain scored lowest among all Sesotho speaking

participants and it was specifically the question on premature ejaculation (0.31-0.46) and quality of female orgasm (0.35-0.58) that had the lowest consistency.

Table 2: Internal consistency and reproducibility

Internal consistency					Test-retest reliability			
QOL	Afrikaans Study (n=20)	Afrikaans Control (n=10)	Sotho Study (n=20)	Sotho control (n=10)	Afrikaans Study (n=100)	Afrikaans Control (n=100)	Sotho Study (n=100)	Sotho control (n=100)
PISQ-12	0.84	0.92	0.83	0.77	0.98	0.99	0.98	0.98
PISQ:1-4	0.63	0.83	0.79	0.71				
PISQ:5-9	0.80	0.76	0.83	0.73				
PISQ:10-12	0.71	0.87	0.63	0.62				

Cronbach alpha for internal consistency. Intraclass correlation coefficient for test-retest reliability.

Reliability

The test-retest intraclass correlation for both the study and control groups in both languages ranged from 0.98 to 0.99 and confirmed very good reliability of the questionnaire. It furthermore confirmed that it was feasible and reliable to perform a telephonic follow-up of the PISQ-12 in this population group.

Measurement error

The LOA are summarized in table 3 for the different language groups. The overall magnitude of the measurement error was calculated by dividing the LOA by the range of all measures. The measurement error was 4.8-4.9% among the study participants in both groups. This confirmed low measurement error in both language groups.

Table 3: Limits of agreement (LOA)

QOL	**Afrikaans Study (n=100)**	**MME (%)**	**Afrikaans Control (n=100)**	**MME (%)**	**Sotho Study (n=100)**	**MME (%)**	**Sotho Control (n=100)**	**MME (%)**
PISQ-12	-2.1 to 2.6	4.9	-1.8 to 1.6	3.5	-1.9 to 2.7	4.8	-2.1 to 1.5	3.8

MME = overall magnitude of measurement error (%)

Construct validity

The Afrikaans group with sexual dysfunction reported higher mean scores (21.1 ± 5.9) than those without (33.2 ± 5.2), ($p < 0.0001$). The Sesotho group with sexual dysfunction reported higher mean scores (20.1 ± 6.7) than those without (32.4 ± 2.5), ($p <0.0001$). This finding supports the specified hypothesis for SD.

Responsiveness

The 3rd round of completion was after an average period of 5.2 months. One hundred participants in each language group completed the 3rd round. The PGI-I results showed improvement in the Afrikaans group in 79% and in 81% among the Sesotho participants. The Afrikaans group had a significant ($P < 0.0001$) mean score change of 4.3 ± 5.6 (95% CI 3.1, 5.6) and the Sesotho group a similarly significant ($p < 0.0001$) change of 5.0 ± 7.6 (95% CI 3.3, 6.7). This confirmed an improvement in sexual function in both groups.

Discussion

The objective of this study was to validate the PISQ-12, a sexual function questionnaire for women with pelvic floor disorders, in South African women for the Afrikaans and Sesotho languages. The psychometric properties of reliability, validity and responsiveness affirmed the validated nature of the questionnaire in this population.

The Cronbach alpha value of 0.83 to 0.84 in the participants in both language groups showed very good consistency. These values are in keeping with those found in other

studies and confirm the linguistic and cultural validity of the PISQ-12 in Afrikaans and Sesotho (9)(10)(33)(13). There was however a discrepancy between the three different components of the PISQ-12, and this was particularly pronounced in the partner-related domain in the Sesotho speaking group. Other PISQ-12 validation studies had a similar finding for the partner-related questions (9)(13)(11). It is not clear whether this might be due to cultural factors among the Sesotho speaking women, for it was specifically the questions on premature ejaculation and orgasm quality that had the lowest consistency. This observation requires further research among African women.

The reliability of this questionnaire was excellent based on the ICC value of 0.98-0.99. The test-retest assessment was by means of telephonic administration, rather than self-administration. This approach created concern in the study design, but it was the only feasible way in which to evaluate reliability in this population in South Africa. Telephonic administration has been validated for other short-form pelvic floor QOL questionnaires, but not for the PISQ-12 (22). Internet-based completion of similar questionnaires and of the PISQ-12 have shown good reproducibility compared to paper-based completion (34)(35). It was found that telephonic administration was feasible and reliable in this population who had been exposed to a previous round of the PISQ-12. Further research is however required in the questionnaire naïve population with regards to telephonic administration. Patient experience with the telephonic administration compared to self-administration was not evaluated. This might be an important attribute to consider due to the sensitive nature of the questions. None of the participants however declined to answer the questions telephonically.

The third round of PISQ-12 scores showed a significant improvement in sexual function and correlated very well with the PGI-I. It additionally affirmed the integral connection of sexual function and pelvic floor disorders.

There were some limitations to this study. The internal consistency was evaluated on a smaller sample of women and the Cronbach alpha value might be altered if a larger sample were analyzed. The second round of completion were conducted telephonically and although the format was structured, it was not possible to ensure this for all interviews. The statistical results were however reassuring in regards to the test-retest reliability. The education level of both language groups were generally limited and we had to verbally explain and demonstrate to the majority of patients the process of filling in and scoring symptom severity for the questionnaire in the first round. This was in addition to having redesigned the questionnaire after the pilot phase to allow ease of completion. This resulted in a labour intensive process and furthermore emphasize the importance of short form questionnaires in an environment with limited human resources, such as South Africa. Longer questionnaires would very likely not be practically feasible in this environment and possibly result in high rates of incompleteness, which subsequently limits its clinical worth. The pelvic floor symptom screening in the third round was not repeated and only the PGI-I was used to calculate responsiveness of the questionnaires. Clinical examination findings were also not included. This lack of additional clinical information had the potential of influencing the evaluation of responsiveness and consequently the determination of improvement or deterioration of function. It was however selected as a reasonable approach due to the complexity of sexual dysfunction and in order to allow for a comparable analysis between the study and control groups.

The strengths of this study are the use of an adequate sample size based on the items evaluated in the questionnaire for both the study and the control groups. The methodological design of this study was according to the recommendations of the COSMIN initiative in order to ensure adequate evaluation of the different psychometric measurement properties for this questionnaire. This is especially important for the validation of patient-reported health outcomes. The control group permitted us insight into the score distribution in women who have not been identified with PFD. Sexual dysfunction was identified in 19.54 -24.21% of these women, which is less than what has been reported in gynecology outpatient settings(36)(3)(7)(4)(37). The role of the questionnaire as a routine screening tool should however be further explored to allow for the identification of SD at a lower level of care and subsequent appropriate referral and management where indicated. It also points out the general lack of epidemiological data that exists for SD among South African and African women (17).

Conclusion

The validation of the PISQ-12 in South African women for the Afrikaans and Sesotho languages has revealed appropriate psychometric properties to permit its use in clinical practice. Practical guidance for the administration of these questionnaires have been recognized in this population and healthcare setting. This questionnaire can aid in further research to address the lack of epidemiological data on SD among South African women with and without PFD.

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CHAPTER 5

IMAGING FOR POSTERIOR COMPARTMENT DISORDERS

5.1 INTRODUCTION

In an editorial in 2006, Dietz stated that “I am convinced that clinical examination alone, in particular without the examiner being aware of its shortcomings, is a woefully inadequate tool with which to assess pelvic floor function and anatomy”. He further emphasized that the clinical examination only focuses on the surface anatomy, without identifying the underlying abnormality and that this has resulted in a plethora of interventions, with little distinction of individual characteristics. (Dietz 2006). He reasons that clinical examination often results in false-negative findings due to levator co-activation and that ultrasound will allow for improved surgical procedures, individualized reconstructive surgery, and ensure that operative complications or failure are detected early and dealt with appropriately. Brusciano et al. also endorsed that women were able to better relax the puborectalis muscle during Valsalva with a TPUS approach compared to both an endovaginal and endoanal evaluation (Brusciano et al. 2007).

Pelvic floor ultrasonography includes several different techniques, namely, transvaginal sonography, endoanal ultrasound and TPUS, using 2D or 3-dimensional (3D) imaging. The main purpose of imaging in combination with clinical examination is to provide an integrated assessment of the individual patient in order to optimise therapeutic outcomes (Santoro & Dietz 2010).

There are several clinical ramifications of being able to directly image the structures of the posterior compartment. Improved surgical outcomes have been achieved in other surgical disciplines through accurate anatomical identification of structural abnormalities (Hsu et al. 2008). The application of functional radiography for the assessment of defecatory disorders and pelvic organ prolapse has highlighted the limitations of physical examination. It has become clear that pelvic floor disorders rarely occur in isolation and that global pelvic floor assessment is necessary (Maglinte et al. 2011). Dietz et al. echoed this opinion and recently stated that ultrasound should be considered the imaging method of choice for women presenting with posterior pelvic floor symptoms. Since pelvic floor structural changes are frequently multi-compartmental, a comprehensive investigation of the entire pelvic floor is useful, especially prior to surgical intervention.(Dietz & Beer-Gabel 2012)

5.2 ANATOMIC AND OPERATIONAL DETAILS

A TPUS is routinely performed with the patient in a supine position and with a comfortable bladder volume. Details of this technique was discussed in Chapter 3. Dietz et al. evaluated 132 women in both the supine and standing positions. They found no significant effect of posture on the ultrasound parameters, other than for the urethrovesical junction measurements in the standing position (Dietz & Clarke 2001).

In a prospective study, women with prolapse were matched to controls without prolapse and the levator ani muscle anatomy was evaluated by means of endovaginal 2D ultrasound using a probe with a 360^0 imaging angle (Athanasiou et al. 2007). The authors evaluated 43 women with and 24 women without prolapse. The reproducibility of the method was assessed by repeated measurements to assess intra-observer and

inter- observer variability. The operator was unaware of the results of the clinical examination. They were able to show good intra-observer and inter-observer reproducibility and reliability. In controls, the pubococcygeus muscle showed more regular echogenicity with no evidence of trauma, whereas in women with prolapse the muscle had mixed echogenicity. The levator hiatal area was significantly larger in women with POP versus controls, measured at rest (17.8 cm^2 versus 13.5 cm^2, $P < 0.001$). The muscle thickness was 7.1 mm in women without prolapse and 6.4 mm in those with prolapse. This was not significantly different. Women with prolapse had a significantly larger levator ani hiatal area compared with women of similar age and parity without prolapse.

It is not only in the posterior compartment where imaging is of value. The anterior compartment is notorious for its association with surgical recurrence (Maher et al. 2013) and the entity of a paravaginal defect is often a source of controversy. Clinical detection of paravaginal defects and levator trauma is difficult and correlates poorly with imaging of the vaginal sulcus. Visualisation of such muscle detachment with ultrasound could assist in objectively recognising defects that may be over or underestimated by clinical examination alone. Quantification may also be possible with this ultrasound technique. (Nguyen 2001) (Dietz et al. 2005). A surrogate for the level II endopelvic fascial paravaginal defects might be the shape of the bladder in the transverse plane. One might hypothesize that a lateral defect will give rise to an asymmetrical shape of the bladder at rest and/or Valsalva, but this hypothesis might however be problematic when there are bilateral defects. Paravaginal defects have not been identified with great accuracy using TPUS.

5.3 TRANSPERINEAL ULTRASOUND

TPUS is an acknowledged imaging modality for use in the assessment of POP (Beer-Gabel et al. 2002)(Dietz 2004). There is however poor correlation between perineal ultrasonography and POP-Q severity for the posterior compartment.(Broekhuis, Kluivers, et al. 2009) (Lone et al. 2012). The evaluation of the posterior compartment should include, but not be limited to, assessment of a rectocele, rectal / recto-anal intussusception, enterocele, anal sphincter defects, perineal descent, puborectalis movement and ARA. Measurement of the ARA can contribute information on puborectalis dyssynergia, through a decrease or insufficient increase (<5%) in the ARA, despite adequate straining effort as represented by sufficient perineal descent (Dam et al. 1994). The amount of change in the ARA has however not been shown to correlate with the presence of a rectocele or symptoms (Yoshioka et al. 1991). It is furthermore a marker of rectal intussusception (Santoro & Dietz 2010). Examination of the posterior compartment can be performed with the rectal installation of ultrasound gel to potentially allow for improved anatomic structural differentiation, but this has not been proven to be of benefit. Rectocele size depends on the position in which the patient is evaluated. Larger surface areas are calculated in the standing versus the supine position. In the supine position the average area determined was 1.78 cm^2 and in the standing position this was an average of 3.20 cm^2 (Prohm et al. 2011).

5.3.1 DIAGNOSTIC CRITERIA IN THE POSTERIOR COMPARTMENT

5.3.1.1 ACCURACY

Image quality is generally best in pregnant women and poorest in menopausal women with marked atrophy. This is most likely due to varying hydration levels and tissue

quality. Vaginal scar tissue can also impair visibility, but obesity virtually never seems to be a problem. (Dietz & Beer-Gabel 2012). In order to achieve maximal or near-maximal organ descent it is necessary to obtain Valsalva pressures of at least 60 cm H_2O for at least 5–6 seconds. This is frequently not achieved during clinical examination. As previously stated, levator co-activation during the Valsalva manoeuver is a significant confounding variable during the assessment of pelvic floor dysfunction and prolapse. Levator co-activation can be corrected by a visual biofeedback method where the woman is shown the monitor during muscle contraction and relaxation (Ornö & Dietz 2007) (Orejuela et al. 2012).

The ultrasound probe can splint a rectocele and will subsequently underestimate the size of the rectocele if the operator does not take care and allow full pelvic organ descent to develop, whilst still maintaining probe contact with the perineum (Hainsworth et al. 2015). Ultrasonography has the following limitations: it is operator dependent; it is usually performed in the supine position; a Valsalva manoeuvre does not represent physiological defecation and the presence of an endocavity probe can prevent development of the prolapse. For these reasons, it may underestimate the extent of a rectocele (Santoro & Dietz 2010).

5.3.1.2 RECTOCELE

The rectocele depth is measured perpendicular to a line projected along the expected contour of the anterior rectal wall. The diagnosis is made if herniation is at least 10 mm in depth(Perniola et al. 2008)(Steensma et al. 2010)(Dietz HP 2005)(Martellucci & Naldini 2011). For ultrasound, there is no standardized method for the further description of rectoceles and enteroceles. Some classify a rectocele as it was

previously defined in defecography: Small (first degree) if < 2 cm in depth, moderate (second degree) if 2-4 cm in depth, and large (third degree) if more than 4 cm in depth (Martellucci & Naldini 2011). Occasionally there is no stool in the ampulla that might be propelled into the rectocele and thus it remains smaller and filled only with rectal mucosa. Distension of the rectocele and thus its appearance on ultrasound is somewhat dependent on the presence and quality of entrapped stool.(Dietz & Beer-Gabel 2012). Dietz et al. proposed a classification system based on retrospective analyses of women evaluated at their Urogynecology unit (H P Dietz & Steensma 2005). They suggested the following:

- Stage 0: rectocele width 18.3 (0-34) mm, height 13.9 (10-23) mm
- Stage 1: rectocele width 21.8 (8-50) mm, height 15.6 (10-33) mm
- Stage 2: rectocele width 28.4 (15-59) mm, height 19.9 (11-44) mm
- Stage 3: rectocele width 49.8 (49) mm, height 29.6 (28-32) mm.

Descent of the rectum 15 mm below the symphysis pubis was found to be associated with symptoms (Dietz & Lekskulchai 2007).

Rectocele measurements in another series of women with posterior prolapse showed a mean depth of 14.5 mm and width of 9.5 mm. In the nulliparous women in this series, the mean rectocele depth were < 10 mm. The author further noted poor agreement between clinical and TPUS findings for rectocele, but good agreement with enteroceles (Barry 2014). This value is in keeping with other published work and the 10 mm cut-off to diagnose rectoceles with TPUS can therefore be used.

5.3.1.3 ENTEROCELE

An enterocele is visualized as downward displacement of abdominal contents into the vagina, ventral to the anal canal. The small bowel may be identifiable because of its peristalsis and sometimes a small amount of intraperitoneal fluid outlines the apex of the enterocele. Distal shadowing is much less common than that obtained with a rectocele and often contents have an irregular isoechoic or ground glass-like appearance. The differentiation from a rectocele is easier once one has identified the rectal ampulla, usually a wedge-shaped area of high echogenicity with distal acoustic shadowing due to filling with stool (Dietz & Beer-Gabel 2012) (Zbar 2013).

Enteroceles can be graded as small (grade 1), when the most distal part descends into the upper third of the vagina; moderate (grade 2), when it descends into the middle third of the vagina; or large (grade 3), when it descends into the lower third of the vagina (Greenberg et al. 2001).

5.3.1.4 RECTAL INTUSSUSCEPTION

During Valsalva there is a characteristic widening of the posterior ARA and on occasion the mucosal infolding of the rectum can be seen (Beer-Gabel et al. 2002). A rectal intussusception may be secondary to an enterocele that develops into the anal canal rather than the vagina. Rectal intussusception is additionally associated with abnormal distensibility of the levator ani and avulsion of the puborectalis muscle (Rodrigo et al. 2011).

5.3.1.5 PERINEAL DESCENT

If there was displacement of rectal ampullary contents (hyperechogenic stool or air) below a reference line through the inferior symphysis margin without evidence of an actual fascial defect, this was defined as perineal hypermobility (H P Dietz & Steensma 2005). Perineal descent during defecography is diagnosed when there is descent of > 2 cm relative to the pubococcygeal line (Ganeshan et al. 2008). The difference in perineal position at rest and Valsalva in reference to the inferior margin of the pubic symphysis can be measured in a similar fashion as with defecography.

5.3.2 PREVALENCE OF ABNORMAL FINDINGS WITH TRANSPERINEAL ULTRASOUND

The clinical prevalence of an isolated rectocele is approximately 12-19% and rectocele repairs are performed in 40-85% of women undergoing pelvic floor reconstruction (Olsen et al. 1997). With the use of 2D and 3D TPUS, a rectocele was diagnosed in 56% of patients in an urogynecology population. Age showed a weak, but significant association with rectal descent (H P Dietz & Steensma 2005)(Steensma & Dietz 2004). This was in keeping with the observed deterioration of levator ani support at the midvaginal level seen in ageing women and in keeping with DeLancey's description of posterior vaginal support mechanisms (DeLancey 1999)(Fox et al. 2006). Rectoceles have also been observed in 12% of nulliparous Caucasians and this finding was associated with higher BMI and symptoms of constipation (Dietz & Clarke 2005). A significantly higher incidence of rectal intussusception was observed in patients with ODS when compared to healthy controls with endoanal (61.9 vs 13.6%, P<0.0001) and dynamic TPUS (51.2 vs 9%, P=0.001). TPUS furthermore showed only moderate

correlation with endoanal ultrasound for the diagnosis of intussusception. A true imaging gold standard for intussusception has not yet been identified.

A theory for the pathogenesis of rectoceles are the development of defects in the RVF. The RVS has been evaluated with sonovaginography and an echogenic area could be visualised. The findings are in accordance with the anatomical knowledge of a thicker distal perineal membrane (4.1 mm) and very little midline support (1.2 mm) in the middle and upper posterior vagina (Condous et al. 2008) (Bignardi & Condous 2008). In a study employing 2D and 3D TPUS, a defect of the rectovaginal septum was rated as present if there was a sharp discontinuity in the ventral contour of the anorectal muscularis and if the herniation measured ≥10 mm in depth. A RVS defect was seen in 39% of a population of 198 women. A rectocele was present in 56% of women in this population. This series showed that a defect was diagnosed in 7.6% of women without posterior compartment prolapse. The authors concluded that in approximately one-third of clinical rectoceles a sonographic defect was not identifiable in the RVS (H P Dietz & Steensma 2005).

Dietz explored this again in 2011 and identified the RVS with 3D TPUS as a hyperechogenic layer between vaginal and anorectal muscularis in 45/46 (97.8%) patients. Gaps in this layer were identified in only 10/28 (35.7%) of women with rectoceles. This echogenic layer had a mean thickness of 1.1 (range, 0.2–2.9) mm and extended on average from 16.8 (range, 3.9–35.4) mm below to 28.5 (range, 6.1–44.9) mm above the anorectal junction. There were no consistent associations between clinical findings of posterior compartment descent or a sonographically detected rectocele on the one hand, and RVS thickness or extent, or the finding of a gap in the RVS on the other. There was only moderate intra-observer repeatability (Dietz 2011). These observations are supportive of the perineal membrane being the

only clearly identifiable structure providing support in the distal 3-4 cm of the posterior vagina.

Imaging in the transverse or coronal plane can provide valuable information on the anal sphincters. The anal mucosa is seen as an echogenic star shape structure and the IAS as a hypoechoic structure surrounded by the echogenic EAS. Obstetric anal sphincter injury is the most common cause for anal sphincteric abnormalities and AI in women. The anal sphincters are traditionally evaluated with an endoanal ultrasound (EAUS) technique. The EUAS is however an expensive instrument and often not widely available. 2D TPUS has been shown to have a sensitivity and specificity of 64% and 85%, respectively, for detecting sphincter defect when compared with EAUS. TPUS can be useful in identifying normality, but it is not sensitive enough to identify an underlying sphincter defect in women following obstetric anal sphincter injury and/or presenting with symptoms of fecal incontinence postpartum. In these cases, an EAUS examination is still recommended (Roos et al. 2011)(Cornelia et al. 2002)(Oom et al. 2012).

The specific population examined need to be taken into account when comparing the imaging parameters described in the literature. In a recent study of South African women, the authors observed that Black South African women had greater pelvic organ descent on ultrasound and clinically as well as increased levator hiatus area, compared to East Asian and Caucasian women (Z Abdool, HP Dietz 2016). Similar findings were documented in a cohort of Ugandan nulliparous women (Shek et al. 2016).

5.3.3 THE CORRELATION BETWEEN ULTRASOUND AND CLINICAL FINDINGS

The POP-Q examination is the currently accepted standard for the description of prolapse presence and severity (Bernard T Haylen et al. 2016). Any imaging investigation has to be scrutinized in its ability to truly detect anatomic abnormalities. In the posterior compartment, there seems to be a statistically significant relationship between all ultrasound data and clinical findings ($p < 0.001$) (H P Dietz & Steensma 2005). Liu et al. showed similar agreement in their evaluation of 564 women in whom they found clinical and US rectoceles in 48% (Liu et al. 2010). Eisenberg et al. however, found that ultrasound was more sensitive than clinical examination for the evaluation of the posterior compartment in women after sacrocolpopexy (V. H. Eisenberg et al. 2014).

Conversely, Brusciano, et al. evaluated women clinically, with TPUS and with EAUS and noted a rectocele in 68/77 (88%) women with digital rectal examination, in 9/77 (9.8%) with vaginal US and 11/41 (27%) with dynamic perineal US. No rectocele was detected at anal US, whereas defecography showed a rectocele in 38/ 43 (90%) patients. They however did not specify their diagnostic criteria for the digital diagnosis of a rectocele. (Brusciano et al. 2007). Imaging does not only evaluate for rectoceles in the posterior compartment. Most enteroceles are not detected on clinical examination, but detection of an enterocele by TPUS compares favourably with that detected by defecography(Beer-Gabel et al. 2008).

It is moreover essential to correlate imaging findings with the presence of symptoms. Dietz et al. examined at what ultrasound measurements women were experiencing vaginal bulge symptoms (Dietz & Lekskulchai 2007). They noted that symptomatic cystoceles descended on average to 23.8 mm below the symphysis pubis (range, 14

mm above to 53.4 mm below) and symptomatic rectoceles descended to 21.4 mm below the symphysis pubis (range, 10 mm above to 43 mm below). From their data, it appears that anterior and posterior compartment descent is unlikely to be symptomatic if the organ in question remains above the inferoposterior margin of the symphysis. A cut-off of 10 mm below the symphysis pubis seemed to be at the midpoint of the ROC curve for the anterior compartment, while a cut- off of 15 mm below the symphysis pubis was more appropriate for the posterior compartment. These cut- off values might become useful whenever there is a need to dichotomize prolapse for research purposes. The integration of a DRE and imaging to the POP-Q system therefore result in superior diagnostic accuracy than any element alone.

5.3.4 A COMPARISON OF TRANSPERINEAL ULTRASOUND AND DEFECOGRAPHY

Defecography has been the gold standard for the evaluation of posterior compartment disorders for a very long time (Kelvin et al. 1994)(Shorvon et al. 1989)(A Mellgren, S Bremmer, C Johansson, A Dolk, R Uden, S Ahlback 1994). TPUS provides the additional advantage of a dynamic evaluation of all pelvic floor compartments, whereas traditional defecography primarily evaluated the posterior compartment. The gold standard diagnostic procedure for posterior compartment disorders still remains dynamic evacuation proctography (DEP), even though it may miss up to 20% of enteroceles. In many cases, conventional defecography must give way to an extended technique of colopocystodefecography. This extended technique is relatively poorly tolerated by patients and delivers a substantial irradiation dose. Some conflicting

results have been published for the comparison of these two modalities (Beer-Gabel et al. 2008).

There is relatively good correlation for the diagnosis of an enterocele in most studies (Steensma et al. 2010)(Martellucci & Naldini 2011)(Beer-Gabel & Carter 2015). When it comes to rectocele and intussusception, the correlation was however of a more variable nature for both TPUS and endorectal ultrasonography. (Perniola et al. 2008)(Beer-Gabel et al. 2008)(Barthet M, Portier F, Heyries L, Orsoni P, Bouvier M, Houtin D, Barriere N, Mambrini P, Salducci J 2000). These differences may be explained by the use of contrast medium, selection and position of the patient, type of probe used and the experience of the operators (Martellucci & Naldini 2011)(Albuquerque & Pereira 2016). Perniola, et al. noted that when ultrasound failed to detect a rectocele or rectal intussusception, defecation proctography frequently showed abnormalities. They recommended that ultrasound may be important as an initial examination, although negative findings may require confirmation with defecography (Perniola et al. 2008).

Beer-Gabel, et al. evaluated 62 women with chronic ODS clinically, with TPUS and with defecography. Operators were blinded to the findings of the other modalities. They noted an association of enteroceles with prior hysterectomy. They showed good correlation in the different imaging modalities, but that TPUS were inclined to upgrade enterocele staging severity. They also found descending perineum syndrome with all cases of culdocele and concluded that the operative confirmation of an enterocele would be the gold standard for comparison. This required further research. Their results showed that there is a similar diagnostic ability of TPUS and DEP for the demonstration of cul-de-sac hernias in patients presenting with evacuatory dysfunction. This information may be critical in operative decision making in some

cases, where the advantages of TPUS are its simplicity, widespread availability, low cost, patient tolerance, and lack of radiation exposure. (Beer-Gabel et al. 2008). The authors repeated this study a few years later and this time included 105 women with the main complaint of FI and constipation. The specificity for the diagnosis of rectoceles was 82% for mid-size rectoceles (2-4 cm defecography depth) and 98% for large rectoceles (>4 cm defecography depth), and the sensitivity was 59 % for mid-size rectoceles and 50 % for larger rectoceles. The level of concordance was good for the diagnosis of mid-size rectoceles (74 %). The sensitivity for the detection of intussusceptions, enteroceles, and rectal prolapse were 82%, 74%, and 75%, respectively. The specificity was 84% for the detection of intussusception, 92% for enteroceles, and 97% for the diagnosis of rectal prolapse. It was thus evident that neither TPUS nor defecography on its own could accurately evaluate the defecation process. This is possibly due to the non-physiological nature of this examination for defecatory disorders. Although TPUS is standardized in its technical aspect, the operator do play a role and this might have explained the observed variations in the sensitivity and specificity of TPUS (Perniola et al. 2008)(Beer-Gabel & Carter 2015).

Introital ultrasound of the posterior compartment was compared to defecography by Grasso et al. (Grasso et al. 2007). They included 43 women with defecatory disorders. Intussusception was diagnosed in 51% with defecography and in 46.5% with ultrasound. They had no formal quantification system for rectoceles diagnosed at ultrasound, but could detect it in the sagittal plane in 100% of the cases of anterior rectocele classified at defecography as being third degree. Rectoceles classified as first degree at defecography were not detected by introital ultrasound. Of the second degree rectoceles diagnosed with defecography, 12% were not detected with ultrasound. The overall rectocele detection rate with ultrasound was thus only 22% in

this study. Although the overall detection rate for rectoceles were low, the rectoceles that were likely to produce clinical symptoms were detected with TPUS in 88% of cases.

The correlation between TPUs and defecography in the posterior compartment was furthermore tested in 54 women. The authors showed a moderate level of agreement between the two methods and clinically relevant rectoceles were equally diagnosed with both methods (Konstantinovic et al. 2007). Weemhof et al. prospectively evaluated 50 women schedule for defecography with TPUS and found that TPUS over diagnosed enteroceles. In regards to intussusception, they showed that when it was diagnosed with TPUS, there was then a high likelihood of this diagnosis being confirmed on defecography (Weemhoff et al. 2013).

These publications showed that there was generally a good clinical correlation between TPUS and defecography for the detection of posterior compartment abnormalities. If there was however remaining clinical suspicion of a disorder not identified with TPUS, the patient would likely benefit from a defecogram.

5.4 MAGNETIC RESONANCE IMAGING OF THE POSTERIOR COMPARTMENT

Magnetic resonance imaging (MRI) has been used extensively to aid our understanding of the functional anatomy of the female pelvic floor (Luo et al. 2012) (Luo et al. 2015) (DeLancey 2016). It was first introduced as a diagnostic modality for POP in 1991 (Yang et al. 1991). Its use in the posterior compartment is recognized clinically, but the cost and accessibility of this imaging modality is a major limiting factor, especially in resource restricted countries (Hutubessy et al. 2002)(Rawat et al. 2009).

MRI is costlier, but does provide potential advantages for the assessment of POP compared to defecography such as better soft tissue visualisation, images in different planes, evaluation of subtler pelvic floor abnormalities, better defined muscles and bony landmarks and no radiation exposure. A disadvantage is that the evaluation is mostly in the supine position, but similar techniques and measurements can be used as for defecography. MRI can additionally identify anismus and intussusceptions. A systematic review showed that MRI can probably contribute most in the posterior vaginal compartment (Broekhuis, Fütterer, et al. 2009). It is however not good at demonstrating endopelvic fascia and neurovascular structures (Stoker 2009).

MRI of the pelvic floor and MR defecography can hence be recommended as an alternative to contrast defecography in young patients, female patients of reproductive age, pregnant patients, and those at risk for adverse reactions to the contrast medium (Bove et al. 2012).

Posterior compartment modelling was recently performed with the use of MRI. The authors used static MR findings and 3D modelling in 20 asymptomatic women to construct the anatomy of the posterior compartment. They found that the optimal plane of imaging was sagittal. The levator ani provided lateral support in the midvagina and a thick perineal membrane which crosses the midline and fuses with the vagina was distal to this. No clear rectovaginal fascia was seen in the midline in the proximal vagina (Hsu et al. 2008). In another 3D model of posterior prolapse in 10 cases and controls in the same unit, the authors noted that rectoceles were associated with a forward folding or bulge of the posterior vaginal wall and in the distal vaginal wall, they noted widening of this surface (Luo et al. 2012). This is a similar to what we have clinically observed with larger rectoceles.

The importance of reference lines in imaging have been underscored in a recent article. If the reference lines were altered, there was a significant difference in prolapse diagnosis.(Onal et al. 2014) What is currently lacking in imaging is the correlation between symptomatology and anatomy in determining the most appropriate reference lines.

The correlation between clinical scores and radiological magnetic resonance evaluated by means of dynamic MRI was 53.3% only. In cases with absence of previous pelvic surgery, there was a discrepancy of 40% of cases, while in cases with history of a previous pelvic surgery, a discrepancy of was found in 60% of cases (Obringer et al. 2011).

5.5 DEFECOGRAPHY FOR POSTERIOR COMPARTMENT DISORDERS

Dynamic defecography is the original radiological diagnostic means used to objectively assess pelvic floor anatomy. Defecography was traditionally only used for anorectal dysfunction, but incorporation of a cystogram allowed evaluation of all pelvic compartments (Maglinte et al. 2011). . Rectocele and intussusception are frequent radiological findings in patients with ODS, but can also be found in asymptomatic women (Shorvon et al. 1989). In this widely referenced paper examining asymptomatic nulliparous volunteers, the authors found intussusception in 50% of women and rectoceles in 81%. The rectoceles measured < 1 cm in 35.3%, 1-2 cm in 58.8%, and > 2 cm in 5.8%. This resulted in the current defecography definition of a rectocele when the defect is > 2 cm. Some authors recommend extending this to 3 cm to avoid diagnosis in mostly asymptomatic women (Greenberg et al. 2001)(Stoker 2009)(Maglinte & Bartram 2007)(Maglinte et al. 2011). This illustrates the lack of

universally accepted radiological criteria for defining POP (Kelvin et al. 2000). The defecography classification of POP is in reference to the pubococcygeal line in contrast to the inferior margin of the symphysis pubis which is used with TPUS imaging.

As has been documented with other imaging modalities, defecography has also been shown to be more accurate for posterior compartment POP compared to clinical exam alone (Kelvin et al. 1994).

Enteroceles are clinically identified in approximately 50% of cases only. The clinical rate of identifying rectoceles is much higher. Altringer and Brubaker were some of the first to show that the diagnosis, and therefore potentially the clinical management, was changed in 75% of cases after defecography compared to clinical examination alone (Altringer et al. 1995).

Finco et al. examined the pre- and postoperative consistency between clinical and defecography findings in patients undergoing surgery for ODS (Finco et al. 2008). They included 20 women who had transvaginal colporrhaphy and transanal mucosal resection (PPH stapler) for ODS and a rectocele. The mean follow-up was for 30 months. The clinical and radiological diagnosis correlated significantly before surgery and specifically, there was no upstaging in rectocele with defecography. The clinical examination was however based on the Baden-Walker and not the POP-Q system. Intussusception was present in 90% and an associated cystocele was seen in 69%. After surgery, rectoceles were clinically absent in 95% and radiologically absent in only 25%. There was significant symptom relief in bowel function and no new onset dyspareunia or FI. The authors concluded that there is no place for post-operative defecography in the absence of surgical failure, but they clearly demonstrated that

clinical examination alone might miss many rectoceles. By comparison with a clinical examination, many authors agree that defecography overestimates the actual anatomical alterations (rectocele, anorectal prolapse) especially during straining(Agachan et al. 1996). This was mostly the case for smaller rectoceles.

In a study looking at the clinical and imaging correlation for posterior compartment disorders, clinical examination was found to have a poor correlation (Cohen's kappa 0.44) compared to the defecography findings (Konstantinovic et al. 2007).

Defecography is thus not absolutely accurate on its own. As with any special investigation it needs to be evaluated in context of the individual patient and in cognisance of the clinical findings (Van Laarhoven et al. 1999).

5.5.1 A COMPARISON OF MAGNETIC RESONANCE IMAGING AND DEFECOGRAPHY FOR DIAGNOSIS OF POSTERIOR COMPARTMENT DISORDERS

There was good correlation between dynamic MRI and defecography for the ARA between the 2 modalities in each phase of evacuation. Dynamic MRI also allowed for assessment of morphology and tone of the levator ani muscle. In addition, the overall sensitivity and specificity of MRI defecography was nearly 98% (G. Hall et al. 2014). Healy et al. in contrast found good overall correlation, but poor correlation for ARA measurement and anorectal descent (Healy et al. 1997)

Faucheron et al. compared these two modalities in 50 women with posterior compartment disorders. The radiologists were blinded to the clinical findings. All patients were scheduled for surgery where the final diagnosis was made. Clinical examination was best for full thickness rectal prolapse and defecography was found

to be best for intussusception and peritoneocele (Faucheron et al. 2014). There was however no overall significant difference between MRI and defecography. Foti et al. evaluated 19 patients with outlet obstruction and also found MR defecography to be similar to conventional defecography in identifying pelvic floor anatomy during Valsalva manoeuvres, but MRI performed better when the evacuation phase was added (Foti et al. 2013). Comparative MRI and cystocolpodefecography imaging studies were done in 35 women known with pelvic floor descent. A rectocele was diagnosed as a defect of ≥ 3cm. Women were only included if they were able to affect a 2cm pelvic floor descent effort during Valsalva. The results showed that defecography was superior to dynamic MRI in the supine position for the evaluation of pelvic floor descent. (Vanbeckevoort et al. 1999).

5.6 IMAGING AND CLINICAL INFLUENCE

It is not clear at this time whether pelvic floor surgical outcomes are negatively impacted by the lack of preoperative evaluation beyond a history and physical examination (Lefevre & Davila 2008).

Imaging that guides clinical management is an essential component in current gynecologic oncology practice and has been shown to influence both short and long-term outcome (Debald et al. 2015)(Doubeni et al. 2016). Imaging has been shown to influence surgical planning and decision making in benign gynaecological disease. It leads to a more accurate diagnosis of the underlying disease process or abnormality and improved patient counselling (Abrão et al. 2015)(D'Antonio et al. 2016)(Upasani et al. 2016). It remains to be seen in urogynecology whether this translates into improved clinical or surgical outcomes.

Non-invasive dynamic MRI in contrast has not been shown to change clinical decision making despite a 10-fold greater cost than videoproctography (Matsuoka et al. 2001). Hubner et al. evaluated surgical management of symptomatic rectoceles based solely on dynamic MRI findings of rectocele defects >2 cm. They found that surgical repair of significantly sized rectoceles improves QOL scores (Hübner et al. 2006). The rectocele depth measured by defecography in contrast seemed to have no impact on the functional outcome following rectocele repair in a study by Stojkovic et al. (Stojkovic et al. 2003). This was however a reflection of the rectocele and its associated symptoms, rather than an evaluation of the contribution of imaging to clinical decision making and outcomes.

Van Dam et al. prospectively evaluated 74 women with rectocele and ODS to evaluate the predictive value of defecography in rectocele surgical outcomes. Neither the size of the rectocele, barium-trapping in the rectocele, intussusception, rectal evacuation, perineal descent or anismus influenced the clinical outcome nor long term results of rectocele repair. They were of the opinion that the main value of defecography is the objective demonstration of a rectocele and any associated abnormalities preoperatively and again in the objective assessment of the postoperative results.(Dam et al. 1994).

Four dimensional (4D) TPUS evaluations were performed in women after laparoscopic sacrocolpopexy with the aim to evaluate the posterior compartment. The authors noted a discrepancy between their clinical findings and ultrasound findings. The authors concluded that ultrasound was more sensitive than the clinical examination for the evaluation of the posterior compartment (V. H. Eisenberg et al. 2014).

The influence of imaging on surgical decision making has been assessed in four studies that could be identified. In the first publication, MR defecography findings led to changes in the surgical approach in 22 (67%) of 33 patients who underwent surgery for FI. This was a small retrospective series including both males and females, and a further possible limitation was the fact that patients were selected from a tertiary referral centre which might have resulted in selection bias (Hetzer et al. 2006). Kaufman et al. looked at the combination of defecography and dynamic MRI and the influence on surgical decision making in a series of 22 women. Physical examination, dynamic magnetic resonance imaging, and dynamic colpocystodefecography were concordant for rectocele, enterocele, cystocele, and perineal descent in only 41% of patients. Dynamic imaging lead to changes in the initial operative plan in 41% of patients. Dynamic magnetic resonance was the only modality that identified levator ani hernias. (Kaufman et al. 2001). In a more recent study, defecography was used as the imaging modality in 113 women with pelvic floor dysfunction (Kim et al. 2014). Defecography identified an additional 10 cases of cystocele, 32 cases of rectocele, 2 cases of enterocele, 4 cases of sigmoidocele, and 8 cases of rectal intussusception compared to clinical examination alone. The initial surgical plan was changed in a total of 24 cases (22.1%), but it is not clear to what extent the assessors were blinded. Brubaker et al. showed that fluoroscopy altered the surgical management in 11/30 (36.6%) of cases compared to clinical examination alone.(Brubaker et al. 1993).

A potential limitation of this approach is the fact that anatomical defects do not always correlate with functional impairment. The gold standard would therefore be to look at the clinical outcomes in those in whom management were changed, compared to those where there was no alteration. This is thus far lacking in the published literature.

5.7 SUMMARY

Imaging has become an essential part of the evaluation of any women in the discipline of Obstetrics and Gynecology, yet there is still controversy surrounding its integration in the routine assessment of pelvic floor disorders. Clinical examination of a woman with POP reveals only the vaginal surface changes of an underlying disorder. The symptoms of PFD furthermore often do not correlate with the observed changes in vaginal topography.

Imaging of the posterior compartment can be performed by means of different modalities, such as defecography, ultrasound and MRI. TPUS is an established method to examine the pelvic floor. It incorporates a spectrum of techniques that ranges from basic 2D imaging to 3D, 4D and endovaginal imaging with 360^0 degree probes. Ultrasound imaging of the posterior compartment not only looks for rectoceles or enteroceles, but for a number of disorders that can give rise to pelvic floor symptoms. A prerequisite of POP assessment is an adequate Valsalva maneuver. Women with PFD are prone to co-activate their levator ani muscle when requested to perform a Valsalva maneuver and this leads to an underappreciation of the extent of POP, a feature that can be overcome with the use of ultrasound.

An ultrasound classification system has been described for anterior and posterior compartment prolapse to allow for a universal descriptive system of findings and comparative analyses. Ultrasound imaging is superior in detecting posterior compartment disorders than clinical examination, but doubt exists whether it is better than defecography. The recommendation is therefore that initial evaluations should be performed with ultrasound and if there is still uncertainty that a defecogram should be requested. Dynamic MRI has been used extensively to expand the knowledge base

on the functional pelvic floor anatomy. It can be combined with an evacuation phase to further outline defecatory disorders. The widespread use of this modality is however limited due to its accessibility and cost.

There is no evidence of the impact that TPUS imaging has on clinical decision making in women with pelvic floor disorders. Imaging has been proven to guide clinical decision making in gynecologic oncology as well as for benign disorders. MR defecography has been shown to alter clinical decisions in 41-67% of women and conventional defecography has been shown to alter the proposed surgical plan in 22-36% of women with defecatory disorders. It remains to be seen whether this translated in superior surgical outcomes.

5.8 SUBMITTED ARTICLE: THE INFLUENCE OF TRANSPERINEAL ULTRASOUND ON CLINICAL DECISION MAKING IN WOMEN WITH PELVIC ORGAN PROLAPSE (ADDENDUM 14)

THE INFLUENCE OF TRANSPERINEAL ULTRASOUND ON CLINICAL DECISION-MAKING IN WOMEN WITH PELVIC ORGAN PROLAPSE

Abstract

OBJECTIVES: Transperineal ultrasound (TPUS) provides a dynamic examination of the female pelvic floor anatomy and is complimentary to the clinical assessment. The aim of this study was to evaluate the influence that this modality has on definitive treatment plans and to compare the influence of clinician experience on the accuracy of assessment in women with pelvic organ prolapse (POP).

METHODS: Women with POP were randomized to a consultant or registrar for clinical assessment. They were subsequently examined with TPUS by an operator blinded to the clinical history and findings. Agreement between clinical and ultrasound findings were calculated and the cases in which the ultrasound findings altered definitive treatment were described.

RESULTS: 101 Women were randomized. The ultrasound findings altered the definitive treatment in 38 (37.6%) of participants. There was a significant difference in the clinical assessment of the anterior compartment between consultant and registrar groups (p-value: 0.0171). Agreement between clinical and ultrasound findings was fair to good (kappa statistic: 0.3226-0.6287) in the consultant group and poor to fair (kappa

statistic: 0.0431-0.3146) in the registrar group. The poorest agreement (kappa statistic: 0.0431) was for the posterior compartment in the registrar group.

CONCLUSION: The addition of transperineal ultrasound findings altered the definitive treatment plan in 37.6% of women. The integration of ultrasound findings to that of the clinical assessment should form part of the routine evaluation of women with pelvic floor disorders.

Keywords: Transperineal ultrasound, treatment, influence, POP-Q, clinician experience

Introduction

The female pelvic floor is a sophisticated and complex anatomic and functional unit (1). Attempts to image the pelvic floor was introduced more than 80 years ago due to the recognized need to integrate the clinical evaluation of pelvic floor disorders with objective imaging information (2). The current clinical examination of women with pelvic organ prolapse (POP) consists of observed changes in the vaginal topography (3), but is has long been known that this does not correlate well with the underlying visceral anatomy (4). Despite the clinical examination being standardized, it is challenging to teach to trainees and not being used in clinical practice by the majority of clinicians (5)(6)(7).

Transperineal ultrasound (TPUS) is an accessible and well described imaging modality which offers a dynamic evaluation of all three vaginal compartments (8). It has been shown to compare well with other imaging methods such as defecography and magnetic resonance imaging (MRI) and is able to improve surgical planning and patient counselling (9)(10)(11). Two-dimensional (2D) TPUS is additionally affordable in resource limited environments in contrast to three-dimensional (3D) ultrasound or MRI. Although TPUS is recognized and recommended to be incorporated into the assessment of women with pelvic floor disorders, there is no literature available on the possible influence it has on clinical decision making (2)(12). Imaging has however been shown to influence surgical planning and decision making in benign gynaecological disease in which it leads to a more accurate diagnosis of the underlying condition and improves patient counselling (13).

The objective of this research was to examine the influence that 2D TPUS has on clinical decision making and furthermore to evaluate the influence of clinician experience in the evaluation of women with POP in a resource limited environment.

Methods

This research was conducted in a referral Urogynecology unit in Universitas Academic Hospital, Bloemfontein, South Africa. This is a resource limited environment, both in regards to equipment and health care workers (14)(15). Approval was obtained from the institutional Ethics committee (ECUFS 12/2014) and it was registered with the national clinical trials registry (NHREC 3661). The study population consisted of women referred with POP between June and December 2014. Definitions used are in accordance with the International Urogynecology Association (IUGA)/International

Continence Society (ICS) terminology for POP (12). Women who were referred to the Urogynecology department due to POP were invited to participate in this study. Consenting participants were then randomized to be clinically evaluated by either a consultant urogynecologist or a registrar rotating in the Urogynecology unit. Registrars were didactically and clinically trained in the use of the ICS pelvic organ prolapse quantification (POP-Q) system prior to participating in this research (3). Randomization was by means of a sequence of consecutive sealed envelopes provided by the Department of Biostatistics at the University of the Free State. The participant was clinically evaluated by the allocated clinician. Prolapse severity was staged according to the POP-Q system. Perineal descent was defined as ballooning of the perineum during Valsalva to ≥ 2cm below the level of the ischial tuberosities (16)(17)(18). A specific management plan was subsequently documented by the clinician, but not communicated to the participant. The participant then proceeded to the next phase of the study, the 2D TPUS examination as described by Dietz (8). The TPUS was performed in a room with dimmed lights by an urogynecology consultant with more than 6 years' experience in this modality and without clinical inspection of the vulva. This person was blinded to the clinical findings and management plan of the participant. The same individual performed the TPUS in all the participants.

The ultrasound staging of prolapse in each compartment was performed at Valsalva and described in reference to the inferior margin of the pubic symphysis (19)(20)(8)(21). In the anterior and apical compartments stage 0 was used for descent > 10 mm cranial to the reference line, stage 1 for descent not distal to the reference line, stage 2 for descent ≤ 15 mm below the symphysis, stage 3 for descent > 15 mm distal to the symphysis and in contact with the probe and stage 4 if the prolapse dislodged the probe from the perineum. In the posterior compartment an enterocele

was classified in the same fashion. A rectocele was however staged according to the height of the defect perpendicular to a line drawn along the expected anterior rectal wall contour (22)(23)(24). A rectocele was classified as stage 0 if the height was < 10 mm, stage 1 when it was 10-20 mm, stage 2 for 20-30 mm, stage 3 for > 30 mm and stage 4 if the posterior prolapse dislodged the probe from the perineum. Perineal descent was diagnosed when there was descent of the rectal ampulla below the symphyseal reference line (24). The TPUS findings were documented and the clinical case was only at that time discussed between the two clinicians. A final decision was then made on the appropriate management by the clinician who initially saw the patient and this was communicated to her.

Data collected at baseline included demographic information, prior pelvic surgical history, symptoms of pelvic floor dysfunction, assessment of quality of life (QOL) and POP-Q staging. The QOL assessment and scoring was obtained from a locally used abbreviated pelvic floor questionnaire compiled from internationally validated questionnaires and consisting of 10 questions (3 on impact on quality of life, 3 on urinary distress impact, 3 on colorectal impact and 1 on sexual function impact). Each question could be scored from 1-5, with a 5 indicating least distress. The numeric score was doubled to give the percentage and a higher score reflected less dysfunction. The POP-Q system is known to be challenging to new trainees. We have also observed this in our unit. We therefore based our sample size calculation on an expected 50% difference in effect size between the consultant and the registrar groups. The sample size calculated was 63 participants in each group given a Type I error rate of 5% and statistical power of 80%.

The data of this study were summarized descriptively. Inferential statistics were based on the Kruskal-Wallis test for quantitative data, and the Freeman-Halton test for qualitative data. Kappa statistics were presented for the analysis of agreement between clinical versus ultrasound findings.

Results

We were able to recruit and randomize 101 participants (Figure 1). Of these, 50 patients were randomized to the consultant and 51 to the registrar assessment groups. The baseline demographic characteristics between the two groups were similar. The mean age in the consultant group was 56 years and in the registrar group 55 years and the median parity was 3 for both groups. Baseline demographic characteristics of participants are summarized in Table 1.

Figure 1: Flow of study participants and randomization.

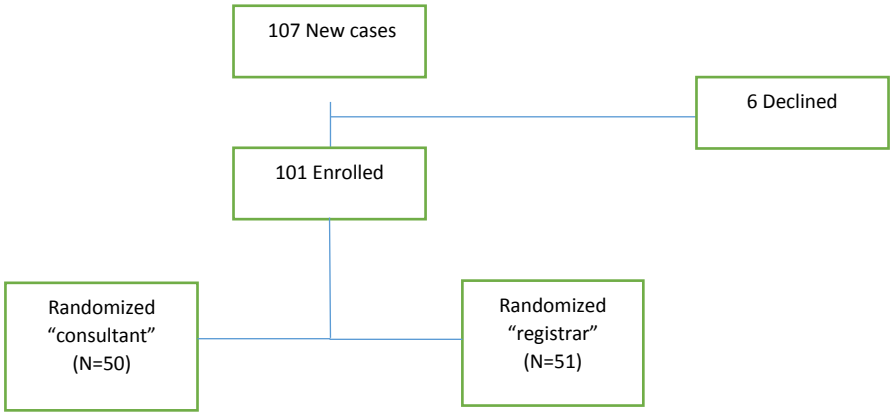

Table 1: Baseline demographic characteristics of participants.

Metric	Consultant (N=50)	Registrar (N=51)	P-value
Age[a]	55.9 ± 12.25	54.7 ± 13.94	0.6686
Parity[a]	3.3 ± 1.20	3.3 ± 1.32	0.9718
Hysterectomy[b]	18 (36.0)	12 (23.5)	0.1961
Previous POP surgery[b]	11 (22.0)	13 (25.5)	0.8158
Previous UI surgery[b]	5 (10.0)	6 (11.8)	1.0000
Menopausal[b]	28 (56.0)	26 (51.0)	0.6914
HRT[b]	10 (20.0)	8 (15.7)	0.6119
Smoker[b]	3 (6.0)	5 (9.8)	0.7152
QOL score[a]	46.84 ± 13.21	46.98 ± 11.87	0.9674

[a] Mean with standard deviation , [b] n and percentage, * p-value ≤ 0.05.

The clinical and ultrasonography findings in regards to POP are summarized in Table 2. The only significant difference observed between the two randomized groups was in the clinical evaluation of the anterior compartment (p-value: 0.0171). The registrars diagnosed significantly less POP-Q ≥ Stage 2 prolapse anteriorly (p-value: 0.0051). The difference in POP staging with TPUS examination did not reach significance in any compartment.

Table 2: Comparison of clinical and ultrasound findings of pelvic organ prolapse

	Clinical			Ultrasound		
Metric	Consultant[a]	Registrar[a]	P-value	Consultant[a]	Registrar[a]	P-value

	(N=50)	(N=51)		(N=50)	(N=51)	
Anterior POP:						
Stage 0	1 (2.0)	7 (13.7)	0.0171*	2 (4.0)	6 (11.8)	0.1469
Stage 1	8 (16.0)	16 (31.4)		10 (20.0)	13 (25.5)	
Stage 2	20 (40.0)	12 (23.5)		20 (40.0)	10 (19.6)	
Stage 3	20 (40.0)	13 (25.5)		17 (34.0)	19 (37.3)	
Stage 4	1 (2.0)	3 (5.9)		1 (2.0)	3 (5.9)	
Apical POP:						
Stage 0	8 (16.0)	15 (29.4)	0.5534	7 (14.0)	10 (19.6)	0.1418
Stage 1	22 (44.0)	18 (35.3)		21 (42.0)	12 (23.5)	
Stage 2	10 (20.0)	8 (15.7)		16 (32.0)	15 (29.4)	
Stage 3	9 (18.0)	8 (15.7)		6 (12.0)	13 (25.5)	
Stage 4	1 (2.0)	2 (3.9)		0 (0.0)	1 (2.0)	
Uterine POP	27 (54.0)	30 (58.8)	0.0753	26 (52.0)	31 (60.8)	0.2497
Vault POP	15 (30.0)	6 (11.8)		17 (34.0)	11 (21.6)	
Posterior POP:						
Stage 0	13 (26.0)	11 (21.6)	0.7828	15 (30.0)	20 (39.2)	0.0553
Stage 1	11 (22.0)	13 (25.5)		16 (32.0)	6 (11.8)	
Stage 2	18 (36.0)	16 (31.4)		8 (16.0)	15 (29.4)	
Stage 3	6 (12.0)	10 (19.6)		11 (22.0)	9 (17.6)	
Stage 4	2 (4.0)	1 (2.0)		0 (0.0)	1 (2.0)	
Rectocele	35 (70.0)	38 (74.5)	1.0000	27 (54.0)	23 (45.1)	0.8779
Enterocele	2 (4.0)	2 (3.9)		8 (16.0)	7 (13.7)	
Both	0 (0.0)	0 (0.0)		0 (0.0)	1 (2.0)	
Perineal descent	8 (16.0)	5 (9.8)	0.3888	12 (24.0)	16 (31.4)	0.5061

[a] n and percentage, * p-value ≤ 0.05.

The interobserver agreement between clinical and ultrasound findings was calculated for each compartment (Table 3). In the anterior compartment the interobserver agreement was moderate (kappa statistic: 0.4633) for the consultant group and fair (kappa statistic: 0.2770) for the registrar group.

The agreement in the apical compartment was respectively moderate (kappa statistic: 0.4333) and fair (kappa statistic: 0.3146), and the agreement in the posterior compartment was fair (kappa statistic: 0.3226) for the consultant group, and poor (kappa statistic: 0.0431) for the registrar group.

Perineal descent had good interobserver agreement (kappa statistic: 0.6287) in the consultant group, but poor agreement (kappa statistic: 0.1603) in the registrar group. The principal cause for the poor agreement was due to the lack of clinically diagnosed perineal descent in comparison to the TPUS measured descent.

The information obtained during TPUS changed the intended clinical management in 38 (37.6%) participants. There was no significant difference between the consultant (n=15) or registrar (n=23) groups for either the change in management (p-value: 0.1513) or the type of management changed (p-value: 0.5381). The change in management comprised a different surgical procedure in 25 (24.7%) participants, conservative therapy offered in 11 (10.9%) participants, and surgery offered where it was not initially proposed in 11 (10.9%) participants.

Table 3: Agreement between clinical versus ultrasound findings

		Kappa Statistic	
Measurement	**Consultant (N=50)**	**Registrar (N=51)**	**Total (N=101)**

Anterior compartment	0.4633	0.2770	0.3739
Apical compartment	0.4344	0.3146	0.3759
Posterior compartment	0.3226	0.0431	0.1766
Perineal descent	0.6287	0.1603	0.3786

The individual factors that resulted in a change in the proposed clinical management were further explored in these 38 participants (Table 4). There were three factors that predominantly influenced the management decision. These were the TPUS findings in the posterior compartment (n=17, 44.7%), the detection of perineal descent (n=6, 15.8%) and clinical under diagnosis of POP severity (n=8, 21.1%).

Table 4: Factors that resulted in a change in clinical management

Factor	**Clinical Management Changed[a]**
	(N=38)
Posterior compartment findings	17 (44.7)
Anterior compartment findings	1 (2.6)
Apical compartment findings	1 (2.6)
Perineal descent findings	6 (15.8)
Clinical under diagnosis	8 (21.1)
Clinical over diagnosis	2 (5.3)
Clinical decision only	3 (7.9)

[a] n and percentage.

Discussion

The inclusion of TPUS findings in women with POP changed the definitive management in 37.6% of this population. Superior interobserver correlation between POP-Q and TPUS staging were observed amongst more experienced clinicians, but the level of experience did not have a significant influence on whether or not the management was altered. This suggests that the TPUS findings carried the most weight in contributing to definitive treatment plans for women with POP and compensated for a lack of clinician experience.

There are several clinical implications of being able to directly image the pelvic floor. It allows for detailed surgical planning, accurate patient counselling and avoids unnecessary operative dissection. Improved surgical outcomes have been achieved in other surgical disciplines through accurate anatomical identification of structural abnormalities (25). In this study population 35 (34.6%) of women underwent previous pelvic floor reconstruction and this potential benefit of imaging changed the definitive management in 38 (37.6%) of participants. A similar outcome was noted by Groenendijk et al. for women with POP, although they included a variety of additional tests and not only imaging as was the case in our population (26). The addition of TPUS findings had the most impact in women with posterior compartment POP. The poorest agreement (kappa statistic: 0.0431) between clinical and TPUS finding was also for the posterior compartment in the registrar group. Previous authors similarly found poor agreement in the posterior compartment (21)(27). This discrepancy has furthermore been documented after surgical procedures such as sacrocolpopexy during which the clinical examination of the posterior compartment was not able to detect the anatomical abnormalities identified with ultrasound (28).

The clinical diagnosis of perineal descent remains troublesome and vaguely described, despite attempts to standardize the examination of POP (12)(29). It is associated with levator plate abnormalities and with ballooning of the levator hiatus (17)(30). These have been identified as inherent risk factors for POP surgery and a higher risk of surgical failure (31)(32)(33). . Perineal descent can be objectively quantified with TPUS and this diagnosis altered the treatment plan in 6 (15.8%) of these high risk individuals in our population. A further feature was the clinical under diagnosis of POP severity especially among the registrar group. Dietz (2) and Brusciano et al. (34) have reported that the false-negative clinical results can be explained by levator muscle co-activation during the clinical Valsalva maneuver. This introduces a significant confounding variable during clinical assessment (35). This has been our observation as well and particularly in women with associated incontinence or when consultations are curtailed due to a high patient volume. The setting of the TPUS examination in a dimmed room and the objective observation of levator movement allows for an optimal Valsalva maneuver to be performed and confirmed by the operator. The agreement between POP-Q and TPUS varies in the literature. Dietz et al. (21) and Eisenberg et al. (36) showed very good agreement, whereas Lone et al. (37) and Broekhuis et al. (27) demonstrated moderate overall agreement, except for the posterior compartment. There are limitations to this study which need to be stated. The number of participants recruited was below the planned sample size due to the specified period for data collection. The demographics however confirmed homogeneity between the randomized groups. The registrars rotate though the Urogynecology unit every 3 months and individual ability could influence the accuracy of clinical examination and proposed management. This was not apparent with random dataset evaluation and no significant differences were observed between the

consultant and registrar findings, except for an underestimation of POP in the anterior compartment. The accuracy of the agreement analyses could additionally have been influenced by the documentation of ordinal POP-Q stages, rather than the numerical measurement values for comparison to the TPUS measurements.

The change in clinical management reflects local policy and approaches to surgery or conservative treatment. The influence of TPUS on clinical decision might therefore differ in different units and healthcare settings. Lastly, we did not report on whether the changed management resulted in improved outcomes for the affected individuals. The strengths of this study include that it was a prospective evaluation of women referred with POP and that a single, experienced operator performed the TPUS examinations. The ultrasound examination was done without any knowledge or observation of clinical findings or presenting complaints. It is furthermore the first report on the influence that the integration of 2D TPUS has on definitive management decisions in women with POP.

This study demonstrated that the addition of TPUS changed the clinical management in 37.6% of women who were referred with POP and that this was most notable for those with posterior compartment prolapse. Further research is required on the influence of TPUS on the objective and subjective outcome of surgical or conservative treatment in women with pelvic floor disorders.

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CHAPTER 6

TREATMENT OF RECTOCELES: CONSERVATIVE AND SURGICAL OPTIONS

6.1 INTRODUCTION

Surgery is often the mainstay for the definitive treatment of symptomatic rectoceles. Several surgical procedures have been described for the repair of a rectocele. There is little evidence to suggest which is the most effective technique, or whether any specific technique is more appropriate than others in certain circumstances (Abbas et al. 2005). The lack of predictability of outcome can currently not be explained. It is unclear why rectocele repair achieves successful functional outcomes in many patients (70–90%), but fails to resolve symptoms in others, even when the structural abnormality is apparently corrected (Mohamed Farid et al. 2010) (Sloots et al. 2003)(Heriot et al. 2004).

Pelvic floor reconstruction is furthermore practiced by gynecologists, colorectal surgeons and urologists. This result in different perspectives and variation in clinical management as well as outcome reporting (Davila et al. 2002). The IUGA and the ICS have addressed this by means of recommended standards of reporting for surgical outcomes, but this is not universally applied in pelvic floor research (Toozs-Hobson et al. 2012). In a recent survey on the management of posterior compartment prolapse in South Africa this variation in clinical management was clearly demonstrated by the finding that urologists tend to favour a primary mesh based posterior repair (Adam et al. 2009). This is generally advised against in the urology literature and this variation

from recommended technique might be reflective of a lack of training, aggressive marketing form the mesh manufacturers, or a combination of these (Ginger & Kobashi 2007) (Marks & Goldman 2012). This variation was however not that evident in an evaluation of gynecologists' and surgeons' practice patterns in the Netherlands (Huizinga et al. 2014), although it is appreciated that coloproctologists and gynecologists view a rectocele differently. The coloproctologist will focus predominantly on the impaired bowel emptying and the gynecologist predominantly on the vaginal bulge (Kahn et al. 1999).

One can however not discuss the surgical management without reference to conservative treatment options. These modalities are not mutually exclusive, but often complimentary in nature and effect. Rectoceles, as any other pelvic floor disorder, are primarily a condition which influences QOL. In many individuals the QOL can be sufficiently corrected through conservative therapy to satisfy the patient. This does not necessarily always imply resolution of symptoms, but improvement to the extent of eliminating daily bother.

6.2 CONSERVATIVE TREATMENT

Conservative treatment is recommended in all cases of PFD as far as it is feasible. It is additionally recommended to be used in conjunction with surgical management to increase the likelihood of long term successful outcomes. It is by and large acknowledged that surgery should be offered to those in whom conservative treatment measures have failed.

6.2.1 MEDICAL MANAGEMENT

Medical treatment consists of avoiding constipating medications, increasing fluid and dietary fiber intake, regular exercise, and practicing timed toilet training. A fiber intake of 20–25 grams per day is recommended, and if required supplemented with psyllium (grade B recommendation). A recent study has shown that dried plums, 50gm BID, are more effective than an equivalent dose of psyllium for mild to moderate constipation. Although medications that promote bowel movement such as stool softeners, stimulant laxatives, and osmotic laxatives can be useful in clinical practice, the American College of Gastroenterology (ACG) task force stated that there is insufficient evidence for these treatments. The ACG gave polyethylene glycol (PEG) a grade A recommendation. A recent 6-month study reported adequate relief of constipation in 52% of patients treated with PEG compared to 11% treated with placebo (Attaluri et al. 2011).

6.2.2 TREATMENT FOR PELVIC FLOOR DYSSYNERGIA

Paradoxical contractions of the puborectalis are also known as puborectalis dyssynergia, non-relaxing puborectalis, paradoxical puborectalis syndrome, dyssynergic defecation, or anismus. It can be diagnosed on physical examination and confirmed by electromyography or defecography. It is more common in women with a history of sexual abuse and in patients with anxiety disorders (Cour et al. 2013) and also generally seen in younger women (Davis & Kumar 2005). Because of the difficulty in relying on the result of any single test alone, a set of diagnostic criteria for pelvic floor dyssynergia have been developed. Diagnostic criteria are as follows: functional constipation (Rome III criteria), adequate pelvic floor descent with Valsalva with

accompanying non-relaxation of the puborectalis muscle, and incomplete evacuation (Van Geluwe et al. 2014)(Azpiroz et al. 2002). Dyssynergic defecation is characterized by paradoxical anal contraction, inadequate anal relaxation, and/or impaired push effort caused by incoordination of abdominal, rectal, and anal muscles (Schey et al. 2012).

Appropriate treatment is with biofeedback therapy. This is the most effective treatment for dyssynergic defecation. The main purpose is to restore a normal pattern of defecation. The specific objectives are to correct the underlying dyssynergia and to improve rectal sensory perception, to improve abdominal push effort, facilitate pelvic floor relaxation, and expel artificial stool. Randomized controlled trials show that biofeedback is superior to laxatives, sham treatments and alternative therapies for the treatment of dyssynergic defecation (Gurland & Zutshi 2010).

6.2.3 BIOFEEDBACK FOR CONSTIPATION AND FECAL INCONTINENCE

Constipation and FI are frequently encountered in women with rectoceles. The exact relationship has not been clearly identified, but these symptoms require treatment as part of the overall emphasis on improving defecatory symptoms and QOL.

Pelvic floor muscle biofeedback therapy is an umbrella term encompassing many modalities addressing PFD. It includes sensation training, electrical stimulation, and the provision of directed visual or audio feedback in response to patient contraction and relaxation using electromagnetic or pressure (manometry) sensors. The initial step is evaluation of the patient to try and identify the cause for the particular dysfunction. Lifestyle factors (exercise, diet, defecatory habits) are addressed first as well as medication and current status of laxative use. Special investigations to be

considered are colonic transit study, anorectal manometry, PNTML, defecography and a bowel diary. The three foremost prevention and management of disruptive behaviour (PMDB) techniques used to treat pelvic floor dyssynergia are sensory training, electromyography feedback, and manometry feedback (Rao & Patcharatrakul 2016)(Murad-Regadas et al. 2016)

A recent comprehensive review demonstrated that PMDB appears to be the preferred treatment for dyssynergic defecation in adults and is superior to the use of laxative in these patients. Overall, success rates are in the range of 70-80%. (Rao & Patcharatrakul 2016). Types of PMDB for fecal incontinence include sensory training (coordination of rectal sensation and compliance); pelvic floor contraction exercises with evaluation by internal EMG, surface EMG, or manometry, pelvic floor exercises guided by verbal cue/manual evaluation alone, exercise training and electrical stimulation. While PMDB has been used as a therapy in the treatment of both constipation and fecal incontinence for nearly 40 years, the success rates of PMDB therapy have varied over time, and the paucity of data and replicable protocols have made it challenging to assess efficacy. The reasons for the variability of data are not clear. However, the variability of protocols, variability in definitions of PMDB (manometry vs EMG vs manual therapy), and variability among providers are likely factors.(Savitt & Thurler 2011).

6.2.4 VAGINAL PESSARIES

Pessary treatment is a generally acceptable modality for women with symptomatic POP that are either not suitable for surgery, those that want to avoid surgery, or as an interim measure for those awaiting surgical intervention. Patients fitted successfully with a pessary generally all experience an improvement in QOL metrics (de

Albuquerque Coelho et al. 2016). In the approximately 50% of women that discontinue the use of pessaries, the reasons are predominantly discomfort, the request for surgery or the inability to remove and refit it themselves. (de Albuquerque Coelho et al. 2016). It has been observed that the women in our population are mostly not in favour of pessaries due to the practical implications of pessary care. The peripheral healthcare facilities are not prepared to perform pessary care and subsequently all patients are referred to the central unit. This implies long distance travel, additional cost, and frequent visits in a socio-economically deprived population.

Factors associated with the unsuccessful fitting of pessaries are younger age, higher BMI, previous pelvic floor surgery and underactive or inactive pelvic floor muscle function (Panman et al. 2016)(Ramsay et al. 2016). Posterior compartment prolapse was also associated with a higher likelihood of failure compared to the other two vaginal compartments (Ramsay et al. 2016) and this might be due to a higher risk of pessary expulsion in these women (Yamada & Matsubara 2011). Ding et al. similarly reported that isolated posterior compartment prolapse was generally not successfully addressed with a ring pessary (Ding et al. 2016). It is often also not the primary indication for pessary use (Panman et al. 2016). The failure is likely due to the positioning of the pessary which is predominantly proximal to the rectocele defect. In such cases a Gelhorn pessary might aid in reduction of the distal posterior compartment, but this type of pessary is not indicated for sexually active women (Ramsay et al. 2016).

6.3 SURGICAL TREATMENT

Surgical repair of the posterior compartment can be approached though four routes: vaginal, transanal, transperineal and abdominal. There are few comparative studies in the literature, and even fewer Level I studies.

6.3.1 INTRODUCTION

From an evolutionary standpoint, posterior compartment repairs have progressed from plication to site-specific defect and fascial-based reconstructive techniques to the implantation of augmenting meshes and grafts. There is no conclusive data on the use of graft material in posterior repairs or rectoceles (Kohli & Miklos 2003). More recently, there has been a re-emphasis on native tissue repairs. Based on the current understanding of the anatomy of the posterior vaginal wall and perineum it is clear that the defect-specific repairs involve plication of the fibromuscular layer of the posterior vaginal wall and based on the initial level of dissection this tissue may be found on the anterior wall of the rectum or may have to be mobilized off the vaginal epithelium to allow an appropriate tension-free plication (Karram & Maher 2013).

In the transanal approach, a vertical incision is made from the dentate line to the apex of the palpable rectovaginal septal defect. The mucosa and submucosa of the rectum are dissected off the rectovaginal septum, and then the fascial defect is vertically or horizontally imbricated and closed. Excess mucosa is excised, and the mucosal defect is closed, completing the repair. The transanal approach has been shown to improve rectal emptying and decrease constipation (M W Arnold et al. 1990) (Berman et al. 2005).

All these techniques share the same aim, which is to correct the anatomical defect, relieve symptoms, and maintain satisfactory pelvic function. Although evidence

indicates that while successful anatomic correction of the deficit is achieved in the majority of patients, the functional sequelae are often less satisfactory, with varying rates of persistent postoperative defecatory dysfunction, namely constipation, digital disimpaction as well as dyspareunia (Davis & Kumar 2005).

The transabdominal approach is mainly suitable for patients with ODS caused by complex rectocele in association with high-grade intussusception. Laparoscopic ventral mesh rectopexy (VMR) has gained much attraction among colorectal surgeons. This technique has initially been described by D'Hoore et al. for treating external rectum prolapse, but its indication has been extended for internal prolapse causing ODS (Riss & Stift 2015) (D'Hoore & Penninckx 2006).

All techniques have its advantages and disadvantages and optimal functional outcomes can likely only be achieved by offering a tailored approach to each individual patient. Consequently, it is essential for pelvic floor surgeons to focus on more than one operative technique to optimize treatment for defecatory disorders (Riss & Stift 2015)(Cundiff et al. 2000).

6.3.2 TERMINOLOGY AND INDICATIONS FOR SURGERY

The restoration of normal anatomy to the posterior vaginal wall is referred to as a posterior repair or colporrhaphy. Although frequently used interchangeably in the literature with the term rectocele repair, the two operations may have vastly different treatment goals. Whereas a rectocele repair focuses on repairing a herniation of the anterior rectal wall into the vaginal canal because of a weakness in the rectovaginal septum, a posterior colporrhaphy is designed to correct a rectal bulge, if it is present, as well as normalize vaginal caliber by restoring structural integrity to the posterior vaginal wall and introitus (Pollak & Davila 2003).

The indications for the surgical correction of a rectocele, as one might expect, vary quite significantly in the published literature. The emphasis however is on identifying anatomical and functional disorders that cause bother, and offer the individual patient a realistic treatment plan accompanied by accurate counseling on the expected outcomes. It is likely that small rectoceles (< 16 mm with defecography) result in poor surgical outcomes (Lu 1990). The likely explanation for this observation is that the associated pelvic floor dysfunction in these cases were due to other causes and not the rectocele.

Recommended surgical indications are ODS, pelvic pressure or heaviness, vaginal bulge, pelvic relaxation, large rectocele (>3 or 4 cm), those with coexisting vaginal prolapse and if it is clear that the rectocele is responsible for defecatory dysfunction (Beck & Allen 2010) (Felt-Bersma et al. 2008) (Schey et al. 2012). The presence of anismus does not necessarily prevent surgery, but such patients all require post-operative biofeedback therapy.(Ayabaca et al. 2002). Symptoms that are expected to respond well to surgery are pelvic pressure, vaginal bulge, digitalisation, and splinting (occurs in 20-75% of symptomatic patients) and outlet obstruction constipation (Gustilo-Ashby et al. 2007). Strict surgical criteria have been used with the incorporation of MRI of the pelvic floor. Hall et al. evaluated patients with ODS and rectoceles. Their criteria for surgery were ODS and MRI findings of an anterior rectal defect >2 cm, incomplete evacuation, and the absence of perineal descent (G. M. Hall et al. 2014). The strict criteria suggested by Hirst et al. were rectoceles with ODS on defecography, no previous surgery, no intussusception and normal colonic transit studies (Hirst et al. 2005).

Janssen et al. used rectal sensitivity testing to predict outcome. They showed that in patients with no previous pelvic surgery, a large urge to defecate volume was an

accurate predictor of a good clinical outcome, particularly in regards to improvement in FI. A transanal approach was utilized in their series and it resulted in increased rectal sensitivity and an earlier urge to defecate, which was seen as a marker of good outcome (L. W. M. Janssen & van Dijke 1994).

6.3.3 RESULTS AND COMPLICATIONS OF SURGERY

While studies support a link between the presence of posterior vaginal wall prolapse beyond the hymen and symptoms of obstructed defecation, especially splinting, the link between the amount or degree of prolapse and symptoms is less clear (Grimes & Lukacz 2012). This makes it challenging to interpret the efficacy of surgical techniques. Additionally, the published outcomes of surgical intervention for symptomatic rectocele are heterogeneous and the extent of preoperative investigations and surgical techniques are variable. Operative indications and postoperative criteria of success are often inconsistent and ill-defined (Goh et al. 2002).

6.3.4 RANDOMISED CONTROLLED TRIALS

There have only been four RCTs published. One incorporated biological graft augmentation in one of the arms (Paraiso et al. 2006) with the other 2 comparing traditional posterior colporrhaphy with transanal repair (Kahn et al. 1999)(Nieminen et al. 2004). Both of the latter trials showed that the transvaginal repair was overall superior to the transanal route. The fourth RCT compared transanal to transperineal repair (Mohamed Farid et al. 2010).The Cochrane review on the surgical management of POP in women is primarily based on the outcomes of the first three trials (Maher et al. 2013).

Nieminen et al. compared a midline fascial vaginal repair (with or without a perineal repair) with a transanal repair (Nieminen et al. 2004). The vaginal repair excluded any levator suturing. The transanal repair was similar to that described by Khubchandani and consisted of mobilization and resection of the excess rectal mucosa, horizontal and then vertical muscularis plication and closure of the mucosal flap (Khubchandani et al. 1983). They included only women with posterior compartment prolapse and had to stop recruitment after 30 patients were randomized due to the slow nature of recruitment. There was no mention of the initial sample size calculation and the study was reported as a pilot study. Additional investigations included defecography, colonic transit study, and anorectal manometry at baseline and 12 months postoperatively. In the vaginal group, defecography showed a significant decrease in rectocele depth, whereas in the transanal group the difference did not reach significance. Obstructed defecation improved non-significantly between the two groups (73% to 7% in the vaginal group and 66% to 27% in the transanal group). Recurrence was significantly less in the vaginal group (7% vs 27%, p=0.04). There were additionally no cases of de novo dyspareunia in any participant.

Paraiso et al. compared posterior colporrhaphy with site-specific rectocele repair with site-specific rectocele repair with biological mesh (3 groups). They included women who underwent concurrent prolapse and/or incontinence surgery, but excluded those who underwent concomitant colorectal procedures. The site-specific posterior repair was performed using the technique described by Cundiff et al. (Cundiff et al. 1998). The posterior colporrhaphy was performed through transverse rectovaginal fascial plication, similar to the technique described by Maher et al. (C. Maher et al. 2004). An onlay porcine graft was anchored after a site-specific repair in the third group. The

vaginal repair excluded any levator suturing. They were able to report on 98 participants with a mean follow-up period of 17.5 months. A concomitant pelvic floor procedure was performed in 96.2% and a perineal repair was performed in 78% of the participants. Their definition for anatomic cure was a posterior POP-Q point Bp score of < -2 cm, which is currently considered inappropriately strict. Posterior colporrhaphy and site-specific rectocele repair resulted in similar anatomic and functional outcomes, but the biological graft was associated with worse outcomes. Obstructed defecation improved significantly in all three groups. Fifty-two subjects (50%) considered themselves sexually active at baseline. There was a significant improvement in PISQ-12 scores from baseline to 1 year after surgery in each treatment group (P <0,001 for each) with no differences between groups. No cases of de novo dyspareunia were reported. The complication rate was 28% in the colporrhaphy group, 27% in the site-specific group, and 35% in the graft group. The mean procedure time was 150, 151 and 169 min respectively and operative blood loss 150, 150 and 200 ml respectively, with a mean hospital stay of 2 days (1-19 days). A gradual deterioration in posterior vaginal support was noticed from approximately 14-17 months, but seemed to remain stable after this period. The mean pre-op PFDI score was 125, PFIQ score 72, and at 1 year the mean scores were 40 and 14.

Very worthwhile to note was that the mean pre-operative UDI-6 score was 43/100, compared to the CRADI-8 score of 34/100 and at 1 year the scores were 12 and 16 respectively. The urinary symptoms were therefore more bothersome initially than the defecatory symptoms and furthermore more pronounced relief was achieved in this domain compared to the colorectal domain. The authors however did not specifically referred to or discussed this observation further (Paraiso et al. 2006).

Kahn et al. randomized women to a posterior colporrhaphy or a transanal repair. Pre-operative evaluation included defecography and anorectal manometry. Levator ani plication was used for the posterior colporrhaphy and mucosal dissection and longitudinal plication of the rectal muscularis was used in the transanal repairs. They reported on 51 women and concomitant pelvic floor surgeries were not excluded. The mean follow-up period was 25 months. Obstructed defecation improved similarly in both groups (p=0.34), but of note was that 19.3% of the population required surgery for an enterocele afterwards. This was however not significantly different between the two groups (p=0.09). Dyspareunia was more prevalent in the posterior colporrhaphy group after surgery. The authors however concluded that the posterior colporrhaphy was superior to the transanal repair, based on this non-significant difference in enterocele occurrence (Kahn et al. 1999)

Farid et al. randomized women with ODS to a perineal repair with levatorplasty, perineal repair without levatorplasty or a transanal repair of their rectoceles. Pre- and post-operative assessments included colonic transit studies, defecography and anorectal manometry. The transanal procedure consisted of mucosal mobilization and excision and horizontal plication of the rectal muscularis. For the transperineal approach, a transverse incision was made above the subcutaneous anal sphincter and dissection was performed between the rectum and vagina. The rectal submucosa was sutured, followed by suturing of the “deeper perineal tissues”. In the levatorplasty group, the puborectalis and perineal body were sutured together to provide distal support. They reported on 47 participants, 6 months after surgery. They were able to show significantly better ODS outcomes in the perineal approach groups compared to the transanal group (p=0.02), but no difference in anatomic success rates. An interesting finding was that there were no cases of de novo dyspareunia in any group.

The authors did however not specify how dyspareunia was defined, the number of participants not sexually active, nor did they make use of a sexual questionnaire (M Farid et al. 2010).

6.3.5 POSTERIOR REPAIR

The 2016 terminology paper of IUGA / ICS describes a posterior repair as a repair of the vagina by excision and suturing of the edges of any defect. This was further sub-classified depending on the type of associated fascial repair into either a midline fascial plication, involving dissection under the full thickness of the vaginal epithelium followed by central plication of the pre-rectal fascia over the bulging rectum with excision of the 'excess' vaginal wall skin, or a site-specific repair (Bernard T Haylen et al. 2016). A hypothetical concern with the traditional vaginal repair is that it approximates the laterally displaced fascia by sutures only. Damaged tissue is therefore attached to damaged tissue and this might be the reason for the high recurrence rate reported in some series. A summary of the published transvaginal tissue repairs are presented in Table 2.

6.3.5.1 POSTERIOR COLPORRHAPHY

The term posterior colporrhaphy (Greek: kolpo – vagina and raphe – suture) developed from the word elytrorraphy and became used from approximately 1888 (Donald 1902). The initial description of the technique consisted of a more widespread perineorrhaphy with narrowing of the vaginal introitus through extensive suturing of the levator ani muscle (Donald 1921)(Fothergill WE 1912).

Nichols believed that rectocele and perineal defects are separate entities, but they can co-exist and he furthermore stated that a rectocele is a vaginal support defect, and not

a rectal defect (DH Nichols 1991). A posterior colporrhaphy is often performed in combination with a perineorrhaphy to address a perineal defect and an enlarged genital hiatus. This is postulated to be the case in low rectoceles (Cour et al. 2016). Lateral dissection takes place to the medial margin of the puborectalis muscle and the fascial plication is performed with interrupted sutures. Traditionally a levatorplasty or levator myorrhaphy was also performed, but this has mostly fall into disuse due to the significant risk for new onset post-operative dyspareunia that was reported (Jeffcoate 1959). Posterior colporrhaphy overall is associated with de novo dyspareunia in 12.5-26%. The addition of an anti-incontinence procedure is associated with less improvement in sexual function (Komesu et al. 2007)(Weber et al. 2000).

A midline rectovaginal fascial repair was reported by Maher et al. (C. Maher et al. 2004). They performed pre-operative defecography on all participants. The technique consisted of dissecting the vagina off the rectovaginal fascia. The lateral pararectal fascial defects were then sutured with polydiaxonone sutures. This was repeated on the both sides. A midline fascial plication was finally performed with a continuous suture. They reported on 38 women after a median follow-up of 12.5 months. The median number of concomitant procedures were two. The anatomical success rate was 87% and the symptomatic success rate was 97%. De novo dyspareunia occurred in 1 (4%) patient.

Milani et al. also used a transverse fascial plication under digital rectal guidance. They reported an anatomical success rate of 80 % and a 63 % functional cure or improvement rate, but did not clearly discrimination between cure and improvement. Of concern was that 17.2 % of their population reported de novo dyspareunia, and this could be indicative of inadvertent puborectalis muscle plication with the fascial repair (Milani et al. 2010). These two trials both did not address a potentially abnormal

anterior rectal wall and might not have fully corrected the distal part of a rectocele just proximal to the perineal body.

Cespedes described the surgical technique of traditional posterior colporrhaphy in brief as consisting of a small diamond-shaped incision made from the perineum to the posterior vaginal mucosa beyond the hymen after injection of a hemostatic solution, and the ellipse of skin is then excised. The posterior vaginal mucosa is undermined and a midline incision is made past the apex of the rectocele. The posterior vaginal epithelium is then dissected in a thin plane off of the Denonvillier fascia (RVF), with the dissection carried laterally to the levator muscles. Plication of the edges of the Denonvillier fascia over the herniated rectum is performed with interrupted stitches of 2-0 delayed absorbable sutures (the authors used 2-0 Vicryl) from the upper edge of the rectocele to the perineal body. The vaginal epithelium is trimmed if necessary and then closed to the hymen with a running 2-0 delayed absorbable suture. Perineorrhaphy is performed as appropriate, and the reconstructed rectovaginal septum is attached to the reconstructed perineal body. The rest of the vaginal and perineal skin is then closed.(Cespedes 2011).

It is thus apparent that the term posterior repair or posterior colporrhaphy refers to the buttressing of the rectovaginal fascia, which, with the current histological evidence, really is the deep fibromuscular portion of the posterior vagina. It is also evident that most authors consider that a perineorrhaphy is often necessary when treating posterior compartment prolapse and that the reconstructed rectovaginal septum can then be attached to the reconstructed perineal body.

6.3.5.2 DEFECT-SPECIFIC REPAIR

This is also referred to as a site-specific repair. The aim of this procedure is to identify and repair the fascial breaks that are present in the RVF. Lukacz et al. stated in 2002 that a site-specific repair should be considered the standard of care for rectoceles (Lukacz & Luber 2002). This technique is based on the hypothesis that rectoceles occur due to specific breaks or tears in the RVF and is based on the work of Richardson (Richardson 1993). He attributed defects to discrete breaks in the RVS and described five types of posterior compartment prolapse based on five discrete breaks in the RVS that lead to loss of support and subsequent bulge. This included a low transverse, midline vertical, lateral, L-shaped and a U-shaped defect. The most common according to him was a low transverse defect.

The original technique as described by Richardson was that the vaginal epithelium was opened transversely at the posterior fourchette and then incised longitudinally in the midline to a level above the bulge of the rectocele. The vaginal epithelium was carefully dissected from the underlying rectovaginal fascia out to its lateral attachment on the pelvic sidewall. Sharp dissection was used to stay just beneath the vaginal epithelium. After completion of the dissection and achieving hemostasis, a rectal examining finger directed anteriorly helped to define the defects in the rectovaginal fascia and to locate the fascial margins. Because there is an avascular plane between the vaginal epithelium and the rectovaginal fascia, bleeding generally occurs from the underlying rectal muscularis, and this provided clues to the location of the break in the rectovaginal fascia. Visual differentiation between the shiny white rectovaginal septum and ruddy rectal muscularis also helped define the location of the defect. The levator ani muscles were not plicated. The vaginal epithelium was not trimmed unless the two sides overlapped after reapproximation of the rectovaginal fascia. If redundant

epithelium was noted, trimming was limited to the overlap and care was taken to not narrow the vagina.

A lot of work on defect-specific repairs have been done by Cundiff and he utilized a similar technique as that described by Richardson (Cundiff et al. 1998). In an attempt to avoid contamination of the surgical field, Cespedes suggested the placement of a rubber finger in the rectum, as used in a transurethral resection of the prostate to prevent intermittently placing a clean finger into the rectum to evaluate the defects and progress of the repair(Cespedes 2011).

Based on recent intraoperative assessment trials, it was determined that most fascial defects were transverse and apical, with separation of the fascia from the vaginal cuff. Thus, after careful dissection, the fascial edge could be reattached superiorly to the cervix or vaginal cuff and usually requires three permanent sutures (Lefevre & Davila 2008).

The total anatomic success rate for defect-specific repairs range from 56-100% in an overall sample of 493 women (Cundiff et al. 1998)(Porter et al. 1999)(Kenton, Shott, et al. 1999)(Glavind & Madsen 2000)(Abramov et al. 2005)(Singh et al. 2003). It is of interest to note that the only symptom reported on by all of these authors, other than anatomic success, was de novo dyspareunia (Table 2). This varied from 0-11%.

Guzman-Rojas et al. incorporated TPUS imaging findings in a retrospective review of defect-specific repairs in 140 women with a mean follow-up period of 1.4 years (Guzmán Rojas, Kamisan Atan, et al. 2015). They found that most of the fascial defects were high and transverse. A rectocele was diagnosed pre-operatively in 90.5% and 9.5% was diagnosed intra-operatively. The mean pre-operative rectocele depth was 20.1 mm. Levator avulsion was diagnosed in 37%, which is more or less consistent with the reported literature in the general population of women with POP.

They found the patient perception of cure to be 85%, while 25% experienced recurrent prolapse symptoms (82% pre-op) and 34% ODS (70% pre-op). The anatomic cure based on clinical examination was 86%. TPUS however showed a recurrence in 20% (mean rectocele depth of recurrence was 16.6 mm). The only significant predictor of recurrence was the presence of a concomitant enterocele.

Defect-specific repairs can also be performed successfully under local anesthesia as a day case procedure (Kuhn et al. 2006). Sardeli et al. reported a series of 51 women who underwent site-specific rectocele repair under local anesthesia. The mean follow-up period was 26.7 months. Whereas pelvic examination revealed recurrence of posterior prolapse in 31% (16 of 51), improvement in rectal emptying was achieved in only 23% (7 of 30), and 23% (7 of 30) of women experienced relief from constipation. One patient developed de novo dyspareunia. Overall, 92% of the patients (47 of 51) would recommend local anesthesia. (Sardeli et al. 2007).

Table 2: Transvaginal repairs

Author	Operation	n	FU	Type	Disc	Indic	Age	Recurr	ODS/C	FI	Dyspar	Bladder
Abramov	DS	124	12	Retro	Gyne	Bulge or constip	69	11%	C 37%	19%	16%	NS
Abramov	PC	183	12	Retro	Gyne	Bulge or constip	68	4%	C 34%	18%	17%	NS
Arnold	Transvag	29	24	Retro	Colorect	Constip	48.5	NS	C 54%	34%	17.2%	10% UR
Cao	TVM	84	55	Retro	Gyne	NS	63.5	9.5%	NS	NS	8.3%	NS
Cao	DS	74	56	Retro	Gyne	NS	65	5.4%	NS	NS	4.1 %	NS
Chung	RVF	24	12	Retro	Coloproct	NS	NS	NS	NS	NS	18%	NS
Glavind	DS	67	3	Pros	Gyne	Bulge	NS	0%	4.5%	NS	3%	NS
Glavind	DS	225	3	Retro	Gyne	Bulge	60.7	NS	NS	NS	NS	UI QOL improved
Guzman	DS	137	17	Retro	Gyne	NS	NS	14%	ODS 34%	NS	NS	NS
Hong	TVM	36	15-36	Pros	Gyne	Constip	NS	NS	C 19.4%	NS	NS	NS
Oster	Biol mesh	15	31	Retro	Gyne	Failed op	62	0%	C 33%	NS	20%	NS
Schmidlin	RVF	54	22	Pros	Gyne	Bulge/ODS	58.1	18.5%	ODS 28%	NS	5.2%	NS
Kenton	RVF	46	12	NS	Gyne	Stage 2	NS	10%	ODS 36% C 23%	NS	28%	NS
Maeda	PC	10	89	Retro	Surgery	NS	68	0%	NS	10%	NS	SUI 10%
Maher	RVF	38	12 - 24	Pros	Gyne	Stage 2 / ODS	54	5%	ODS 13% C 24%	13%	5%	NS
Milani	RVF	208	14	Pros	Gyne	NS	59	19.7%	ODS 16% C 19%	14.2%	19%	OAB 23%, Obstr 23%
Mourtialon	TVM	78	36	Pros	Gyne	Stage ≥ 2	NS	5.2%	CRADI 34	NS	NS	NS
Petros	TFS	35	36	Retro	Gyne	Low rectocele	NS	3.8%	NS	17%	NS	Cure SUI 92%, Urge 91%
Schwandner	TVRR	55	18	Retro	Colorect	Bulge	60.9	NS	ODS 2%	NS	6%	NS
Tsar'kov	TVM	21	19	Pros	Surgery	ODS	51.8	10%	NS	NS	NS	NS
Wagenlehner	TFS	30	12	Retro	Colorect	Stage 2/ ODS	61	NS	ODS 10%	NS	NS	NS
Sardeli	DS	51	26.7	Retro	Gyne	NS	NS	31%	76%	NS	2%	NS

FU: Follow-up (months), Disc: discipline, Indic: indication, Recurr: recurrence, ODS/C: Obstructed defecation/constipation, FI: fecal incontinence, Dyspar: dyspareunia, DS: defect-specific, PC: posterior colporrhaphy, TVM: transvaginal mesh, RVF: fascial repair, TFS: tissue fixation system, Retro: retrospective, Pros: prospective, NS: not specified, UR: urinary retention.

6.3.5.3 TRANSANAL REPAIR

The transanal approach became more generally used for rectoceles after the work of Marks (Marks 1967). He reasoned that the prolapsed anterior rectal wall mucosa was a source of defecatory difficulty and worsened hemorrhoidal disease and that this rectal defect was not corrected by means of a posterior vaginal wall or rectovaginal fascial repair. Marks stated that an adequate surgical repair of the symptomatic rectocele entails replacement and reinforcement of the musculofascial layer in the posterior vaginal wall, removal of the excess vaginal mucosa and rebuilding of the weakened perineal body. When this was done, there still remained the loose inner lining of the rectocele in the rectal ampulla. If this was not corrected, he observed that it soon acted as a mass in the rectum and stimulated the impulse to defecate. It was evident to him that a vaginal repair of a rectocele alone was inadequate for complete comfort of the patient. The rectal side of the deformity had to be corrected. This combined approach of Marks was however fraught with recurrence and rectovaginal fistulas. Block reported a similar technique to that of Marks, but did not open the rectal wall. He simply plicated the excess rectal mucosa without excision. This technique is less popular because some patients complained of persistent tenesmus and the urge to defecate if the mucosa is not removed. In addition, necrosis of the plicated rectal mucosa has led to postoperative infection in his patients (Block 1986).

Sullivan et al. propagated the endorectal approach for a rectocele and recommended a plication of the rectal muscularis (Sullivan et al. 1968). The endorectal approach garnered more attention due to the poor defecatory outcomes often reported with vaginal repairs and the improved understanding of the anatomy of the rectovaginal septum. The procedure can briefly be summarized as follows: after infiltration of the mucosa and submucosa overlying the rectocele, a mucosal flap is raised until the apex

of the rectocele is reached. The defect in the rectovaginal septum is repaired by a longitudinally interrupted plication closure of the anterior rectal musculature using polyglycolic acid 3/0 sutures. The excess mucosa and submucosa is trimmed to prevent postoperative tenesmus and the mucosal flap is closed similar to an advancement anoplasty (Zbar et al. 2003). A side-effect of the transanal approach is the amount of peri-operative pain that patients experience in comparison to the transvaginal approaches for rectoceles (Leanza, Intagliata, Leanza, M. Cannizzaro, et al. 2013).

Sarles et al. described a further transanal modification (Sarles et al. 1989). A midline incision was made in the anterior rectal wall and the mucosa was resected. Longitudinal plication sutures were then inserted in the rectal muscularis and incorporated the rectovaginal septum. Their technique was adapted from the transverse rectal plication that Khubchandani described (Khubchandani et al. 1983). They reasoned that the anatomical abnormality was in effect due to a weakness of the circular muscle of the lower rectum, the horizontal fibers of which were spread apart and attenuated by the progressive distension of the anterior rectal wall. Thus, vertical plication sutures were deemed more likely to reconstitute the rectovaginal septum. They reported excellent outcome in 11/16 (68.8%) of their patients, but the functional outcome was limited to the subjective reporting of defecatory symptoms.

Tjandra et al. describe similarly good clinical outcomes with their transanal technique of imbrication of the rectal wall and employing an inverted T-shaped incision instead of a longitudinal anterior rectal mucosal incision. They however cautioned that anismus was observed to be a marker of poor functional outcome after this procedure. (Tjandra et al. 1999).

Van Dam et al. prospectively reported on a combined transanal/transvaginal repair in 69 women. They showed improvement in defecatory symptoms in 71%, but of concern was that de novo dyspareunia develop in 41% of their population (van Dam, Huisman, et al. 2000). The disadvantages of a transanal approach include the inability to concurrently repair prolapse in other vaginal compartments, limited exposure, the inability to access high rectoceles and enteroceles, and a possible increased risk of rectovaginal fistula formation. An advantage of the transanal approach is the ability to perform concurrent rectal procedures in the same positioning.

If one attempts to summarise reported transanal repairs, it becomes evident that there is significant heterogeneity in the quality and extent of the reporting (Table 3). The literature originates mostly from colorectal / coloproctology departments with an emphasis on defecatory function. There is lots of variation in outcome reporting compared to the gynecological literature. The overall anatomic success rate was 70-100%, although not all authors reported on anatomic success. The overall population consisted of 949 women. An improvement in constipation was the defecatory symptom most commonly reported on (Sullivan et al. 1968)(S Sehapayak 1985)(L. W. Janssen & van Dijke 1994)(Murthy et al. 1996)(Khubchandani et al. 1983)(Ho et al. 1998)(Tjandra et al. 1999)(Ayabaca et al. 2002). The transperineal repairs are similar in nature to the transanal procedures (Table 4). The leading difference is the initial incision that is made on the perineum, rather than endo-anal. The outcomes reported are therefore as expected similar to that of the transanal procedures. Table3 provides a summary of the published transanal procedures and Table 4 a summary of the transperineal procedures.

Table 3: Transanal repairs

Author	Operation	n	FU	Type	Disc	Indic	Age	Recurr	ODS/C	FI	Dyspar	Bladder
Abbas	Ant Delorme	107	48	Retro	Colorectal	ODS, FI	56	5.6%	21.5%	5.6%	NS	NS?
Arnold	Transanal	35	24	Retro	Colorectal	Constip	48.5	NS	C 54%	34%	14.7%	14% UR
Block	Obliterative suture	60	18-48	Retro	Colorectal	ODS	NS	0%	0%	NS	NS	NS
Boccasanta	Endorectal	136	24.2	Retro	Coloproct	NS	50.4	5.9%	5.9%	NS	NS	NS
Boccasanta	Transrectal	30	25.7	Pros	Colorectal	ODS / C	52.9	30%	16.6%	NS	28.6%	NS
Capps	Transrectal	50	NS	Retro	Colorectal	ODS / C	47.3	6%	NS	NS	NS	41% UR
Chung	Transanal	26	12	Retro	Coloproct	ODS / C	NS	NS	NS	NS	0%	NS
Cruz	TTREMS	75	21	Pros	Coloproct	Rectal prolapse ODS	49.6	10.6%	Imptoved	NS	NS	NS
Leal	TTREMS	35	12	Pros	Coloproct	Rectal prolapse ODS	47.5	12%	Improved	Improved	NS	NS
D'Avolio	EndoGIA	15	3	Pros	Coloproct	NS	57	0%	Improved	NS	NS	NS
Dippolito	Modified Delorme	27	16	Retro	Colorect	ODS/ Intussusc	62	7.6%	Improved	NS	NS	UI 0%
Farid	Half Delorme	16	6	RCT	Surgery	ODS / Rectocele	NS	NS	C 50% ODS 56%	NS	0%	NS
Gaj	STARR and suture	25	6	Retro	Coloproct	Constip	NS	0%	NS	NS	NS	12% UR
Ho	Transanal	21	6	Pros	Colorect	Constip / Rectocele	47.7	NS	NS	Worsened	NS	NS
Janssen	Endorectal	76	12	Pros	Surgery	Rectocele	NS	0%	NS	NS	NS	NS
Khubchandani	Endorect	59	19	Retro	Colorect	NS	53	NS	NS	NS	NS	NS
Sehapayak	Transrectal	355	NS	Retro	Surgery	ODS		2%	C 23% RectPain 20%	5.6%	NS	NS
Shafik	STARR	84	NS	Retro	Surgery	ODS	51	NS	ODS 6%	No change	2.4%	NS
Tjandra	Transanal	59	19	Pros	Surgery	ODS	58	NS	Anism 62%	NS	NS	NS
Heriot	Transanal	45	24	Retro	Colorect	Rectocele/ODS	57	NS	Improved	No change	NS	NS

FU: Follow-up (months), Disc: discipline, Indic: indication, Recurr: recurrence, ODS/C: Obstructed defecation/constipation, FI: fecal incontinence, Dyspar: dyspareunia, Retro: retrospective, Pros: prospective, NS: not specified, Anism: anismus, RectPain: rectal pain, UR: urinary retention.

Table 4: Transperineal repairs

Author	Operation	n	FU	Type	Disc	Indic	Age	Recurr	ODS/C	FI	Dyspar	Bladder
Boccasanta	Levatorplasty	126	27.5	Retro	Coloproct	NS	52.5	55.9%	6.4%	NS	NS	NS
Farid	Transperineal plication	32	6	RCT	Surgery	ODS Rectocele	48.4	NS	12.5%	NS	39.4%	NS
Liberman	Delorme	34	43	Retro	Surgery	ODS / Intuss	61.4	23.6%	C 11.5% ODS 10.3%	NS	NS	NS
Leventoglu	TVM	83	6	Retro	Colorect	Rectocele	NS	11.8%	Improved	NS	NS	NS
lieberth	Delorme	76	43	Retro	Colorect	Prolapse	NS	14.5%	NS	NS	NS	NS
Mills	Transperineal plication	117	6	Retro	Surgery	FI / ODS	NS	NS	0%	6.3%	NS	NS
Nano	Perineal	22	48	Retro	NS	Rectocele	NS	NS	0%	NS	NS	NS
Park	Delorme	17	20	Retro	Colorect	DD	68	21%	ODS 74%	NS	NS	NS
Tomita	Plication / Levatorplasty	12	24	Retro	Surgery	Rectocele/ FI	63	50%	Improved	NS	NS	NS
Trompetto	Delorme	1	3	Retro	Coloproct	Rectocele Intussusc	54	0%	Improved	NS	NS	NS
williams	EXPRESS	17	12	Retro	Surgery	Rectocele Intussusc	NS	39.5%	Improved	NS	NS	NS

FU: Follow-up (months), Disc: discipline, Indic: indication, Recurr: recurrence, ODS/C: Obstructed defecation/constipation, FI: fecal incontinence, Dyspar: dyspareunia, Retro: retrospective, Pros: prospective, NS: not specified, TVM: transvaginal mesh, Intussusc: intussusception.

6.3.5.4 STARR

The stapled transanal rectal resection (STARR) is a transanal technique employing a stapler that is an expensive single-use item. An economic evaluation found that the STARR, when not used in combination with other procedures, such as rectopexy, are comparative in overall cost (Schiano di Visconte et al. 2006). The current inclination, especially in Europe, is that coloproctologists combine the STARR procedure with an abdominal rectopexy for women with obstructed defecatory symptoms in the presence of rectal intussusception, rectocele or rectal mucosal prolapse (Schiano di Visconte et al. 2006). A large registry (n 5 379) reported on patients undergoing the STARR procedure. Complications included 3% bleeding requiring reoperation, 2% anal stenosis requiring dilatation, 3% fecal incontinence and 2 reports of rectal injury and sepsis requiring fecal diversion. (Schwandner et al. 2011). It remains a viable option for women with rectal intussusception associated with rectoceles, those with rectal mucosal prolapse, those with recurrent posterior compartment prolapse and those not suitable for an abdominal suspensory procedure (Renzi et al. 2016).

6.3.5.5 RECTOCELE FASCIAL PLICATION

This procedure is similar to the rectocele plication that is performed in the Urogynecology unit at UAH. The plication sutures are however inserted into the RVF – or otherwise vaginal fibromuscular layer – instead of the rectal muscularis (Schmidlin-Enderli & Schuessler 2013). The authors excluded patients found to have a fascial defect intra-operatively. There was no patient (n=87) in this series in whom an identifiable defect of the rectovaginal fascia

was found during surgery and no one had to be excluded because of intraoperatively found enteroceles. All patients (100 %) suffered from obstructed defecation and 38 (70.4 %) had bulge symptoms preoperatively. Sexual inactivity was documented in 29.6% of their population. Concomitant prolapse surgery occurred in 31 patients (57.4 %) and included additional repair of a cystocele and/or uterine prolapse and in 23 (42.6 %) for stress urinary incontinence. No major intra- or postoperative complication occurred. The median follow-up was 22 months in 54 patients only. Anatomic success was 92.1% and vaginal bulge symptoms were resolved in 73.6% of patients. De novo dyspareunia was however reported in 5.2% of these women. The prolapse failure rate did not correlate with an increase in the duration of post-operative follow-up time.

6.3.5.6 TRANSVAGINAL RECTAL WALL REPAIR

Schwandner et al. described a transvaginal technique that corrects the abnormal anterior rectal wall in women with rectoceles (Schwandner et al. 2009). They recognized that rectoceles result in a lengthening and enlargement of the rectum with functional impairment with regard to evacuation. The transvaginal rectal repair (TVRR) is a transvaginal, anatomical correction of the rectocele. This procedure corrects the bulging of the anterior muscle wall of the rectum, thus leading to the restoration of physiological rectum capacity and function. At the same time, the weakened tunica muscularis is suspended and stabilized. The authors reasoned that in comparison to gynecological procedures such as the posterior colporrhaphy, which does not correct the rectocele, but rather create a pelvic floor plasty by uniting the levators, the

TVRR produces an anatomic correction of the rectocele by sagittal shortening of the rectum wall. They excluded women with intussusception, a small rectocele or slow-transit constipation and the indication to proceed to surgery was persistent evacuatory outlet obstruction. The rectal wall repair consisted of separate U-shaped sutures inserted into the rectal wall from proximal to distal. This resulted in a transverse gathering of the rectocele with a strengthening of the high-pressure area of the rectal wall. This transverse gathering was hypothesized to provide better stabilization of the high-pressure area of the rectocele without reducing the vaginal diameter. Their mean operative time was 36.5 min and the hospital stay 4.1 days.

As for functional postoperative results, 85 patients (83%) were symptom-free or improved following surgery, (n=48 (47%) symptom-free, n=22 (22%) significantly improved, n=15 (16%) somewhat improved) and n=17 (17%) experienced no improvement. The authors stated that they were able to achieve good results in their study with muscle shortening alone and that postoperative dyspareunia occurred in 6% (n=6) of the cases in their study. There was however a significant loss to follow-up. From the initial 102 women operated on, there were only 55 that could be examined at 12 months.

6.3.5.7 TISSUE FIXATION SYSTEM

This technique is based on the differentiation between a high and a low rectocele. A high rectocele is argued to have an associated uterosacral ligament support defect, whereas a low rectocele is mostly associated with a perineal defect (Wagenlehner et al. 2013) (Petros & Richardson 2005). Petros described the technique of low rectocele repair which is based on the

approximation and lifting of the laterally displaced PB using the Tissue Fixation System (TFS), a 7-mm-wide tensioned macroporous polypropylene sling (Petros P 2013). In low rectocele, the PB between the rectum and vagina is thinned and laterally displaced but still attached to the deep transverse perineal muscle. The sling is then inserted into the lateral aspects of the deep transverse perineal muscles and tightened to reapproximate the perineal body. Wagenlehner et al. reported complications in 10% of women with the use of the TFS and after 1 year 27 patients (90%) reported normal defecation with an associated significant reduction in the median obstructive defecation syndrome score ($p < 0.001$) (Wagenlehner et al. 2013). This technique and theory is however controversial in current clinical practice.

6.3.5.8 MESH OR GRAFT AUGMENTED RECTOCELE REPAIRS

The use of vaginal mesh in POP surgery in general remains controversial and the likely benefits overestimated (Maher et al. 2013). Mesh consists of synthetic or biologic products. Amid's classification of synthetic mesh provides a collective awareness of mesh properties and is the terminology currently referred to in pelvic floor publications (Iyer & Botros 2016). Biologic implant alternatives used in pelvic floor surgery may be divided into 3 main groups: allografts (human donor), autografts (self-donor), and xenografts (animal donor). The literature regarding intra- or postoperative complications after mesh repairs for posterior compartment prolapse is scarce and of variable quality. Commonly reported complications are those of mesh erosions, infection, and dyspareunia. (Maher et al. 2013). The use of different mesh and graft materials, different surgical techniques, different applications (mesh overlay, mesh inlay,

armed meshes), as well as different definitions, indications, and outcome measures limits the comparability of studies. It additionally remains uncertain whether the surgical technique or the employed mesh caused the complications that one encounters (Baessler et al. 2009). The concept of reinforcing deficient rectovaginal tissues with grafts seemed logical at first, but the emergence of mesh related complications and more rigorous evaluation and reporting of both subjective and objective operative outcomes soon dampened the initial enthusiasm. The current evidence is that mesh is overall not superior to tissue repairs, and unlikely to provide any benefit in the posterior compartment(Maher et al. 2013)(Karram & Maher 2013). This was confirmed in a recent meta-analysis that concluded that the use of biologic grafts in posterior compartment repair was not superior to the repair using the patient's native tissues. The use of synthetic absorbable grafts in the posterior compartment has not been shown to improve anatomic outcomes over posterior colporrhaphy alone (Schimpf et al. 2016). The indication for its use therefore remains elusive and likely subject to individual interpretation, rather than based on published evidence.

Altman et al. compared porcine collagen mesh to posterior colporrhaphy in women with rectoceles. They were not able to show any benefit 6 months post-operatively (Altman et al. 2004). A similar absence of benefit was found in two further RCTs (Paraiso et al. 2006)(Sung et al. 2012). There is currently no high quality data to support the use of mesh or graft over the use of traditional tissue repair and insufficient data for posterior vaginal mesh kits (Maher et al. 2013). Polypropylene mesh has been reported to provide a100% cure rate, but dyspareunia increased from 6% pre-operatively to 69% post-operatively (Milani et al. 2005).

Mesh can however be extended to the perineal body during a sacrocolpoperineal repair (Grimes CL, Lukacz ES, Gantz MG, Warren LK, Brubaker L, Zyczynski HM, Richter HE, Jelovsek JE, Cundiff G, Fine P, Visco AG, Zhang M 2014)(Cronjé 2004)(Cronjé & de Beer 2008a).The effect of this extended posterior mesh placement in women with rectocele have been evaluated by van Dam et al. They found that if the mesh detached from the perineal body (28%), then there was rectocele recurrence. The higher the mesh detachment, the higher the stages of posterior POP (van Dam, Hop, et al. 2000).

6.3.5.9 RECTOPEXY

The role of rectopexy in the treatment of rectal disorders have received a lot of attention in recent times due to the minimally invasive nature of endoscopic rectopexy procedures (Samaranayake et al. 2010) (Table 5). Rectocele, ODS, rectal intussusception and rectal mucosal prolapse are the leading indications for this procedure (Portier et al. 2006). The D'Hoore VMR and some modifications of it are widely used in current practice. Only the Denonvillier's fascia is dissected to expose the anterior rectal wall and a single length of mesh is sutured onto the anterior aspect of the distal rectum. Posterior dissection is avoided and limited only to clearing the sacral promontory sufficiently for mesh fixation. Proponents of VMR report low recurrence rates and functional improvements for both fecal incontinence and constipation. (D'Hoore & Penninckx 2006). If a symptomatic rectocele or perineal descent is present, the dissection can be carried down to the perineal body and pubococcygeus

muscles for additional support. The rectum should not be placed under tension. (Cullen et al. 2012).

Vermeulen et al. reported on anterolateral rectopexy in women with rectoceles. They inserted the mesh between the rectum and vagina to the level of the pelvic floor. After surgery, all rectoceles were improved as shown by postoperative defecogram. Anorectal symptoms (incomplete evacuation, continuous urge, prolapse, digital evacuation) were improved in 40%. New-onset symptoms of dyspareunia (50%), digital support (55%) and incomplete evacuation (75%) were however documented after surgery. Most of the patients with larger rectoceles (>3.5 cm) had increased anorectal complaints after surgery (Vermeulen et al. 2005). They were not able to adequately explain their unusual clinical findings. It is however likely that the polytetrafluoroethylene (Teflon) mesh that they used played a role in the inferior outcomes (Vermeulen et al. 2005).

Samaranayake and colleagues performed a systematic review of VMR and identified 12 nonrandomized case series with a total of 728 patients.(Samaranayake et al. 2010). Seven studies used the Orr- Loygue procedure and five studies used the D'Hoore VMR technique. Recurrence rates for rectal prolapse across all studies were estimated at 3.4%. Complication rates varied from 14 to 47% and urinary tract infection and incisional hernia (n=16) were the most common ones. Only one vaginal mesh erosion (polypropylene mesh) occurred. The overall mean decrease in postoperative constipation rate over all studies was estimated at 23.9%. New onset constipation after surgery was observed in seven studies with a mean rate of 14.4%. Studies that used VMR without posterior rectal mobilization reported a

greater reduction in postoperative constipation and lower rates of new-onset constipation compared with patients with posterior rectal mobilization. The overall mean decrease in FI rate after VMR was 44.9%. These studies are however limited as a result of the lack of randomization or comparison to other techniques, heterogeneity in patient selection and follow-up and variability on definitions and outcome measurements. Table 5 summarizes the abdominal procedures used for repair of a rectocele.

6.3.5.10 SACROCOLPOPEXY FOR RECTOCELES

Sacrocolpopexy is the gold standard procedure for the correction of multi-compartment POP. The extension of the posterior mesh during open or laparoscopic sacrocolpopexy can reach the rectovaginal septum and concomitantly address a rectocele.

Kyriakou et al. reported on the laparoscopic outcomes in 697 women in whom the posterior mesh was attached to the levator muscle and not the posterior vagina. The mean follow-up period was 28 months. They found anatomic success for rectoceles in 74%, but a side effect was temporary constipation in the first 3 months in 38% (Kyriakou et al. 2006).

Sacrocolpopexy is discussed in extensive detail in Chapter 7.

Table 5: Abdominal procedures

Author	Operation	n	FU	Type	Disc	Indication	Technique	Age	Recurr	ODS	FI	Dyspar	Bladder
Abet	VMR lapsc	38	7	Pros	Colorect	Complex rectocele	D'Hoore	61.7	0%	NS	NS	27%	NS
Formijne	VMR lapsc	224	30	Retro	Colorect	Rectocele Intussusc	Mesh	62	NS	19%	14%	NS	NS
Laubert	Resect rectop lapsc	161	58	Retro	Colorect	ODS	Resection rectopexy	61	19.1%	NS	NS	NS	NS
maggiori	VMR lapsc	30	42	Pros	Surgery	NS	NS	NS	6%	Improved	NS	NS	NS
Oom	Rectopexy	33	74	Retro	Colorect	ODS Rectocele	Anterolat mesh	55	20%	ODS 55%	NS	0%	NS
Van der Hagen	VMR lapsc	27	12	Pros	Colorect	Rectocele >4cm	Comb with post colporr	67	NS	Improved	Improved	4%	No change

FU: Follow-up (months), Disc: discipline, Indic: indication, Recurr: recurrence, ODS: Obstructed defecation, FI: fecal incontinence, Dyspar: dyspareunia, Retro: retrospective, Pros: prospective, NS: not specified, VMR: ventral mesh rectopexy, Resect: resection rectopexy, Lapsc: laparoscopic, Intussusc: intussusception.

6.4 SUMMARY

A rectocele is prevalent among females and mostly encountered in association with other pelvic floor anatomical disorders. The clinical picture can vary from an asymptomatic co-incidental finding to a spectrum of pelvic floor dysfunction which can comprise urinary, defecatory, sexual and prolapse symptoms. A person that presents with a symptomatic rectocele requires a structured approach in terms of management. Associated defecatory disorders need to be comprehensively evaluated and contributing factors identified. Conservative therapy is the recommended first line of treatment and includes lifestyle and dietary changes, treatment of constipation, pelvic floor muscle rehabilitation and biofeedback, or vaginal pessary treatment. Vaginal pessaries have however been shown to have a high overall failure rate role in women with rectoceles.

Surgical repair of the posterior compartment can be approached though four routes: vaginal, transanal, transperineal and abdominal. The indications for surgical repair includes failed conservative treatment, improvement of functional disorders and anatomic correction. This often requires an individualized approach and it is essential to offer the woman a realistic treatment plan based on accurate counseling of anticipated outcomes. It is however not a straight forward process, for the association between anatomic findings and functional disorders are often found to be tenuous and variable.

It becomes apparent when reviewing most of the surgical reports that there is not that much difference in anatomic success of the procedures (Table 6). Only four RCTs for native tissue repair of rectoceles have been published. The

results of these trials were found to be in favour of a transvaginal approach over that of a transanal approach. The methodology and population for these trials were of a heterogeneous nature which limits the generalizability of their findings. Posterior colporrhaphy traditionally included a midline approximation of the levator ani muscle. This non-anatomic repair is associated with a significant risk for post-operative dyspareunia and is not presently recommended. The RVF repairs are predominantly used and consists of either a midline fascial plication or a defect-specific fascial repair.

The numerous surgical options generally report good anatomic outcomes, but varying functional outcomes. The anatomic outcomes are mostly based on clinical examination and it is apparent from these publications that underlying rectal disorders often persist in the absence of clinical evidence thereof when imaging is incorporated in the post-operative assessment.

Table 6: Comparative trials

Author	Operation	n	FU	Type	Disc	Indic/Complic	Age	Recurr	ODS	FI	Dyspar	Bladder
Harris	STARR vs TV	TV 37 ST 36	NS	Retro	Colorect	ODS	TV 57 ST 53	NS	NS	NS	NS	NS
Hirst	TA vs TP vs Mesh	TA 42 TP 33 M 7	NS	Retro	Colorect	Rectoc with ODS, no intussusc	NS	31%	31%	NS	NS	NS
Mahmoud	STARR vs TA	TA 23 S 22	12	Retro	Surgery	ODS	NS	Size decr Defecogr	NS	NS	Improved	NS
Mantoo	VMR robotic vs Lapsc	R 44 L 74	NA	Retro	Surgery	PFD	ODS sign more impr R,	No diff	NS	NS	Improved	NS
Carey	Mesh vs no mesh	M 69 N 70	12	RCT	Gyne	Erosion 5.6%	NS	M 19% N 34.4%	NS	NS	NS	NS
Sokol	Mesh vs no mesh	M 32 N 33	NA	RCT	Gyne	Erosion 15.6%	NS	M 21.8% N 18.2%	NS	NS	NS	NS
Withagen	Mesh vs no mesh	M 93 N 97	NA	RCT	Gyne	Erosion 16.9%	NS=	M 4.1% N 24.5%	NS	NS	NS	NS
Nieminen	TA vs TV	TA 15 TV 15	12	RCT	Gyne & Surgery	Rectocele	ODS TA 66-27% , TV 73-7%	TA 40%, TV 7%	TA 62% TV 59%	NS	0%	NS
Ohazuruike	STARR vs TA	S 23 D 12	NA	Retro	Colorect	ODS	Sign impr ODS score and C score	NS	NS	NS	NS	NS
Paraiso	PC vs SS vs SS Biol graft	PC 37 SS 37 SS B 32	17.5	RCT	Gyne	Bulge	All QOL improved sign, but no diff between groups	SSB 46% SS 22% PC 14%	NS	NS	0%	Improved
Smirnov	TV LP vs TP LP vs TP mesh rep	TV 22 TL 21 TM 20	NA	Retro	Surgery	NS	Worst C outcome TL group	TV 27% TL 9.5% TM 5%	NS	NS	Mesh best	NS
Tang	TV long fascial vs TV transv fascial	TVL=74 TVT=72	NA	Pros	Coloproct	NS	TVL fail 11.1% TVT fail 1.4%	Compl 40.3% both	NS	NS	NS	NS
Thornton	Lapsc ASCS vs TA	L 40 TA 40	44	Retro	Colorect	Rectocele	TA higher pt satisfy <0.003	TA Improved	L 28% TA 63%	NS	NS	NS

Tsujinaka	TA vs TV	TA 71 TV 40	12	Pros	Surgery	ODS	ODS sign impr both <0.001	TA 56 TV 67	TA more AI	NS	NS	NS
Wong	VMR robotic vs Lapsc	L 40 R23	6	Pros	Surgery	Rectocele > 3cm,	No recur 6/12	L59 R 61	NS	NS	NS	NS

FU: Follow-up (months), Disc: discipline, Indic: indication, Recurr: recurrence, ODS: Obstructed defecation, FI: fecal incontinence, Dyspar: dyspareunia, Retro: retrospective, Pros: prospective, NS: not specified, TA: Transanal, TV: transvaginal, TP: transperineal, LP: levatorplasty, VMR: ventral mesh rectopexy, Resect: resection rectopexy, Lapsc: laparoscopic, PC: posterior colporrhaphy, SS: site-specific repair, ASCS: abdominal sacrocolpopexy, Intussusc: intussusception.

CHAPTER 7

RECTOPEXY AND SACROCOLPOPEXY IN THE TREATMENT OF POSTERIOR COMPARTMENT DISORDERS

7.1 INTRODUCTION

Sacrocolpopexy and rectopexy separately and concomitantly have been used for the surgical correction of a rectocele. The hypothetical mechanism of improvement with a distal posterior mesh insertion during a sacrocolpopexy is a combination of apical correction and RVF reinforcement. The hypothetical mechanism of improvement with a rectopexy is a combination of straightening of the stretched anterior rectal wall and concurrent elimination of rectal intussusception when it is present. These hypotheses have however not directly been proven in the published literature.

The term sacrocolpopexy in the literature does not reflect an exact procedure. Variation exists in regards to the nature of abdominal access (open or endoscopic), type of mesh used and the extent of distal mesh placement in both the anterior and posterior vaginal compartments. It is however the current gold standard for the correction of apical compartment prolapse (Maher et al. 2013). It additionally provides a superior outcome for patients with multi-compartment POP when compared to other surgical procedures (Callewaert et al. 2016). Endoscopic sacrocolpopexy has the additional advantage of shorter hospitalisation, faster recovery, and less morbidity compared to a laparotomy, without any sacrifice in clinical outcomes (Maher et al. 2013). There is however no proven benefit of a robotic sacrocolpopexy over that of a laparoscopic sacrocolpopexy (Callewaert et al. 2016).

7.2 PERINEO-COLPO-SACROSUSPENSION

The perineo-colpo-sacrosuspension (PCSS) is an operation that was introduced by Cronje (Cronjé 2004) in 1998 and originated in philosophy from the total pelvic floor repair described by Sullivan (Sullivan et al. 2001). A concern with Sullivan's published series was the post-operative outcome of these patients. He reported on 205 patients with a 10-year follow-up and the median age was 64 years. The reported clinical outcomes consisted of a vaginal bulge in 54%, de novo dyspareunia in 3%, rectal prolapse in 48%, cystocele in 60%, perineal descent in 63% (this was also the primary motivation for the total pelvic mesh repair), enterocele in 47% and rectocele in 44%. The posterior mesh was anchored to the perineal body via vaginal suture attachment to the mesh and the mean procedure time was 192 minutes and hospital stay 6 days. Complication related surgery was required in 10%, and additional pelvic floor procedures was required in 64%. This consisted of 36% that required additional anterior compartment surgery and 28% that required posterior compartment surgery.

The PCSS was modified to prevent the high recurrence rates seen in Sullivan's series. This procedure is an abdomino-vaginal sacrocolpopexy with the anterior mesh extending from the distal urethra in a cranial direction, and the posterior mesh extending similarly from the perineum (Cronjé 2004). The surgical technique entails abdominal dissection of the vesicovaginal space from the vault to the urethrovesical junction and vaginal dissection from the distal urethra to join with the abdominal plane of dissection. In the posterior compartment the dissection of the rectovaginal space was initiated abdominally and completed by means of the transvaginal dissection from the perineum to align with the abdominal dissection. A type 1 polypropylene mesh was inserted in the anterior and posterior compartments along the full plane of dissection and additionally anchored at the vaginal apex and the anterior longitudinal ligament at

S1, i.e. a perineo-colpo-sacrosuspension. The purpose was thus to provide an all-encompassing pelvic floor repair, augmented with the use of mesh.

The initial outcomes reported by Cronje in a series of 140 women after a median follow-up period of 8.5 months included a median blood loss of 400 ml and recurrent prolapse in 11 patients (8%), nine of which were posterior compartment recurrences (Cronjé 2004). Of importance is that a rectopexy was simultaneously performed in this series of 140 women, but no concomitant posterior repair. This suggests that the extension of the posterior mesh to the perineal body was not sufficient to correct a rectocele. With a follow-up period of 8.5 months, it was unlikely a recurrence, but more likely a persistence of the posterior compartment defect.

In a later series, Cronje et al. reported on 117 women with a culdocele who underwent a PCSS procedure (Cronjé & de Beer 2008a). The mean age was 61 years and 95% had a previous hysterectomy. Most patients (96%) received a concomitant ventral mesh rectopexy and a perineal body repair was performed in 72% of women. The outcomes reported after a mean follow-up period of 14.7 months included a mean blood loss of 383 ml and recurrent prolapse in 12 patients (10.3%), all of which had a posterior compartment recurrence. Obstructed defecation improved from 40.2% at baseline to 12% post-operatively.

Procedures similar in concept have been described by other authors. Sarlos et al. reported on the outcomes of a laparoscopic sacrocolpopexy after 5 years (Sarlos et al. 2014). Their posterior dissection was to the level of the levator fascia with the mesh attached to the levator muscle. The anterior dissection was to the level of the urethrovesical junction. They were able to report on 5-year follow-up data in 68 patients. The anatomical recurrence was 16.2% (8.8% anterior, 5.9% posterior, and

1.5% apical). The repeat operation rate was 3.5%. The subjective cure rate according to QOL improvement however was 95.3%.

Extension of the posterior mesh to the perineum and obliteration of the POD does not altogether prevent the formation of rectoceles. A prospective study by Baessler et al. showed that although there were no clinically detected rectoceles on Valsalva, defecography enabled the diagnosis of rectocele recurrence in 57% of cases and de novo rectocele was diagnosed in 3%. Outlet constipation was present in 64% preoperatively and persisted or was altered in 57% after sacrocolpopexy. The severity of the rectocele was significantly associated with symptoms of outlet constipation preoperatively, but not postoperatively. (Baessler & Schuessler 2001). This is comparable to the reports from Cronje after the PCSS operation, where the majority of recurrences in the two case series occurred in the posterior compartment. Cronje et al. did however not utilise imaging in those women to evaluate for the possible persistent rectal defect beneath the vaginal mesh (Cronjé 2004)(Cronjé & de Beer 2008a).

7.3 SACROCOLPOPEXY AND RECTOCELES

7.3.1 MECHANISM OF ACTION

A sacrocolpopexy has the ability to correct a rectocele in regards to its pathogenesis in different ways. The first possible mechanism is through the provision of apical support in cases where a high rectocele exists in accordance to DeLancey's hypothesis (DeLancey 1999). The second possible mechanism is through bridging of the rectovaginal fascial defect with the insertion of the posterior sacrocolpopexy mesh to the level of the distal vagina in accordance with the theories of low rectoceles and

rectovaginal fascial defects (DeLancey 1999)(Abendstein et al. 2008)(Cundiff et al. 1998). The third possible mechanism is through addressing an abnormal levator plate. Suspensory procedures, such as a sacrocolpopexy and/or a rectopexy, are the only type of reconstructive procedures able to elevate an abnormal levator plate as seen in women with levator dysfunction. Excessive perineal descent has also been associated with displacement of the levator plate as a result of levator ani dysfunction (Beco 2008)(Dietz et al. 2016)(Rostaminia et al. 2015). The importance of perineal support was underlined by the incorporation of imaging in the assessment of rectoceles through which perineal descent was found to be significantly associated with rectoceles in nulliparous women (Dietz & Clarke 2005). Perineal descent is furthermore associated with levator ani muscular injuries (Clark et al. 2010). This improvement of an abnormal levator plate will plausibly lead to an improvement in level 3 vaginal support and subsequently perineal support, i.e. resulting in correction of the pathogenesis suggested to be present in low rectoceles (DeLancey 1999)(Abendstein et al. 2008).

7.3.2 BOWEL SYMPTOMS AFTER SACROCOLPOPEXY

It has been established that rectoceles often presents with defecatory disorders, but that defecatory disorders can also often be a reflection of a more extensive dysfunctional pelvic floor (Pescatori et al. 2006). A sacrocolpopexy can provide anatomical correction to all three vaginal compartments and it could therefore be anticipated to result in an overall improvement in defecatory function.

There is a usually a poor correlation between the severity of posterior vaginal prolapse and the presence or severity of defecatory dysfunction (Cara L Grimes et al. 2014)

(Jelovsek et al. 2005) (da Silva et al. 2006). Conversely, a posterior repair is often associated with an improvement in defecatory symptoms (Cundiff & Fenner 2004) (Gustilo-Ashby et al. 2007).

Bradley et al. evaluated bowel symptoms 1 year after a sacrocolpopexy in a series of 298 women (Bradley et al. 2007). This was an ancillary analysis of the multicentre Colpopexy and Urinary Reduction Efforts (CARE) study. They found that bowel symptoms improved significantly (71-88%) in women undergoing sacrocolpopexy with or without rectopexy. A concurrent posterior repair (n=87), performed at each surgeon's discretion, was associated with a larger genital hiatus and more obstructed defecation symptoms at baseline. This suggests that this subgroup of women had a combination of more severe and generalised POP with associated levator dysfunction (avulsion or functional impairment). The post-operative POP-Q measurements did not differ significantly in those who did or did not receive a concomitant posterior procedure. After surgery, all bowel symptoms scores as measured with the CRADI questionnaire were significantly improved in both groups. The post-operative CRADI and CRAIQ scores were not significantly different between the groups. Beassler et al. showed that constipation significantly improved after sacrocolpopexy from 68% to 36%, n=33 (Baessler & Schuessler 2001). Maher et al. on the other hand found no significant improvement in constipation or ODS after sacrocolpopexy, n=47 (C. F. Maher et al. 2004).

A further subgroup analysis of the Extended-CARE (E-CARE) trial looked at whether perineal descent was associated with more severe bowel symptoms and whether the improvement in bowel symptoms after surgery was different in those with perineal descent compared to those without (Cara L Grimes et al. 2014). Surgical failure was defined as either posterior prolapse measured at point Ap ≥ 0 cm and ODS, or

posterior compartment reoperation. This was a 5-year post-operative analysis of 90 women. In those with no initial posterior repair, the failure rate was 9%. Of those who had an initial posterior repair, 14% underwent a repeat procedure and 12% had recurrent posterior prolapse. ODS improved in all groups irrespective of concomitant posterior repair, but were overall still present in 17-19% of women at 5 years. This confirms that the presence of perineal descent is a marker of a more severe pelvic floor disorder and that it has a higher risk of surgical failure, irrespective of concomitant posterior or perineal reconstruction. The conclusion from the authors in this analysis was that it is not necessary to perform a concomitant posterior repair with a sacrocolpopexy, and that expectant management can be recommended in regards to the posterior compartment. They however did recommend that "*Prospective trials assessing the risks and benefits of concomitant repair of the posterior compartment when undergoing sacrocolpopexy are warranted to guide treatment recommendations"*.

7.3.3 SACROCOLPOPEXY AND THE PERSISTENCE OF RECTOCELES

The likely mechanism through which a sacrocolpopexy will correct a rectocele has been highlighted. The question that needs to be explored is whether this procedure do correct rectoceles and to what extent this happens.

If the 5-year E-CARE trial data is analysed, the following is observed: In those who received a posterior repair, 31.2% suffered with ODS at baseline, and 4/11 (36.4%) required a repeat posterior repair. These women initially had a sacrocolpoperineopexy with a perineal repair (79%) or a perineal repair with a sacrocolpopexy (21%) (Cara L Grimes et al. 2014). In this group the mesh extended to the perineal body, but the

rectocele recurred or persisted beneath this repair and manifested clinically in a significant percentage of women.

Maher et al., in a RCT of sacrocolpopexy or sacrospinous colpopexy, reported that a rectocele was present in 35/47 (74.5%) of the sacrocolpopexy participants (C. F. Maher et al. 2004). The posterior sacrocolpopexy mesh was inserted distally nigh on the perineum (7-8 cm distally). A posterior colporrhaphy was performed in 11 (31.4%) of these women. Among the 24 women who did not receive a posterior repair, a rectocele recurrence was diagnosed in 8 (33.3%) of them. This was despite the very distal insertion of the posterior mesh.

Cronje reported the presence of a rectocele in 16/140 (11.4%) of his population who received a PCSS procedure (Cronjé 2004). There was no concomitant posterior repair performed in this series. A rectocele was diagnosed at follow-up in 9 (56.2%) women. This was likely due to the persistence of the rectocele and not due to a recurrence, seeing that the median follow-up period was 8.5 months. This high percentage of rectoceles occurred in a procedure where the posterior mesh was inserted to the perineal body and where a concomitant perineal repair was performed in the majority of patients.

In a further series, Cronje et al. documented a rectocele in 37/117 (31.6%) of their population who received a PCSS procedure (Cronjé & de Beer 2008a). There was also no concomitant posterior repair performed in this series. A rectocele was diagnosed at follow-up in 12 (37.4%) women. This was however at a mean follow-up period of 14.7 months and again occurred despite the distal posterior mesh placement during the sacrocolpopexy.

These publications, although heterogeneous in the nature, therefore demonstrated that a rectocele persists or recurs in 33.3 - 56.2% of women after a sacrocolpopexy where the posterior mesh was mostly inserted to the level of the perineum.

7.4 RECTOPEXY AND RECTOCELES

A rectopexy generally consist of three types of approaches: mesh, suture, and resection. Over 200 different techniques have been described to treat rectal prolapse and allied disorders. A typical procedure should include rectal mobilization and rectal fixation and the recurrence rates should not exceed 2 to 4% (Kuijpers 1992). The emphasis is however, similar to a sacrocolpopexy, on tension-free suspension. The initial description of VMR was the Orr-Loygue technique for total rectal prolapse and this involved anterior and posterior rectal mobilisation with anterolateral mesh attachment (Portier et al. 2006). The D'Hoore modification is a nerve sparing approach for ventral mesh rectopexy which involves only anterior rectal dissection and mesh placement (D'Hoore & Penninckx 2006). VMR entails dissection of the RVS to the level of the pelvic floor. Mesh is then fixated to the anterior rectal wall and to the sacrum at the level of S1. Concomitant vaginal vault attachment to the mesh can provide additional support and eliminate a deep pouch of Douglas (N. Alam et al. 2015). The mesh used can be synthetic or biological. A systematic review of biological VMR found no RCTs and showed that porcine dermal collagen was the most commonly used type of biological mesh. Recurrences were found in 7.5 % of cases (N. Alam et al. 2015).

7.4.1 RATIONALE

The rationale for offering a rectopexy to patients with a rectocele is that it might improve functional bowel symptoms by providing suspensory support to the rectum and apical vaginal compartment and simultaneously avoid iatrogenic autonomic denervation. An additional motivation for a rectopexy for patients with rectoceles is the ability to correct concomitant anorectal and pelvic floor disorders. A VMR was used by Cronje et al. to eliminate a culdocele via a concomitant vault suspension (Cronjé & de Beer 2008a). These reasons all point to the effect of the suspensory procedure on the levator plate as discussed for the sacrocolpopexy mechanisms of action. This observation was primarily reported only in the colorectal literature, where it was observed that the perineal approaches with the Delorme and Altemeier procedures resulted in a high recurrence rate in patients with rectal prolapse and these were subsequently superseded by abdominal rectopexy (Faucheron et al. 2015). An additional concern with perineal approaches were raised by D'Hoore et al. who stated that it can reduce rectal capacity and compliance, which may result in persistent post-operative AI (D'Hoore & Penninckx 2006).

The primary indications for a rectopexy are rectal prolapse or rectal intussusception. The demographic profile of these candidates often mirror that of the typical urogynecology population. Women older than 50 years are six times more likely than men to present with rectal prolapse and they typically are multiparous with a third experiencing associated urinary dysfunction and vaginal prolapse (Cullen et al. 2012) (González-Argenté et al. 2001). Rectopexy has also been recommended as efficacious by Abet et al. for complex rectoceles, defined as those ≥ 3 cm with an associated enterocele or associated intussusception (Abet et al. 2012). These recommended indications are all reflective of multi-compartment PFD, an entity which

is being increasingly encountered and which is associated with an ageing population (Doumouchtsis & Chrysanthopoulou 2013).

Many of the symptoms of a rectocele overlap with those of other pelvic floor disorders such as rectal intussusception, enterocele, anismus or spastic pelvic floor syndrome. Vermeulen et al. reported on nerve sparing antero-lateral rectopexy for rectoceles in a sample of 20 women (Vermeulen et al. 2005). Pre-operative symptoms included ODS in 80% and a vaginal bulge in 70%. The mean hospital stay was 8.5 days. They found that ODS improved in 50%, bulge resolved in 71%, and no rectocele > 2 cm was seen with post-operative defecography. Lower abdominal pain and lower back pain improved in 28%, but dyspareunia occurred in 50%. Subjectively, 65% of women were not satisfied with their outcome and would not undergo the procedure again. They concluded that the treatment of a symptomatic rectocele by anterolateral rectopexy provided good anatomic results, however functional outcome remained poor and overall anorectal symptoms were improved in only 40% of the patients. The majority of poor outcomes were however noted in the subgroup with rectoceles ≥ 3.5 cm on initial defecography. Other investigators conversely, have found no relation between the size of the rectocele and functional outcomes (Dam et al. 1994) (Stojkovic et al. 2003).

7.4.2 RECTOPEXY OUTCOMES

The recommended anatomic recurrence rate for a rectopexy should not exceed 2 to 4% (Kuijpers 1992). The majority of recurrences have been found to occur in the first year after the procedure (Benoist et al. 2001). The overall recurrence rate nowadays with VMR is generally 5% or less (Brown et al. 2005) (Samaranayake et al. 2010)

(Faucheron et al. 2015). This seems to be a reproducible procedure with reported recurrence rates of 5.9% for rectopexy in a multicentre trial and it occurred at a median follow-up period of 43 months (Raftopoulos et al. 2005). The mechanism underlying the majority of failures as described by D'Hoore et al. were due to failure at the level of promontory fixation (D'Hoore & Penninckx 2006). Complication rates in a systematic review varied from 14-47% with urinary tract infection and incisional hernia being the most common ones (Samaranayake et al. 2010) (Faucheron et al. 2015). The majority of complications were Dindo grades 1-2. Mesh related complications were documented in 1-2% of the population and this included vaginal mesh exposure as well as rectal mesh erosions (Faucheron et al. 2015) (Cullen et al. 2012) (van Iersel et al. 2016). Rectopexy complications associated with endoscopic approaches ranged from 3.6 – 23.5% for Dindo grades 1-2 and 0 – 7.7% for Dindo grades 3-4 (van Iersel et al. 2016). This confirmed that there was no significant difference between the open or endoscopic approaches in regards to the complications reported.

The reporting on functional outcomes, as is observed with most surgical trials, vary significantly. The majority of publications on rectopexy are contained in the colorectal literature and the emphasis of functional outcome reporting is primarily in relation to defecatory symptoms. It is however recognized that the functional outcomes are improved with nerve sparing rectopexies (Kneist et al. 2013). The importance of nerve-sparing dissection was evident in the reports from a prospective study where the mean colonic transit time doubled after posterior and lateral rectal mobilisation with an associated decrease in mean resting pressure and rectal compliance, but with no significant change in anorectal function (Mollen et al. 2000).

Constipation is traditionally a common problem and seen in 30-75% of patients selected for rectopexy (Benoist et al. 2001) (Brown et al. 2005). The overall

improvement in constipation with modern VMR was 23.9%, with new onset constipation observed in 14.4% according to a recent systematic review (Samaranayake et al. 2010). Constipation improvement in a systematic review of anterior rectopexy ranged from 3-72% and worsened in 0-20% (Faucheron et al. 2015). The avoidance of posterior rectal mobilisation has been shown to be associated with improved constipation outcomes. Portier et al. reported that constipation was cured in 51.9% of cases with total rectal prolapse, in 60% of cases with rectal intussusception, and that new onset constipation occurred in 4% with the Orr-Loygue technique (Portier et al. 2006). Dulucg et al. found constipation improved in 36% of patients after a posterior Wells rectopexy using a circumferential mesh fixation technique (Dulucq et al. 2007). Resection rectopexy on the other hand have been found to have no clinical effect on ODS in 25% of patients (Ihnát et al. 2016). It needs to be considered that patients with rectal prolapse often also experience abnormal hindgut motility (Brown et al. 2005). Post-operative testing has shown that colonic pressure reduces to normal values after rectopexy, but that high-amplitude propagated contractions are not restored and subsequently often there is not an improvement in colonic transit and constipation (Brown et al. 2005). It might not necessarily be a case of surgical denervation alone, but also that of a pre-existent neuropathy due to the rectal prolapse with associated stretching of the autonomic nerves.

Fecal incontinence have also generally been shown to improve after rectopexy in up to 75% cases. Most authors however did not differentiate between flatus and fecal incontinence. The specific mechanism for improvement is uncertain, but is thought to be due to improved anorectal sensation and rectal compliance (Benoist et al. 2001). A recent systematic review reported that the mean decrease in fecal incontinence was 44% after VMR (Samaranayake et al. 2010).

Obstructed defecation is another symptom often present in patients selected for a rectopexy. Resection rectopexy has been found to have no clinical effect on ODS in 25% of patients (Ihnát et al. 2016). A clear correlation between the surgical correction of the anatomical abnormalities with a rectopexy and improvement in ODS has not been demonstrated (Lundby & Laurberg 2015). A systematic review found a significant overall improvement in ODS after VMR ($p < 0.0001$) (Gouvas et al. 2014).

Sexual function is often not reported on either in the baseline evaluation or in the operative outcomes. Sexual function is furthermore often neglected in the pre-operative surgical discussion and more than 50% of women have been found not to view potential dyspareunia as a surgical concern (Buvat et al. 2009). Endoscopic rectopexy has been shown to be associated with an improvement in sexual function and no new onset dyspareunia (n=41) (Abet et al. 2012). This was confirmed by Gouvas et al. in a systematic review of VMR, where they were able to report an improvement in sexual function from 64.5% to 13.8% ($P < 0.0001$) among a sample of 1469 patients (Gouvas et al. 2014). Vermeulen et al. however recorded de novo dyspareunia in 25% of their small sample who had a VMR for a rectocele (Vermeulen et al. 2005).

7.4.3 RECTOPEXY IN COMBINATION WITH SACROCOLPOPEXY

An abdominal approach to correct severe general POP is mostly recommended for younger patients due to its durability and minimal possibility for sexual dysfunction (Ayav et al. 2005). It is feasible to perform a VMR concomitant with a sacrocolpopexy, particularly in women with severe general POP, or in those with associated rectal disorders. The anatomic advantage of this type of operation is that it can result in

splinting of the pelvic floor with the mesh, reducing the rectocele size, and avoiding redundant bowel in the pelvis (Lim et al. 2007) (Cronjé & de Beer 2008a).

Tancer et al. were among the first to report on colpopexy with rectopexy after hysterectomy for combined genital prolapse. They described the outcome in two women who were followed up for less than 12 months and found no anatomic recurrence of POP (Tancer et al. 1987).

Zhioua et al. then reported their outcomes in a series of 6 women who underwent a colpopexy with rectopexy for combined genital prolapse. The mean age was 60 years and the mean follow-up period was 20 months. They used the Orr-Loygue rectopexy technique. The anatomic success was 100%, but unfortunately no symptomatic outcomes were reported on (Zhioua et al. 1993). Silvis et al. performed an abdominal rectovaginopexy for patients with combined posterior prolapse and bowel dysfunction (Silvis et al. 1999). This is in essence similar to a rectoperineopexy. The vagina was not incised or opened, nor where the vaginal vault suspended. The uterosacral ligaments were however sutured to the mesh. They reported on 27 women followed up for 4 years and found that constipation improved from 62.9% to 18.5% ($p = 0.005$) and remained stable after 4 years. Fecal incontinence improved from 62.9% to 29.6% ($p = 0.007$) after one year, but this became non-significant at 4 year follow-up. Recurrent rectoceles were present in 40%, intussusception in 5.9%, but no recurrent enteroceles were detected. There was no change in rectal sensation for distension after the rectopexy.

A colporectosacropexy procedure was reported on in a series of 62 women by Jean et al. They noted recurrence of enteroceles in 1.6%, relief of pelvic pressure in 73%, but no improvement in ODS, lower abdominal pain, and urinary incontinence in their

series (Jean et al. 2002). Abdominal colporectopexy with pouch of Douglas closure for combined rectal and genital prolapse was described by Collopy et al. (Collopy & Barham 2002). This retrospective review with a mean follow-up period of 5 years, reported on a combined colorectal and gynecologic abdominal approach in 60 women who all had a previous hysterectomy. The mean operating time was 90 minutes. The surgery consisted of a Wells mesh rectopexy, closure of the pouch of Douglas via a Moschowitz procedure, proximal vaginal sacrocolpopexy and vaginal colporrhaphy. A 10% vaginal prolapse recurrence was observed (primarily anterior compartment and expected due to the lack of abdominal anterior support during the sacrocolpopexy) and repeat prolapse surgery was required for 6% of patients and UI surgery for 6.6%. Symptomatic improvement was found among all symptom domains. There was no de novo dyspareunia. Constipation and/or ODS were present in 14% after surgery, compared to 69.6% before surgery. No QOL instruments were however used in the determination of subjective improvement.

Enteroceles are observed mostly after hysterectomy (Kuah et al. 2000) (Cronjé et al. 2004). Kuah et al. used a Zacharin rectopexy technique, which consisted of mesh rectopexy, abdomino-vaginal posterior sacrocolpopexy and abdominal levator plication. This was a retrospective study of 126 women, 75% of whom had previous prolapse surgery. Anatomic cure was 92.4% and subjective cure 94.9%. Re-operation rate was 5%. Urinary dysfunction was present in 30.5% after surgery, constipation in 43% (from 16.6% pre-operatively), dyspareunia in 11.2%, and 40.4% required peri-operative blood transfusion, with an overall complication rate of 42.3%. (Kuah et al. 2000).

Lim et al. performed mesh sacrocolpopexy with mesh rectopexy for combined genital prolapse in 29 women. The indication for this surgery was middle compartment

prolapse stage ≥ 2 and rectal intussusception or rectal prolapse. The median age was 66 years and the median follow-up was 26 months. Of note was that all patients had a previous hysterectomy. Polypropylene (Prolene) sutures were used for the VMR. Pre-operative symptoms included a vaginal bulge in 73%, rectal intussusception in 17%, urinary symptoms in 79%, constipation in 31% and FI in 21%. They did not specifically identify ODS symptoms. A normal EAS and IAS was identified in 25/29 (86%) patients with the use of anorectal manometry testing. They observed no anatomic recurrence at 6 months, but at 26 months the failure rate was 10%. The QOL was reported with the use of the PFDI-20 questionnaire. The total score was significantly improved as were the subscales. The least difference was however present in the CRADI subscale. There was an association with no improvement in bowel function and the presence of rectal intussusception. The authors attempted to identify criteria for patients who would benefit from this type of procedure and recommended it specifically for patients with mixed urinary and bowel symptoms (Lim et al. 2007).

A laparoscopic sacrocolporectopexy for combined POP was reported on by Sagar et al. (Sagar et al. 2008). They inserted a mid-vaginal mesh and combined this with a VMR laparoscopically. They reported outcomes in 10 women, median age 47 years and after a follow-up period of only 6 months. There was no operative morbidity, the PFDI-20 questionnaire improved in all scales and there was no recurrent rectoceles. Perineal descent was found to have been corrected as well.

Watadani et al. described a sacrocolpopexy with rectopexy in a retrospective review of 110 women after a mean follow-up period of 29 months (Watadani et al. 2013). The indication for surgery was combined apical and posterior compartment prolapse. The pre-operative workup included anorectal manometry, pudendal nerve latency and

defecography. Validated QOL questionnaires were used to assess symptom bother. The rectopexy was similar to that described by D'Hoore and the sacrocolpopexy consisted of mesh attached only to the vaginal apex. The median age was 55 years and a concomitant hysterectomy was performed in 30%. The 30-day peri-operative complication rate was 32.7%. The mean hospital stay was 4 days. Constipation resolved or improved in 82% women, FI resolved or improved in 82% women and no rectal prolapse recurred. QOL data revealed a significant improvement in overall QOL as well as with fecal bother. This was one of the largest studies reporting functional outcome, quality of life, and recurrence rate after combined sacrocolpopexy and rectopexy.

Van der Hagen et al. performed a laparoscopic VMR in combination with a defect-specific posterior repair (van der Hagen et al. 2012). They postulated that a posterior colporrhaphy without a mesh rectopexy would result in more rectocele recurrences. They included only patients with large rectoceles, defined as ≥ 4 cm on dynamic MRI. Patients with enteroceles and rectal intussusception were excluded. Their prospective series consisted of 27 women with a median follow-up time of 12 months. The median hospital stay was 3 days and the median operation time 56 minutes. There was a significant improvement in ODS and FI QOL scores ($p < 0.0001$). Urinary symptoms improved in 25.9% of women and there was no voiding dysfunction post-operatively. Sexual function however deteriorated in 22.2% and new onset dyspareunia was observed in 3.7%.

A laparoscopic posterior fascial repair for patients with rectocele in association with anterior and apical prolapse was described by Thornton et al. (Thornton et al. 2005). The pre-operative workup consisted multichannel urodynamics, videocystometry, anorectal manometry, pudendal nerve latency testing and rectal sensitivity testing.

They dissected the pararectal spaces and entered the rectovaginal space. Here they performed a midline fascial plication and additionally plicated the uterosacral ligaments to the vaginal apex. This essentially resulted in a form of rectopexy combined with a sacrocolpopexy. They reported outcomes in 40 women after a median follow-up of 20 months. A concomitant posterior colporrhaphy was performed in 40% and perineal repair in 32.5%. Pre-operative symptoms consisted of a vaginal bulge in 78%, urinary dysfunction in 80% and bowel dysfunction, including ODS, in 100%. The median age was 65 years and 38% had previous prolapse surgery. Functional improvement was most pronounced for bulge and urinary symptoms, but least for bowel symptoms. They found that rectocele size was not associated with a poorer outcome. The mean time to deterioration in symptoms was 11 months, after which all categories deteriorated. De novo dyspareunia occurred in 35%, but could not be associated with any pre- or intra-operative factors. The authors additionally compared this cohort with a matched cohort of 40 women who underwent a transanal repair of a rectocele (M J Thornton et al. 2005). At 44 months median follow-up, the transanal approach resulted in significantly more patients reporting bowel symptom alleviation ($P < 0.002$) and higher patient satisfaction ($P < 0.003$). The bowel symptom improvement was also sustained over a significantly longer period ($P < 0.03$). Factors associated with superior outcome were a larger rectocele and ODS, but not FI. Postoperative dyspareunia was however reported by 24 patients in total (30 percent), with significantly more in the transanal group ($P > 0.05$).

This section summarised a large number of trials with the purpose to illustrate the feasibility of a combined approach, but furthermore to highlight the varying clinical outcomes reported across these publications.

7.5 SUMMARY

Sacrocolpopexy and rectopexy can separately and in combination improve the clinical outcomes in women with a rectocele. This combined modality would however generally be limited to those with evidence of generalised and more severe pelvic floor disorders. This can be said due to the potential for associated morbidity and the extent of anatomical correction that is facilitated with this approach. The main correctional benefit with the suspensory approach is in the effect on the levator plate. Levator plate descent is more prevalent in women with levator avulsion injuries, levator muscle dysfunction and is clinically evident through a larger genital hiatus and perineal descent, or sonographically through ballooning of the levator hiatus. The risk for surgical failure is increased in these women, even in the presence of extensive suspensory pelvic floor reconstructive procedures.

The extension of posterior mesh to the level of the perineal body can still result in rectocele persistence or recurrence in 33 – 57% of women. This is a likely reflection of the associated rectal defect that is present in rectoceles and which require a surgical procedure directed to correcting the anterior rectal wall. The incorporation of a rectopexy resulted in lower rectocele recurrence rates, but often did not correct isolated rectoceles. It is likely of more benefit in those patients with associated rectal intussusception or rectal mucosal prolapse.

7.6 PREPARED ARTICLE: RECTOPEXY AT THE TIME OF A SACROCOLPOPEXY (ADDENDUM 15)

Rectopexy at the time of a sacrocolpopexy: Results from a randomized controlled trial

ABSTRACT

BACKGROUND: Sacrocolpopexy is the gold standard procedure for women with advanced pelvic organ prolapse (POP) that invariably includes descent of the apical compartment. The addition of a rectopexy can additionally eliminate a deep cul-de-sac and is associated with improved defecatory outcomes, especially in women with associated symptomatic rectoceles or rectal intussusception. Uncertainty exists whether the combination of these procedures provide a superior clinical result.

METHODS: This was a randomized controlled trial performed in an Urogynecology referral center in women with advanced multi-compartment POP scheduled for a sacrocolpopexy. Participants were randomly assigned to undergo either a sacrocolpopexy alone or combined with a rectopexy. An interim analysis was planned after approximately 50 participants. The primary objective was anatomic and functional outcome after 12 months. These were respectively evaluated by means of the pelvic organ prolapse quantification (POP-Q) system and validated condition-specific quality of life (QOL) questionnaires.

RESULTS: Between June 2011 and June 2014, 69 women were randomized (36 to the rectopexy and 33 to the sacrocolpopexy groups). Rectopexy did not provide any significant benefits to that of sacrocolpopexy alone in this population. Anatomic success rates at 12 months were 87.9% for rectopexy and 93.5% for sacrocolpopexy (p-value 0.6729). The QOL scores improved significantly in both groups, but the colorectal-anal distress inventory

(CRADI-8) score of the pelvic floor distress inventory (PFDI-20) showed significantly better improvement in the sacrocolpopexy participants (24.52%) than in those randomized to rectopexy (49.21%) (P-value ≤ 0.0500).

CONCLUSION: There was no apparent benefit of routinely adding a rectopexy to a sacrocolpopexy for women presenting with advanced multi-compartment pelvic organ prolapse.

Keywords Sacrocolpopexy, rectopexy, colpoperineopexy, mesh, obstructed defecation, randomized

INTRODUCTION

Sacrocolpopexy is currently regarded to provide the optimal surgical outcome for women with multi-compartment and advanced pelvic organ prolapse (POP) (1)(2) . The term sacrocolpopexy as used in the published literature does however not reflect an exact technique. Variation exists in regards to the type of abdominal access (open or endoscopic), the type of mesh used and the extent of distal mesh placement in both the anterior and posterior vaginal aspects. A comprehensive form of abdomino-vaginal sacrocolpopexy, where the anterior mesh is inserted to the distal urethra and the posterior mesh is inserted to the perineum, has been reported with a short term success rate of 92% (3). It is based on the principles of a total pelvic floor repair as described by Sullivan (4). Some publications have confirmed that the further distal the mesh is inserted during sacrocolpopexy, the better the associated clinical outcomes are (5)(6)(7)(8).

A rectopexy is less commonly performed at the time of a sacrocolpopexy (9). The potential benefits of the rectopexy is that it is associated with improved bowel function, it eliminates a deep culdocele, decreases enterocele and rectocele recurrences and further lessens the

burden on the levator plate in conjunction with a sacrocolpopexy, thereby improving clinical results (10)(6)(11)(12)(13)(14). Obstructed defecation (OD) is a specific element of bowel dysfunction which is very bothersome, often co-exist with pelvic floor disorders, and which might be successfully addressed with a rectopexy (15)(16)(17)(18) The three types of rectopexy largely utilised are mesh, suture, and resection rectopexy. The outcomes described for rectopexies differ in both nature and success rates, but it is clear that autonomic nerve preservation is an essential element related to superior functional outcomes (19)(20)(21)(22)(23). The ventral mesh rectopexy (VMR) procedure, particularly for patients with rectal intussusception and rectoceles, has become popular due to complications encountered with endorectal techniques and as a result of the advancement of laparoscopic procedures (24)(25)(26)(27)(28).

Sacrocolpopexy combined with rectopexy for combined recto-genital prolapse has been described with the aim to provide improved functional outcomes across all pelvic floor domains (26)(22)(29)(30)(31)(32). The majority of studies were however retrospective, consisted of a hybrid version of a sacrocolpopexy and reported mixed clinical results. This limits the ability to identify criteria for patients who would benefit from this type of procedure and to determine the true value of this combined procedure (33).

The objective of this randomized investigation was therefore to evaluate the anatomic and functional outcomes after an abdomino-vaginal sacrocolpopexy with or without a VMR in women with advanced POP.

Methods:

This study was performed in the Urogynecology unit at Universitas Academic Hospital, a tertiary referral and teaching hospital in Bloemfontein, South Africa. Ethics committee approval was obtained prior to recruitment (ECUFS 09/2011) and the trial was registered at the South African National Clinical Trials Registry (NHREC 2516). From June 2011 until June 2014,

women older than 18 years who presented with International Continence Society (ICS) pelvic organ prolapse quantification (POP-Q) stage ≥ 2 multi-compartment POP and who, after assessment by the attending clinician qualified for a sacrocolpopexy, were invited to participate. Exclusion criteria were women without a hysterectomy, those who had previous POP surgery with mesh and ethnic black women. The exclusion of ethnic black women was to limit heterogeneity. We have observed epidemiological differences for pelvic floor disorders in regards to ethnicity in this population. Similar observations have been documented in other populations and countries (34)(35)(36)(37). At baseline, each subject underwent a standardized history, a gynecologic examination in the supine position using the ICS POP-Q classification (38), a two-dimensional (2D) transperineal ultrasound (TPUS) (39), and a sacral neurologic examination. A similar clinical evaluation was performed at 3, 6 and 12 months after surgery. Terminology and definitions used were in accordance with the most recent International Urogynecology Association (IUGA) / International Continence Society (ICS) classification (40). OD was defined as excessive straining with the use of manual manoeuvres to defecate. Each subject completed 3 validated condition-specific quality of life (QOL) questionnaires, the pelvic floor impact questionnaire (PFIQ-7), the PFDI-20 and the pelvic organ prolapse/incontinence sexual questionnaire (PISQ-12) at baseline and at 3, 6, and 12 months after surgery (41)(42).

Participants were randomly assigned to a sacrocolpopexy with or without a rectopexy according to a randomization list provided by the Department of Biostatistics, University of the Free State. Group assignments were concealed in consecutively numbered, sealed envelopes which were opened at the initiation of surgery by the theatre sister and contained either a rectopexy or sacrocolpopexy label. Patients remained blinded to the procedure as did staff subsequently involved in the post-operative assessments. The follow-up clinical examinations were therefore not performed by the operating surgeon and a single clinician performed all 2D TPUS examinations.

The surgical technique as described by Cronje et al (3) for the abdomino-vaginal sacrocolpopexy was followed albeit with some modification in specifically the anterior compartment. The abdominal incision and posterior dissection were performed as described by Cronje et al. A concomitant rectocele and/or perineal repair was performed as was deemed necessary by the surgeon before vagino-abdominal insertion of a rectangular length of a type I polypropylene mesh (Ultrapro©, Johnson & Johnson, South Africa) along the posterior compartment. The vesicovaginal space was dissected via the abdominal access to the level of the bladder neck. An anterior full thickness vaginal incision was subsequently made via a vaginal approach and the vesicovaginal space was dissected to meet with that of the abdominal dissection. A second rectangular length of mesh was inserted via the vaginal incision into the abdomen along the anterior compartment. It was anchored either side of the distal urethra with a 2/0 nylon suture. Vaginal wall trimming occurred in neither the anterior nor posterior compartments. The anterior and posterior lengths of mesh were attached to the vault with 0 polydiaxonone sutures and to the level of S1 with a 1/0 nylon suture. The VMR was performed according to the Orr-Loygue technique (43) with the specific aim to avoid injury to the hypogastric nerve supply to the rectum. The rectal wall was attached to the mesh with a running 2/0 polypropylene suture. The posterior peritoneum was closed with a running 2/0 polydiaxonone suture to cover the mesh and an acriflavine impregnated vaginal pack was inserted and removed after 48 hours. The surgical procedure was performed by skilled operators, each having performed more than 50 such procedures, following this standardised approach.

The sample size was calculated based on previous publications (3)(Cronjé & de Beer 2008). With an expected improvement of OD due to rectopexy from 40 to 15%, compared to 40 to 30% without rectopexy, the sample size was calculated to be 134 cases per group (Type 1 error rate of 5% and statistical power of 80%). For recurrent posterior compartment prolapse, a similar improvement was expected. An interim analysis was planned after an overall

recruitment of at least 50 cases with a minimum follow-up of 12 months. This manuscript reports on this interim analysis.

The clinical data for this study were summarized descriptively by randomized group. The statistical analysis was performed using SAS® Version 9.4. Inferential statistics were based on the Kruskal-Wallis test for quantitative data and the Freeman-Halton test for qualitative data. The primary outcomes were the POP-Q findings, the reported symptomatic results and the PFIQ-7, PFDI-20 and PISQ-12 scores at 3, 6 and 12 months after surgery. The secondary outcomes reported on were further interventions, peri-operative parameters and mesh related complications.

Results:

Seventy-two women were eligible for participation (Figure 1). Three declined enrolment and sixty-nine women were enrolled and randomised to undergo either a rectopexy with a sacrocolpopexy (n=36) or a sacrocolpopexy alone (n=33). The percentage of participants who followed up at 3, 6 and 12 months were 100%, 91.7%, and 91.7% in the rectopexy group and 100%, 93.4% and 93.4% in the sacrocolpopexy group. The overall loss to follow-up was 7.2%. There were no protocol violations. The baseline characteristics are summarised in Table 1. Approximately half of the participants in either group had previous pelvic floor surgery.

Figure 1: Flow diagram of study participants and randomization

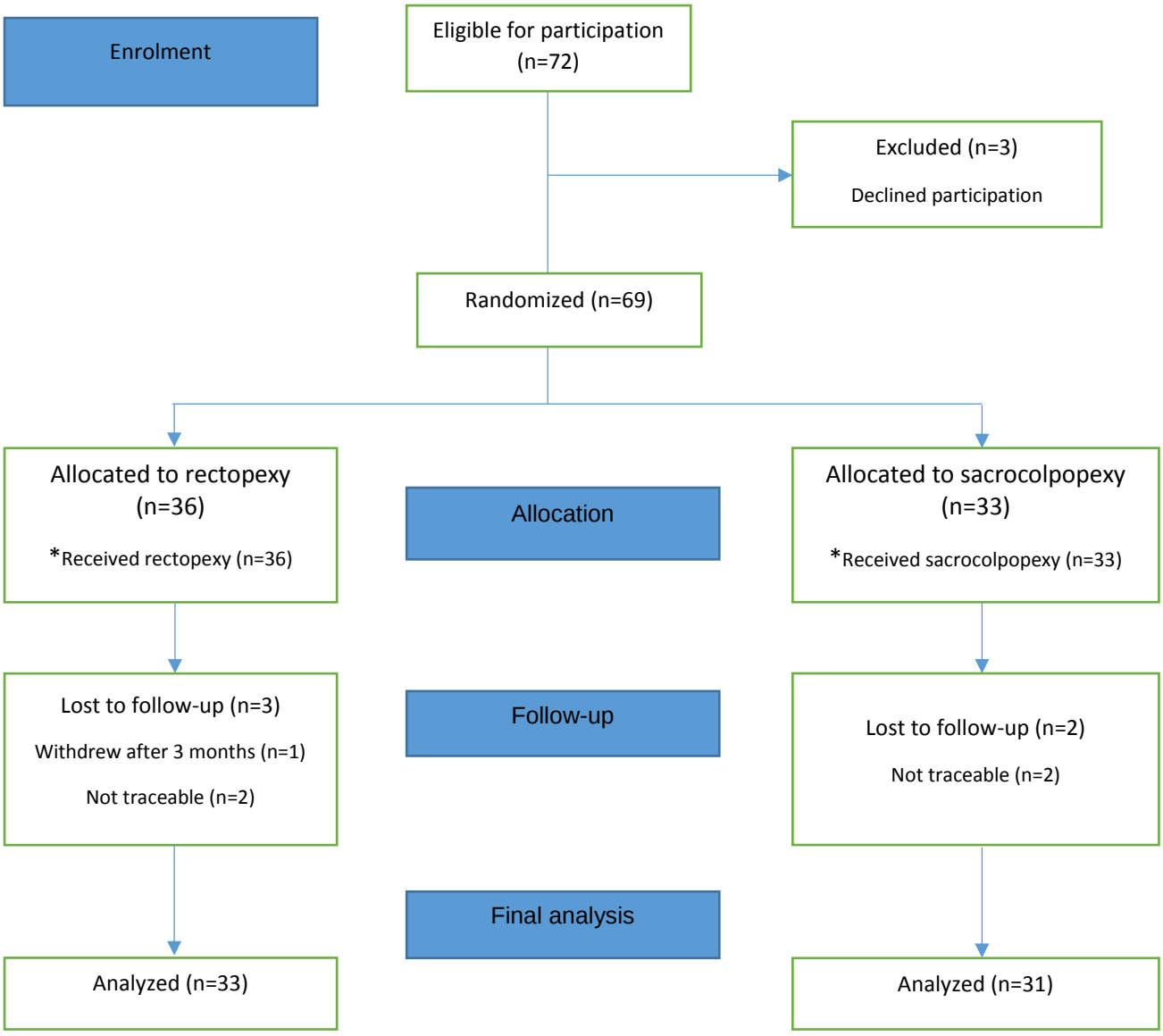

Table 1: Baseline participant characteristics

Metric	**Rectopexy (N=36)**	**Sacrocolpopexy (N=33)**	**p-value***
Age[a]	57.8 ± 7.8	59.5 ± 8.7	0.5160
Parity[b]	3 (0-5)	3 (0-8)	0.2424

BMI[a]	27 ± 2.9	27.8 ± 4.2	0.6785
Race - Caucasian[c]	29 (80.6)	25 (75.8)	0.2409
Previous POP/UI surgery[c]	17 (47.3)	18 (54.5)	0.6324
Menopausal[c]	28 (77.8)	29 (87.9)	0.3478
HRT[c]	9 (25.0)	7 (21.2)	0.7804
Smoker[c]	8 (22.2)	4 (12.1)	0.3478
Diabetes[c]	4 (11.1)	5 (15.2)	0.7278

BMI: Body mass index. POP: Pelvic organ prolapse. UI: Urinary incontinence. HRT: Hormone replacement therapy. [a] Mean (standard deviation). [b] Median (range). [c] Number and percentage. * P-Value ≤ 0.05.

The participants' symptoms at baseline were comparable (Table 2). The only significant difference noted with follow-up was less dyspareunia at 6 and 12 months (p-value ≤ 0.0500) in the sacrocolpopexy group. New onset dyspareunia was seen in only 2 (6.1%) participants (rectopexy group).

Table 2: Pre- and post-operative syymptoms

Symptom	**Rectopexy (N=36)**	**Sacrocolpopexy (N=33)**	**p-value***
Vaginal bulge			
Pre-op	35 (97.2)	28 (84.8)	0.0968
3 months	3 (8.3)	2 (6.1)	1.0000
6 months	2 (5.6)	2 (6.1)	1.0000
12 months	3 (8.3)	4 (12.1)	0.7039
Dyspareunia			
Pre-op	13 (36.1)	7 (21.2)	0.3714
3 months	8 (22.2)	5 (15.2)	0.7733

6 months	6 (16.7)	0 (0.0)	**0.0486***
12 months	6 (16.7)	0 (0.0)	**0.0486***
Overactive bladder (dry)			
Pre-op	18 (50.0)	10 (30.3)	0.1409
3 months	17 (47.2)	8 (24.2)	0.0784
6 months	13 (36.1)	5 (15.2)	0.0528
12 months	11 (30.6)	5 (15.2)	0.1519
Urge urinary incontinence			
Pre-op	12 (33.3)	8 (24.2)	0.4386
3 months	7 (19.4)	4 (12.1)	0.5176
6 months	3 (8.3)	4 (12.1)	0.7039
12 months	7 (19.4)	3 (9.1)	0.3048
Stress incontinence			
Pre-op	17 (47.2)	13 (39.4)	0.6282
3 months	5 (13.9)	4 (12.1)	1.0000
6 months	5 (13.9)	4 (12.1)	1.0000
12 months	2 (5.6)	3 (9.1)	0.6673
Obstructed voiding			
Pre-op	20 (55.6)	16 (45.5)	0.6330
3 months	4 (11.1)	1 (3.0)	0.3587
6 months	3 (8.3)	3 (9.1)	1.0000
12 months	3 (8.3)	2 (6.1)	1.0000

Constipation			
Pre-op	27 (75.0)	21 (63.6)	0.4326
3 months	11 (30.6)	10 (30.3)	1.0000
6 months	18 (50.0)	12 (36.4)	0.2224
12 months	21 (58.3)	12 (36.4)	0.0790
Obstructed defecation			
Pre-op	18 (50.0)	14 (42.4)	0.6308
3 months	4 (11.1)	2 (6.1)	0.6750
6 months	6 (16.7)	4 (12.1)	0.7338
12 months	8 (22.2)	5 (15.2)	0.5389
Anal incontinence			
Pre-op	14 (38.9)	9 (27.3)	0.4436
3 months	7 (19.4)	6 (18.2)	1.0000
6 months	8 (22.2)	7 (21.2)	1.0000
12 months	9 (25.0)	7 (21.1)	0.7804
Lower back pain			
Pre-op	15 (41.7)	13 (39.4)	1.0000
3 months	10 (27.8)	5 (15.2)	0.2510
6 months	9 (25.0)	3 (9.1)	0.1093
12 months	11 (30.6)	5 (15.2)	0.1519

Number of subjects and percentage. * P-Value ≤ 0.05.

The ICS POP-Q staging and TPUS evaluations at baseline confirmed a mean multi-compartment stage 2 prolapse in both groups (Table 3 and Table 4). There was significant overall anatomic improvement in both groups. The only significant differences after 12 months

between the groups, were a superior ICS POP-Q point Ap measurement in the sacrocolpopexy group (-1.88 vs -2.26, p-value ≤ 0.0500) and a higher prevalence of enteroceles as seen with TPUS in the sacrocolpopexy group (12.1 vs 0.0%, p-value ≤ 0.0500).

Table 3: Pre- and post-operative POP-Q measurements

POP-Q measure	**Rectopexy (N=36)**	**Sacrocolpopexy (N=33)**	**p-value***
Aa			
Pre-op	-0.47 (1.53)	-0.20 (1.30)	0.2333
3 months	-1.97 (0.51)	-1.92 (0.78)	0.9579
6 months	-1.80 (0.45)	-1.90 (0.65)	0.1973
12 months	-1.67 (0.77)	-1.82 (0.68)	0.4938
Ba			
Pre-op	-0.19 (1.83)	0.32 (1.56)	0.2021
3 months	-2.15 (0.44)	-2.03 (0.73)	0.6065
6 months	-2.06 (0.46)	-2.02 (0.57)	0.9587
12 months	-1.70 (0.91)	-1.95 (0.61)	0.2308
Ap			
Pre-op	0.46 (1.75)	0.65 (1.56)	0.6834
3 months	-2.51 (0.49)	-2.15 (1.18)	0.2012
6 months	-2.20 (0.54)	-2.29 (0.78)	0.2742
12 months	-1.88 (0.76)	-2.26 (0.63)	**0.0416***
Bp			
Pre-op	0.39 (1.69)	0.56 (1.59)	0.6393
3 months	-2.57 (0.48)	-2.35 (0.73)	0.1811

6 months	-2.23 (0.55)	-2.31 (0.78)	0.3232
12 months	-2.02 (0.83)	-2.27 (0.60)	0.2254
C			
Pre-op	-0.82 (3.69)	-1.27 (3.60)	0.5423
3 months	-8.18 (1.16)	-8.11 (1.24)	0.8873
6 months	-8.12 (0.84)	-7.9 (1.07)	0.4015
12 months	-8.00 (0.94)	-7.66 (1.20)	0.3286
TVL			
Pre-op	9.25 (1.14)	8.65 (3.47)	0.8748
3 months	9.67 (1.06)	9.70 (1.14)	0.8509
6 months	9.56 (0.97)	9.10 (3.23)	0.8493
12 months	9.38 (1.08)	9.10 (3.30)	0.4709
GH			
Pre-op	4.72 (1.33)	4.32 (1.20)	0.2863
3 months	3.81 (0.98)	3.71 (0.79)	0.6527
6 months	3.59 (0.76)	3.65 (0.73)	0.9225
12 months	3.64 (0.83)	3.15 (2.17)	0.2580
PB			
Pre-op	2.68 (0.96)	3.02 (0.78)	0.0889
3 months	3.04 (0.51)	3.00 (0.57)	0.8384
6 months	2.94 (0.56)	2.89 (0.53)	0.6750
12 months	2.91 (0.51)	2.95 (0.51)	0.5546

Number of subjects and percentage. * P-Value ≤ 0.05.

Table 4: TPUS measurements at Valsalva (mm)

TPUS	**Rectopexy**	**Sacrocolpopexy**	**p-value***
	(N=36)	**(N=33)**	
Anterior[a]			
Pre-op	2.86 (15.57)	5.00 (13.21)	0.5926
3 months	-18.19 (6.31)	-16.49 (7.38)	0.5004
6 months	-16.64 (6.43)	-16.68 (8.18)	0.6813
12 months	-14.94 (7.59)	-16.23 (8.16)	0.3461
Rectocele[a]			
Pre-op	18.94 (8.97)	18.21 (7.10)	0.5883
3 months	8.53 (4.32)	9.00 (5.13)	0.8850
6 months	8.94 (4.43)	9.74 (6.26)	0.9302
12 months	10.21 (5.10)	8.74 (5.29)	0.1611
Intussusception[b]			
Pre-op	8 (22.2)	6 (18.2)	0.7693
3 months	1 (2.8)	3 (9.1)	0.3427
6 months	2 (5.6)	5 (15.2)	0.2499
12 months	3 (8.3)	5 (15.2)	0.4681
Enterocele[b]			
Pre-op	21 (58.3)	13 (39.4)	0.1503
3 months	1 (2.8)	1 (3.0)	1.0000
6 months	0 (0.0)	3 (9.1)	0.1079
12 months	0 (0.0)	4 (12.1)	**0.0495***

[a] Mean (standard deviation). [b] Number of participants and percentage (presence). * P-Value ≤ 0.05.

There was an overall significant improvement in the QOL questionnaires across all domains after surgery (Table 5). This was comparable for both groups, except for a lower (better) PFDI-20 score at 12 months in the sacrocolpopexy group (p-value ≤ 0.0500). This may be due to the significantly lower CRADI-8 score in the sacrocolpopexy group (p-value ≤ 0.0500). We could not detect any significant difference between the two groups for OD, either as a symptom identified during clinical history or as measured by the POPDI-6 and CRADI-8 scales of the PFDI-20 questionnaire.

Table 5: Quality of life questionnaire scores

Questionnaire	**Rectopexy (N=36)**	**Sacrocolpopexy (N=33)**	**p-value***
PFIQ			
Pre-op	173.17 (71.78)	159.94 (76.80)	0.5088
3 months	32.97 (34.68)	21.55 (32.45)	0.0712
6 months	35.21 (39.48)	24.71 (35.89)	0.1934
12 months	29.46 (42.35)	15.29 (23.92)	0.2440
PFDI			
Pre-op	180.58 (53.68)	172.12 (58.06)	0.6137
3 months	37.56 (32.78)	29.21 (38.90)	0.1124
6 months	39.45 (36.18)	30.65 (41.58)	0.1256
12 months	38.97 (49.21)	19.65 (24.52)	**0.0425***
PISQ			
Pre-op	23.73 (9.54)	25.75 (6.85)	0.6094
3 months	30.25 (7.04)	30.10 (7.13)	0.7585
6 months	31.08 (6.38)	33.72 (5.56)	0.3835
12 months	31.58 (6.88)	34.94 (6.52)	0.2878

PFDI and PFIQ mean score/300 (standard deviation). PISQ mean score/48 (standard deviation). * p-Value ≤ 0.05.

The difference in the median procedure time of 122.5 (76-170) minutes in the rectopexy group compared to 108 (67-130) minutes for sacrocolpopexy was statistically significant (p-value 0.0004). Additional procedures in the rectopexy and sacrocolpopexy groups respectively consisted of a rectocele (63.9% vs 57.6%, p-value 0.6288) and a perineal body repair (72.2% vs 48.5%, p-value 0.0521). The median blood loss in the rectopexy and sacrocolpopexy groups was respectively 180 (65-500) and 170 (80-350) millilitre (p-value 0.5161). Peri-operative complications with rectopexy and sacrocolpopexy in turn occurred in 15 (41.1%) and 8 (24.2%) participants (p-value 0.2008). These were all Dindo grades 1-2, except for one Dindo grade 3 case in each group. The leading complication was an increased operative blood loss. We defined a blood loss of > 250 ml as an operative complication. This occurred in 12 rectopexy participants (mean 337 ml) and in 3 sacrocolpopexy participants (mean 317 ml) (p 0.0196). The other complications in the rectopexy compared to the sacrocolpopexy group were ileus (1 vs 3), urinary tract infection (3 vs 2) and a single case of sheath dehiscence, which required surgical intervention, in the sacrocolpopexy group. The median hospital stay was 4 days for both groups.

Anatomic success, defined as a POP-Q value of ≤ -1 cm in any compartment, was confirmed in 29 (87.9%) for rectopexy and 29 (93.5%) for sacrocolpopexy at 12 months' follow-up (p-value 0.6729). There were 6 (16.7%) mesh related complications seen with the addition of a rectopexy and 3 (9.1%) for sacrocolpopexy alone (p-value 0.4764). The mean interval for these complications to present was 8 months for rectopexy and 2.5 months for sacrocolpopexy. Surgical excision was required in 3 participants in the rectopexy group (CTS classification: 1BT3S2, 2BT3S1, 2BT3S2) compared to 1 in the sacrocolpopexy group (CTS classification: 1BT3S2) (p-value 1.0000)(45). All symptoms were resolved after treatment. A repeat prolapse procedure was performed in 3 participants in each group at a mean interval

of 12 months after rectopexy and 9.7 months after sacrocolpopexy (p-value 0.1840). Four (11.1%) participants from the rectopexy group and 3 (9.1%) from the sacrocolpopexy group received a mid-urethral sling in the 12 months after the index procedure (p-value 1.0000).

The overall mean follow-up period to date is 39 months for rectopexy (n=33) and 37 months for sacrocolpopexy (n=31) (p-value 0.2109). Anatomic success at the last visit was present in 23 (69.7%) and 25 (70.9%) respectively (p-value 0.3919) and symptomatic outcomes likewise revealed no significant difference between the two groups. The anatomic failures occurred predominantly in the anterior compartment.

Discussion

In this randomized trial, the addition of a rectopexy at the time of a sacrocolpopexy did not result in an improved objective or subjective outcome after 12 months. The abdomino-vaginal sacrocolpopexy was modelled on the principle of a total pelvic mesh repair as describe by Sullivan (4). In his series, additional surgery was required in the anterior compartment in 36% and in the posterior compartment in 28% of cases. The posterior recurrences were rectoceles, which occurred despite the extension of the posterior mesh to the perineal body. The ability of a sacrocolpopexy to correct the posterior vaginal bulge, but not necessarily the rectal defect has been described with rectocele recurrences seen with imaging in up to 57% of cases after a sacrocolpopexy after not having been diagnosed clinically (46). A rectopexy was added to a sacrocolpopexy to limit the locally observed posterior compartment recurrence rate, which was approximating that described by Sullivan. Recent reports have confirmed that superior anatomic outcomes are associated with extending the distal insertion of mesh during sacrocolpopexy (8). The anatomic success at 1 year was 87.9% and 93.5% for rectopexy and sacrocolpopexy respectively and at approximately 3 years it was 69.7% and 70.9% in this study. The short term success was similar to the 92% reported by Cronje et al. using this technique for sacrocolpopexy (3). Intermediate term anatomic recurrences in any

compartment after a sacrocolpopexy have been reported in 16.2-61.8% in recent literature and it confirmed the observation made in this population that the anterior compartment was more prone to suffer recurrence over time(8)(5)(47).

Previous reports created the expectation of a significant improvement in OD with the addition of a rectopexy to the sacrocolpopexy. This was not confirmed in this prospective evaluation and a possible reason might be the high number of concomitant posterior repairs performed in both groups. The literature is conflicting in terms of bowel symptoms after a sacrocolpopexy with or without a rectopexy. Certain authors have documented improvements of up to 88% (48)(46)(22)(30)(49) whilst others did not find any significant improvement (47)(50)(25)(29). Nerve sparing techniques during a rectopexy is however an essential element to avoid worsening bowel function (23)(22). Sexual function improved in both groups, but the rectopexy participants mentioned significantly more dyspareunia as a symptom than the sacrocolpopexy participants after 1 year. This difference was however not reflected in the PISQ-12 scores. It is not apparent what the reason for this might be as there is a deficiency in the reporting on sexual function after sacrocolpopexy or rectopexy in the existing literature (1). Maher et al. in a randomised trial showed a similar outcome to ours for sexual function after a sacrocolpopexy, whereas Abet et al. in contrast to our findings reported an improvement in sexual function after rectopexy (26)(47). Mesh-related complications occurred in 9.1% of sacrocolpopexy and in 16.7% of rectopexy participants. The abdominal-vaginal placement of mesh carries the potential for increased complications compared to the traditional mesh placement for sacrocolpopexy. Older research noted mesh erosions in 40% of cases where this technique was followed (51). Research on mesh properties and surgical techniques when mesh is used have however developed significantly in the last decade. More recent publications reported vaginal mesh erosion rates of 6.7-8% in abdominal-vaginal procedures (52)(53). Vaginal mesh erosion occurs in sacrocolpopexy in 0-12% of cases (54)(1)(55). This is in contrast to a recent Cochrane review which reported mesh erosion rates of 18% with the

use of vaginal mesh, of which 9% required a surgical intervention (1). The mesh complications seen in our population were thus in line with that reported for abdominal sacrocolpopexy.

This study has some limitations. It was an interim analysis and was therefore not adequately powered. It is however unlikely that the required sample size would have been achieved due to the length of recruitment time and based on the similarity in results between the procedures in this analysis. The surgical technique required were moreover technically demanding and it is likely that the outcomes will differ in other settings. Secondary analyses were not possible due to the diminishing numbers in these calculations and we could therefore not determine the factors which might warrant the addition of a rectopexy to a sacrocolpopexy. The strength of the study lies in the limitation of surgeons to only two, the blinding of the post-operative assessors as well as the patients to the randomisation and the structured longitudinal analysis of the participants using validated instruments.

Conclusion

This is the first report of a randomized controlled trial evaluating the possible benefits of a concomitant rectopexy at the time of an abdominal sacrocolpopexy. The specific surgical technique described was a comprehensive pelvic floor repair and was selected in women with advanced multi-compartment POP. At 1 year follow-up, there was no significant benefit with the addition of a rectopexy, and specifically none in regards to the relief from OD. The potential contribution and clinical indications for a rectopexy at the time of a sacrocolpopexy remains poorly defined and requires further evaluation in a significantly larger population.

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CHAPTER 8

RECTOCELE PLICATION FOR THE REPAIR OF A RECTOCELE

8.1 INTRODUCTION

This chapter will follow a narrative approach for the description of a novel transvaginal procedure for the surgical repair of a rectocele. This method was chosen to allow for the conveyance of personal experience in the procedure that is to be chronicled. It was stated in a recent article that scholars have two responsibilities, answering questions and telling the story (Pollock & Bono 2013). Often the emphasis is on the former with the importance of storytelling becoming lost in academic literature. Reflective writing is not a new concept in the health sciences, and along with the close reading of literary publications, has carved out a well-deserved place in medical training for nurturing professional growth and providing a therapeutic platform for clinician well-being (Baruch 2013). It is allowed to proceed without much of the limitations of formal academic writing, thus allowing for a communication mirrored closely to those of personal interactions with the writer. Narrative writing's contribution is not limited to the transfer of knowledge alone, but also to that of knowledge transformation and creation (Hirvela & Du 2013).

The literature in regards to the surgical options utilized for rectocele repairs have been summarized in Chapter 6. The pertinent details can be stated as the following: Surgery is often the mainstay of definitive treatment of symptomatic rectoceles. There is, however, little evidence to suggest which is the most effective technique, or whether any specific technique is more appropriate than others in certain circumstances (Abbas et al. 2005). It is acknowledged that coloproctologists and gynaecologists have

differing approaches to a rectocele. The coloproctologist will focus predominantly on the impaired bowel emptying and the gynecologist predominantly on the vaginal bulge (MA Kahn 1998). It is imperative to integrate these outcomes and correct both the bulge and the defecatory complaints. The Cochrane review on surgery for POP found vaginal fascial repairs to be superior to transanal repairs, but the limitations of this conclusion were acknowledged (Maher et al. 2013). The rectocele plication procedure corrects the defective anterior rectal wall encountered in women with symptomatic rectoceles, but does so through a vaginal approach.

8.2 SURGICAL PHILOSOPHY AND TECHNIQUE

A rectocele is seen as a bulge in the posterior vaginal wall as a result of the protrusion of the anterior rectal wall. What resulted in this protrusion is a matter of controversy, for the different proponents of pathogeneses theories share diverging points of view. The surgical procedures employed to correct a rectocele are reflective of these theories. The currently recognized transvaginal procedures are the midline fascial plication and the defect-specific fascial repair. Both are based on the assumption that the observed bulge in the posterior vaginal wall is a result of a defective rectovaginal septum or fascia. These defects are thought to occur either as a result of childbearing with consequent laceration(s) or gradual attenuation of this layer due to a combination of factors, such as childbearing, neuropathy, chronic straining and genetic predisposition. The attention of repair for the defect-specific procedure is on identifying these discrete defects by means of a careful surgical dissection and individually repairing each defect. The midline plication varies slightly from the defect-specific approach in that it assumes that this layer is defective and thus employs an

encompassing correction of it, rather than attempting to identify specific areas of deficiency. Both approaches are anatomically questionable if one doubts the existence of a rectovaginal fascia. Recent publications suggest that this is absent proximal to the perineal membrane and that the layer being repaired is thus likely the split fibromuscularis layer of the posterior vaginal wall.

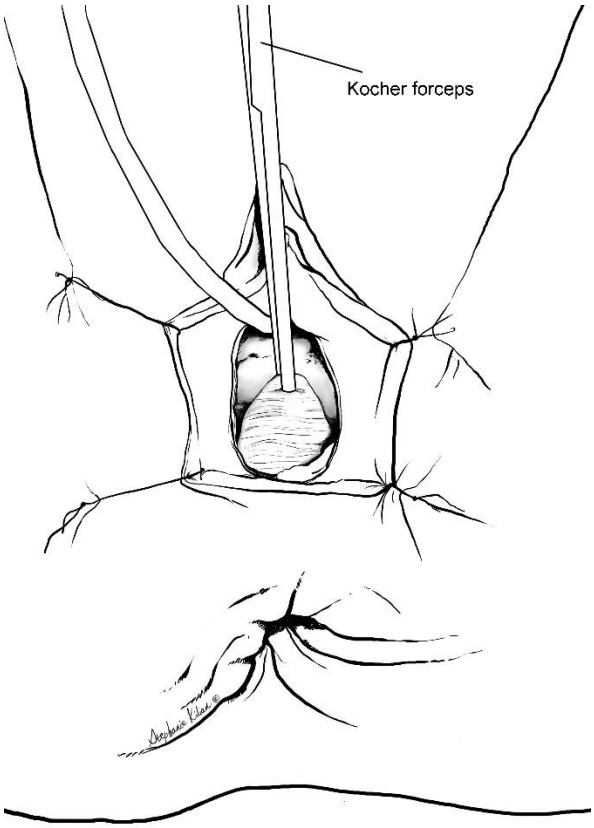
The transanal procedures on the other hand recognizes the abnormal rectal wall and is not that concerned with correcting the vaginal bulge. It is mostly utilized by the colorectal surgeons and the focus is mostly on improving an associated defecatory disorder. The reported outcomes vary, as can be expected when surgical outcomes with inherent subtle variation are reported, but both approaches result in similar anatomic outcomes. The transanal procedures do however tend to result in superior defecatory outcomes, but side effects include that of sexual dysfunction.

It is from this background that a rectocele plication evolved in our urogynecology unit. This is a vaginal approach, but the focus of correction is the anterior rectal wall and not the rectovaginal fascia. It can therefore be said that it is a philosophical union of the gynecologic and colorectal approaches.

The procedure starts with the patient receiving a single prophylactic dose of intravenous antibiotic, which was mostly 2g of Cefazolin, prior to anesthesia. Anesthesia could be either general or regional, depending on the individual patient profile and the assessment of the anesthetist. She is then positioned with her legs in lithotomy poles, buttocks on the edge of the operating table and hips flexed to approximately 70^0. After cleaning and draping of the patient, a transurethral catheter is inserted and left in-situ for the remainder of the procedure to allow free drainage of urine. The catheter is required due to the use of a vaginal pack at the end of the

procedure and if this was not done, the patient would not be able to void adequately after surgery. An examination of the vaginal compartments are then performed to assess the anatomy and confirm the planned surgical approach prior to the first incision. Four 2/0 black silk sutures are inserted into the labia minora to provide retraction. These are loosely tied so that there is no resulting labial ischaemia with a risk of subsequent necrosis. An alternate option would be to use a retractor system, but the suture approach has been deemed optimal in our setting. A Kocher's forceps is applied in the midline posterior vaginal wall and elevates it (Figure 3).

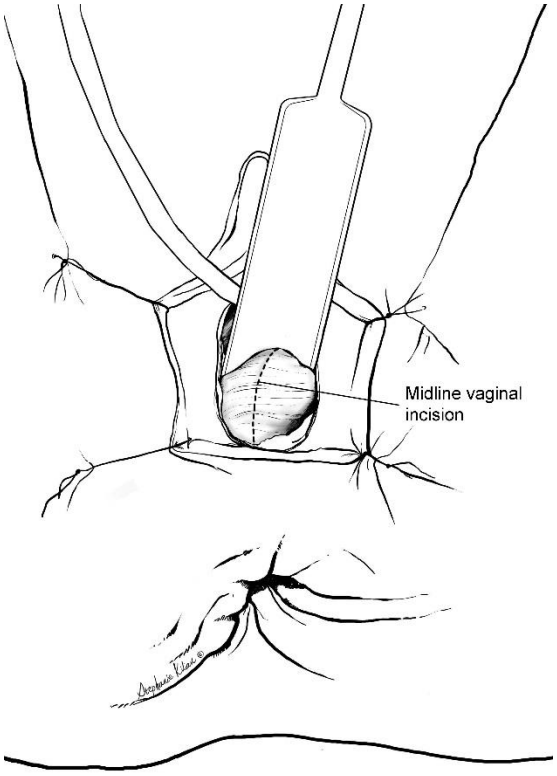
Figure 3: Illustration of prepared surgical field prior to incision.



A solution consisting of a vasoconstrictor and saline is injected under the posterior vaginal wall and the surgeon's goal is not to split the vagina, but to insert this solution into the avascular rectovaginal plane. The quantity of fluid that is used varies depending on the individual requirements in regard to the surface area of the defect.

A midline posterior, full thickness vaginal incision is (Figure 4).

Figure 4: Posterior vaginal incision.



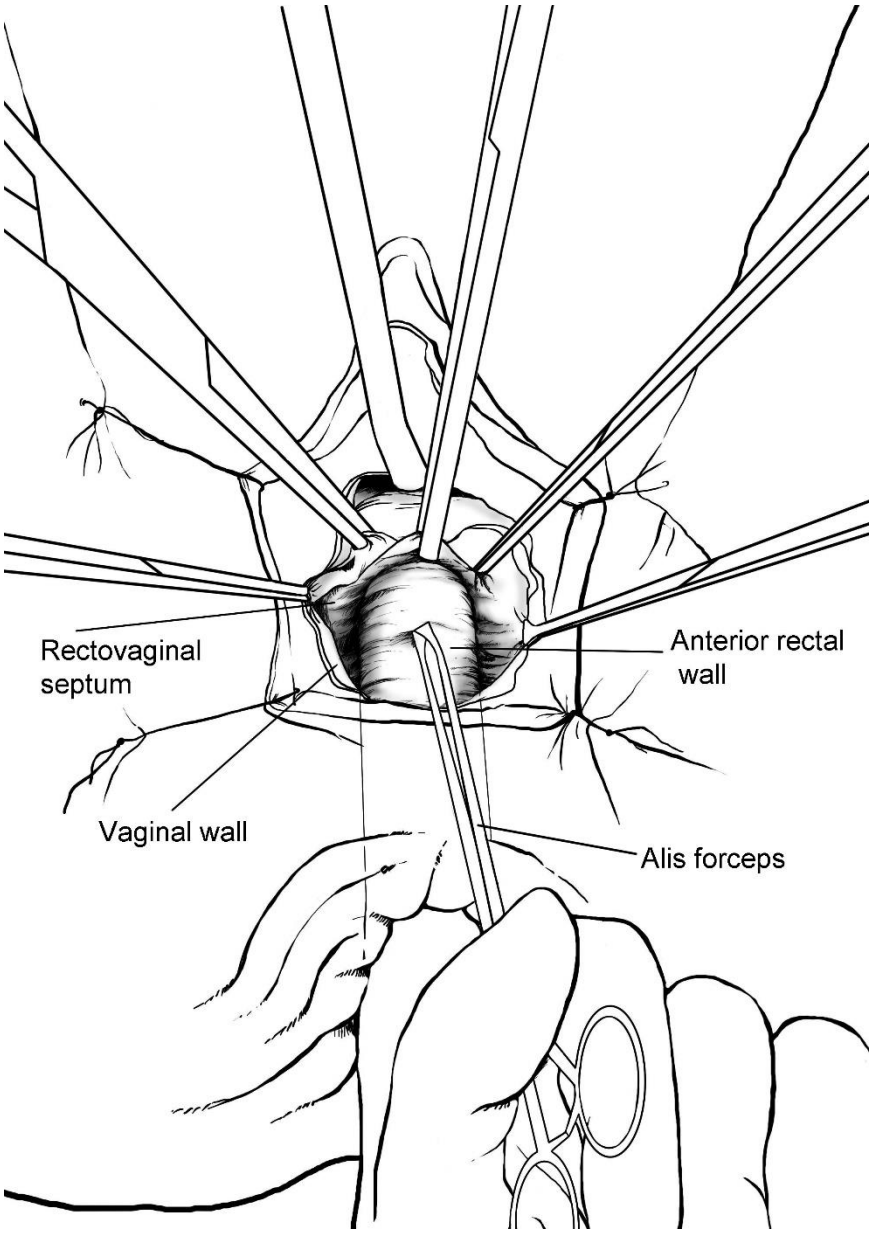
An Alis forceps is attached each side of the incision and secured to the surgical drapes by means of artery forceps (or similar). The surgeon grasps the Alis forceps on the patient's right side with his left hand and with the index finger on the outer vaginal surface. Sharp dissection is then used to distally separate the perineal membrane from the vagina and this avascular plane of dissection is continued cranially. The index finger continuously controls the correct thickness of dissection and avoids inadvertent vaginal buttonhole injuries on the one hand and straying to the rectum on the other. This procedure is duplicated on the patient's left side.

The rectum is then dissected off the vagina in the midline and this dissection occurs with little difficulty above the perineal membrane, i.e. proximal to the lower 3-4 cm of the vagina. In cases of previous native tissue or mesh augmented surgery, this plane

does not develop easily and sharp dissection is continued until the abnormal tissue is passed. Separation of the rectum form the vagina continues until 1 cm above the apex of the defect, or in most cases to the level of the posterior fornix or the vaginal vault. Areas where care is specifically required are laterally where the decussating puborectalis fibers become visible. These can easily bleed when injured and such injury is believed to be associated with acute complications such as hematoma formation, post-operative pain and post-operative urinary retention, as well as the possibility of chronic complications and risk of pelvic floor dysfunction. The bleeding from this area often requires hemostatic suturing due to the failure of both compression and electro-cautery. The midline vaginal incision can be extended cranially to allow adequate visualisation of the prepared surgical field if required.

A second glove is then used on the surgeon's left hand and inserted into the anorectum and directed anteriorly to expose the full circumference of the rectal wall defect. The posterior prolapse is attentively inspected and palpated to ensure that the presence of an enterocele is not overlooked prior to the suturing of the rectocele. If an enterocele is found to be present, it is dissected off the anterior rectal wall prior to insertion of the anterior rectal wall sutures and finally repaired after completion of the rectocele plication. An Alis forceps grasps the anterior rectal wall and gentle caudal traction is applied by the surgeon, using his left hand to expose the cranial aspect of the defect (Figure 5).

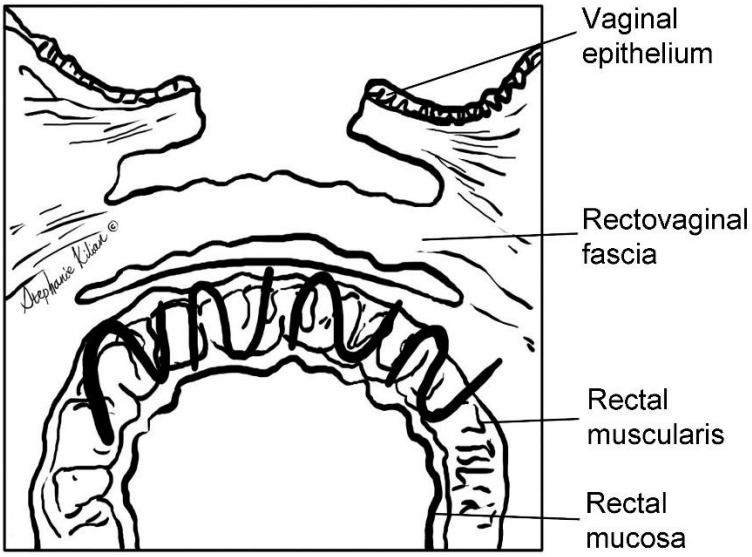
Figure 5: Posterior dissection prior to suture insertion.



The anterior rectal wall can become quite thin and excessive traction will result in the forceps causing lacerations to the applied area. The surgeon is handed a 2/0 polydiaxonone (PDS) suture with an artery forceps attached to its distal tip. The surgical assistant elevates the posterior vaginal wall to enable visualisation of the apex of the anterior rectal wall dissection. The suture is now inserted, starting from the patient's right side and lateral aspect of the rectal defect. It is imperative that the suture

be inserted into the rectal muscularis and not superficially in the endopelvic fascia (Figure 6).

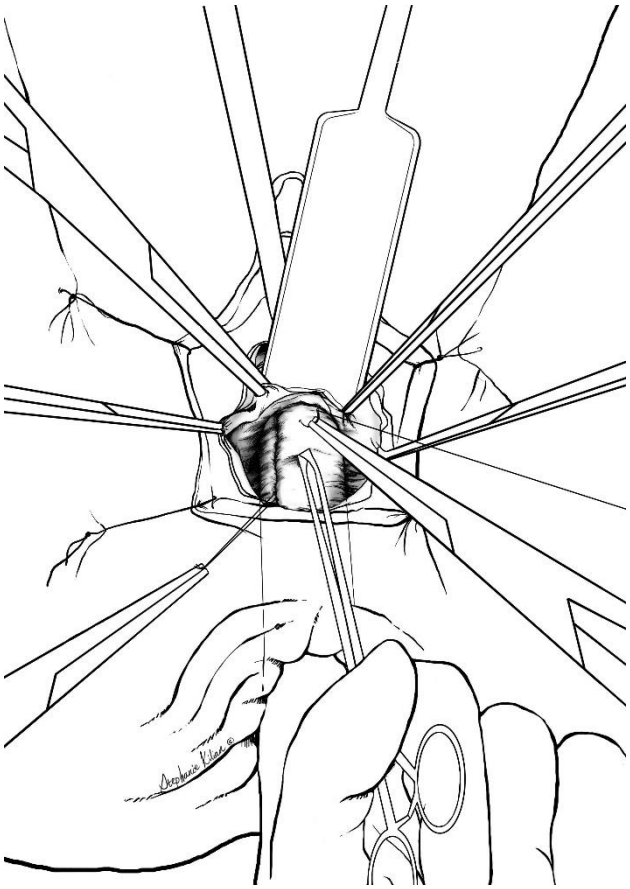
Figure 6: Diagram of correct suture placement.



Sutures illustrated with solid black lines.

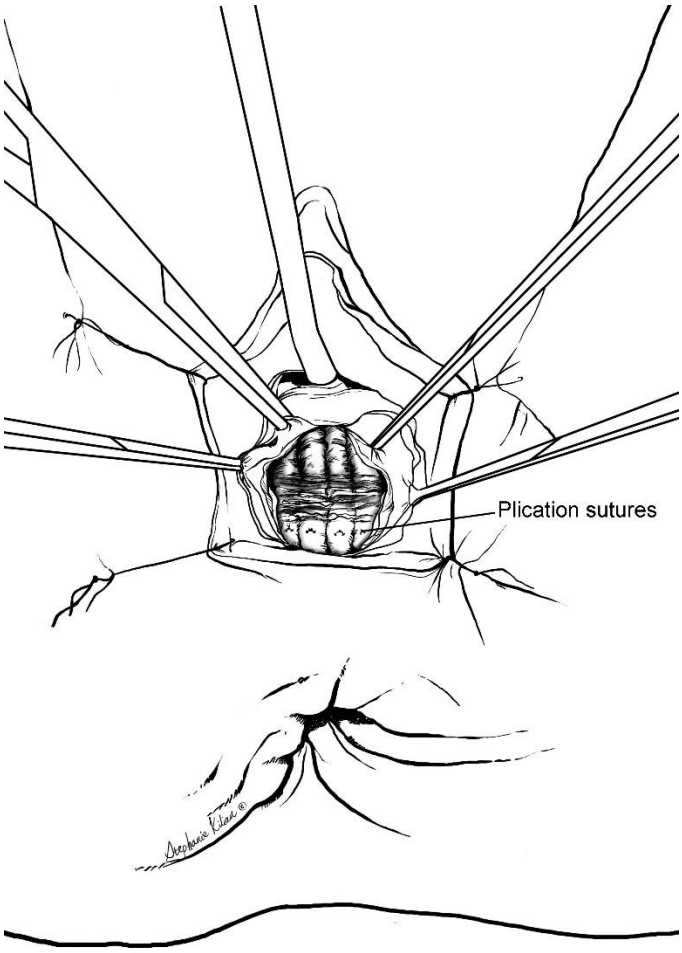
The presence of the rectal finger ensures and correlates this suture placement at each bite. The lateral defect can often be underestimated and if not appreciated will result in a residual rectal wall defect after the repair. To avoid this, the assistant pushes laterally with the suction tip at the apex and the surgeon simultaneously rotates his rectal finger in the opposite direction to expose the lateral margins of the defect and allow correct insertion of the suture. The sutures are then inserted in a zig-zag fashion distally to the level of the perineum. Caution is required when one reaches the level of the puborectalis muscle fibers to not include this in the suture placement and thus to stay medial of these. The next sutures are all inserted in a similar fashion and 2 sutures should be completed with one length of suture material. Each subsequent suture is inserted approximately 10 mm medial to the previous one (Figure 7).

Figure 7: Illustration of anterior rectal wall suture insertion.



In most cases, four sutures would be required, but the number of sutures depend on the extent of the rectal wall abnormality. There has been cases where eight sutures have been required, although these are few and far in-between. After completion of the last suture, the assistant elevates the lengths of sutures. This allows the surgeon to remove his rectal finger without risk of contaminating the material or surgical field with fecal matter. The sutures are individually tied, normally starting with the last one placed and moving to the right side. The result is bunching of the abnormal anterior rectal wall in an anterior direction (Figure 8).

Figure 8: Final result of plicated rectocele.



This tissue with gradually undergo necrosis and resorption over the next 6 weeks. The posterior vaginal wall is pushed cranially and if there is excess vaginal tissue, this can be trimmed. Mostly this is avoided to limit the possibility of dyspareunia in the sexually active patients. Concomitant pelvic floor procedures, such as sacrospinous suspensions, enterocele repairs, perineal repairs or anterior compartment repairs can then be performed as deemed necessary. After closure of the posterior vaginal wall, a rectal examination is once more performed to ensure no mucosal injury or suture penetration. I f this is found, the suture is cut transanal. The labial sutures are removed. An acriflavine impregnated vaginal pack is inserted and removed with the catheter the following day. All patients receive stool softeners to use as necessary.

8.3 PREPARED ARTICLE: DESCRIPTION OF THE RECTOCELE PLICATION TECHNIQUE AND ASSOCIATED CLINICAL OUTCOMES (ADDENDA 16 & 17)

Rectocele plication: Description of a novel surgical technique and review of clinical results

Abstract

INTRODUCTION AND HYPOTHESIS*:* A rectocele is the bulging of the anterior rectal wall into the posterior vaginal compartment. It frequently accompanies pelvic organ prolapse (POP) in other compartments and a concomitant posterior repair is performed in 40-80% of cases of POP surgery. The route of repair can be transvaginal, transrectal or transperineal, as well as abdominal. The aim of this retrospective study is to describe a novel transvaginal surgical procedure and investigate the associated subjective and objective clinical outcomes.

METHODS*:* Database records were retrieved for all women who underwent a rectocele plication with or without a perineal body repair for the period January 2010 until December 2015 in a referral urogynecology unit. Pre- and post-operative symptoms, clinical findings and quality of life (QOL) metrics were evaluated and reported on. A minimum follow-up period of 12 months was a prerequisite for inclusion.

RESULTS: 139 Women met the initial inclusion criteria with full data available for 123 women. The presenting symptoms included a vaginal bulge in 73 (52.5%), overactive bladder (OAB) in 73 (52.5%), recurrent urinary tract infection (RUTI) in 26 (18.7%), constipation in 57 (41%), obstructed defecation (OD) in 49 (35.3%) and anal incontinence (AI) in 35 (25.2%). The majority of women (n=72, 51.8%) had stage 3-4

posterior prolapse. The mean follow-up period was 27 ± 15 months. The post-operative symptoms were vaginal bulge in 10 (8.1%), OAB in 35 (28.5%), RUTI in 8 (6.5%), constipation in 35 (28.5%), OD in 17 (13.8%) and AI in 25 (20.3%). The symptomatic improvement was statistically significant for all, except AI (p=0.43). There was a significant improvement in posterior prolapse ($p < 0.001$) with the majority of women noted to have a stage 0 or 1 (n=109; 88.6%) posterior prolapse at follow-up. The overall peri-operative complication rate was 17.3% (n=24), none of which required surgical intervention.

CONCLUSION*:* The transvaginal rectocele plication is a novel surgical technique with good subjective and objective clinical outcomes in the medium term.

KEYWORDS*:* Posterior repair, prolapse surgery, rectocele, rectocele plication rectocele repair, quality of life.

Introduction

Pelvic organ prolapse (POP) is a prevalent condition and nearly 1 in 5 women will require a pelvic floor reconstructive surgical procedure in their lifetime (1). The posterior vaginal compartment is frequently a site of surgical repair, often simultaneously combined with repairs in other vaginal compartments (2). A vast array of surgical procedures have been described to correct anatomical abnormalities and symptoms perceived to be associated with the posterior compartment (3). There are generally two clusters of approach for the repair of a rectocele and this is divided along the two primary disciplines involved in treating these patients. The colorectal surgeon

tends to approach this repair via the transanal, transperineal or abdominal route, whereas the gynecologist mostly perform a transvaginal repair (4) (5) (6)(7).

The primary procedures for the surgical correction of a rectocele in gynecology are the defect-specific repair and midline fascial plication (8) (9). The rationale for these procedures is that the posterior vaginal bulge is the effect of a deficiency in the rectovaginal fascia which creates the space for the rectum to protrude into. These fascial defects can be transverse or lateral and are individually identified and repaired (10).

A symptomatic rectocele has also been shown to reflect a defect in the rectal wall itself, which needs to be corrected in order to restore anatomy and function (11). A transvaginal procedure, referred to as a rectocele plication, with its focus on repairing the anterior rectal wall defect has been performed in the local urogynecology unit for the past 8 years. The purpose of this manuscript is to describe the surgical technique involved in this procedure and report on the clinical outcomes of these patients.

Methods

This is a retrospective report on the surgical outcomes of a cohort of women who underwent a rectocele plication in the urogynecology unit of Universitas Academic Hospital in Bloemfontein, South Africa. This is a tertiary referral unit in a teaching hospital. Reporting is according to the Strobe guidelines (12) and ethics committee approval was obtained (ECUFS 116/04). Clinical information was extracted from an electronic database for the period January 2010 until December 2015. The inclusion criteria were all patients undergoing a rectocele plication with or without a perineal body repair and who have followed up for a minimum period of 12 months after

surgery. Exclusion criteria were patients who underwent concomitant pelvic floor procedures, those where mesh was used in the posterior compartment and where the follow-up period was less than 12 months. The initial data as well as follow-up clinical data were captured in the urogynecology unit's database. Definitions used in regards to pelvic floor symptoms were based on the International Urogynecological Association (IUGA) / International Continence Society (ICS) joint report on the terminology for female POP and that of pelvic floor dysfunction (13). The quality of life (QOL) assessment and scoring was obtained from a locally used abbreviated pelvic floor questionnaire compiled from internationally validated questionnaires and consisting of 10 questions (3 on POP, 3 on urinary distress, 3 on colorectal symptoms and 1 on sexual function impact). Each question could be scored from 1-5, with 5 carrying the most weight and a higher score thus reflecting less dysfunction. Data collected included basic demographic information, clinical symptoms, the QOL questionnaire, clinical examination and a transperineal ultrasound (TPUS) evaluation. A standard digital rectal examination was performed as part of the clinical examination. The patient was asked to perform a Valsalva maneuver with the ensuing rectal bulge size noted in centimeters above the posterior fourchette. A perineal body defect was diagnosed as either a bulging perineum during Valsalva or where the anatomic integrity of the perineal body was abnormal on rectovaginal palpation. The 2-dimensional (2D) TPUS was performed according to the technique described by Dietz ((14). Follow-up visits were at 6 weeks, 3 months, 6 months and then annually after surgery. Successful primary surgery was anatomically defined as a posterior compartment pelvic organ prolapse quantification (POP-Q) stage of <2. Surgical complications were classified by means of the Dindo classification system (15). The clinical findings at the latest visit were retrieved from the database and reported on.

There was no control group as the primary aim of this manuscript was to describe the surgical technique of a rectocele plication and report the clinical outcome. Variables were limited by excluding patients who underwent concomitant pelvic floor procedures and a surgical team consisting of two consultants either performing the surgery themselves or supervising a trainee. The indication for surgery was a symptomatic vaginal bulge, obstructed defecation (Rome III criteria), sexual discomfort due to the bulge, or obstructive urinary symptoms in women with a rectocele ≥ stage 2. The operating surgeon was not permitted to perform the post-operative clinical examination. All quantitative data were recorded in a similar and structured fashion pre-operatively as well as during the post-operative visits and analyzed accordingly. The qualitative metrics were compared and analyzed with the Chi-square and Fisher's exact tests and the continuous variables with the student-t test with statistical significance set at a value of $p < 0.05$. Patients with incomplete data and those lost to follow-up were excluded from the final reporting.

Surgical technique

The patient received a general or regional anesthesia and was then placed in the lithotomy position with her hips flexed to approximately 70 degrees. A single dose of prophylactic intravenous antibiotic, Cefazolin 2g, was given. Bilateral 2/0 silk sutures were used to retract the labia laterally and expose the surgical field. These were removed at the end of the procedure. The apex of the posterior vaginal wall defect was grasped and elevated with a Kocher's forceps. The rectovaginal space was infiltrated with 40-80 ml of a solution containing a vasoconstrictor and saline (16). A full thickness midline vaginal incision was made from the posterior fourchette to the

apex of the defect. An Allis forceps was attached to each vaginal edge and with the use of sharp dissection, the rectum was mobilized off the full thickness of the vaginal wall. This dissection was carried laterally to the pararectal borders and cranially to the apex of the vagina. Injury to the puborectalis muscle fibers were avoided. The surgeon then inserted an index finger inside the rectum and exerted caudal traction on the anterior rectal wall by means of an Allis forceps. Polydioxanone 2/0 sutures were inserted into the rectal muscularis from the apex of the defect and this was continued in a zig-zag pattern caudally to the level of the perineum. The rectal finger continuously guided the depth of suture placement to avoid mucosal injury on the one hand and too superficial placement on the other. The first suture was placed laterally and each subsequent suture was located approximately 10 mm medial from the previous one. In the vast majority of cases four such sutures would be required, however more might be needed in cases of broader anterior rectal wall defects. The sutures were then individually tied after all had been placed. A final rectal examination was done to exclude any mucosal injury during suture placement. The vaginal epithelium was closed and an acriflavine impregnated vaginal pack was inserted and removed the next morning. All patients received a stool softener for four weeks after surgery.

Results

There were 1349 pelvic floor procedures performed during this period. Of these, 849 (59.6%) involved a rectocele plication and of these, 139 underwent only a rectocele plication with/without a perineal body repair. Complete follow-up data of ≥ 12 months could be retrieved for 123 of these cases. Of the 16 cases not included in the final report, 3 did not attend any follow up, 8 attended until 3 months, and 5 until 6 months

only. The basic demographic characteristics are summarized in Table 1. The median age was 58 years (range 19-82) and the mean body mass index was 28.2 kg/m^2.

Table 1: Baseline demographic characteristics of study population

Characteristic	**Results (n=123)**
Age[a]	57 ± 13.1
BMI[a]	28.2 ± 4.7
Parity[b]	3 (0;8)
Race	
Black[c]	49 (35)
White[c]	71 (51)
Other[c]	19 (14)
Menopausal[c]	101 (72.7)
HRT[c]	38 (27.3)
Previous hysterectomy[c]	57 (41)
Previous POP surgery[c]	29 (20.1)
Previous UI surgery[c]	16 (11.5)
Smoker[c]	15 (10.8)
Diabetes mellitus[c]	18 (13)
Hypertension[c]	36 (25.9)

BMI: Body mass index, HRT: Hormone replacement therapy, POP: Pelvic organ prolapse, UI: Urinary incontinence. [a]mean ± standard deviation; [b] median (range); [c] n (%).

Pre- and post-operative pelvic floor symptoms are summarized in Table 2. The mean follow-up period was 27 ± 15 months. There was a significant improvement in the majority of clinical symptoms and this was correspondingly reflected in an improved QOL score. Sexual function did not significantly differ from the pre-operative findings. The median procedure time was 31 (19; 52) minutes and the operative blood loss 62 (15; 105) milliliters. A concomitant perineal body repair was performed in 51 (36.7%) women. Peri-operative complications according to the Dindo grading system were identified in 24 (17.3%) women. This consisted of surgical site infection (SSI) in 2 (1.4%), urinary tract infection in 7 (5%), wound hematoma in 7 (5%), rectal injury in 6 (4.3%), and excessive pain (pain score > 5/10 on discharge) in 10 women (7.2%). The

women with the higher pain scores included both SSIs and 6 of the patients with hematomas. The rectal injuries occurred during pararectal dissection for the perineal body repair and all were repaired during the initial procedure. All occurred where the trainee was the primary surgeon. There were no incidences of fistula formation in these women. None of the complications required additional surgical intervention. The median hospital stay was 3 (2; 9) days.

Table 2: Pre- and post-operative pelvic floor symptoms

Symptom	Pre-operative: n=139 (%)	Post-operative: n=123 (%)	p†
Bulge	73 (52.5)	10 (8.1)	< 0.001†
OAB (wet)	30 (21.6)	13 (10.6)	0.02†
OAB (dry)	43 (30.9)	22 (17.9)	0.02†
Stress urinary incontinence	18 (12.9)	11 (8.9)	0.4
Recurrent UTI	26 (18.7)	8 (6.5)	0.006†
Constipation	57 (41)	35 (28.5)	0.04†
Obstructed defecation	49 (35.3)	17 (13.8)	0.001†
Anal incontinence	35 (25.2)	25 (20.3)	0.43
Sexual			
Dyspareunia	25 (18)	15 (12.2)	0.25
Not sexually active	38 (27.3)	34 (27.6)	0.95
Quality of life score*	51.6 ± 16	74.2 ± 15	< 0.001†

OAB: Overactive bladder, UTI: Urinary tract infection. * mean %; ± standard deviation, † statistical significance. Chi-square and unpaired t-test.

The pre- and post-operative findings at clinical examination are displayed in Table 3. The 7 patients with a pre-operative POP-Q stage 1 rectocele all had a larger defect on rectal examination which was in keeping with a stage 2-3 posterior prolapse.

Table 3: Pre- and post-operative clinical findings.

Measurement	Pre-op: n=139 (%)	Post-op: n=123 (%)	p†
Posterior compartment			
Stage 0	0 (0)	48 (39)	< 0.001†
Stage 1	7 (5)	61 (49.6)	< 0.001†

Stage 2	60 (43.2)	11 (8.9)	< 0.001†
Stage 3	64 (46)	3 (2.4)	< 0.001†
Stage 4	8 (5.8)	0 (0)	0.01†
Rectal examination (defect size)			
0 cm	0 (0)	63 (51.6)	< 0.001†
1 cm	2 (1.4)	36 (29.5)	< 0.001†
2 cm	36 (25.9)	14 (11.5)	0.004†
3 cm	85 (61.2)	8 (6.6)	< 0.001†
≥ 4 cm	16 (11.5)	1 (0.8)	0.001†
Anterior compartment			
Stage 0	18 (12.9)	22 (17.9)	0.34
Stage 1	96 (69.1)	75 (61)	0.21
Stage 2	25 (18)	26 (21.1)	0.62
Apical compartment			
Stage 0	120 (86.3)	88 (71.5)	0.005†
Stage 1	19 (13.7)	35 (28.5)	0.005†
Perineal body defect	42 (30.2)	12 (9.8)	< 0.001†

† Statistical significance.

The transperineal ultrasound findings are illustrated pre- and post-operatively in Table 4.

Table 4: Pre- and post-operative transperineal ultrasound findings

Measurement	**Pre-op: n=139 (%)**	**Post-op: n=123 (%)**	**p†**
Rectocele	126 (90.7)	9 (7.3)	< 0.001†
Enterocele	11 (7.9)	10 (8.1)	0.94
Rectal intussusception	20 (14.4)	5 (4.1)	0.005†
Paradoxical puborectalis movement	13 (9.4)	9 (7.3)	0.65

† Statistical significance.

An anatomically successful outcome was achieved in 109 (88.6%) women and a repeat procedure was performed in 7 (5.7%) women. A different pelvic floor reconstruction procedure, i.e. not a rectocele repair, was performed in 24 (19.5%) women at a median period of 30 (12; 66) months after the index operation.

Discussion

This report on a novel surgical technique for the repair of a rectocele is one of the largest case series for transvaginal rectocele repair without mesh (17) (18). It entails an approach which embodies a philosophical union in thinking between the mostly transvaginal approach by gynecologists and the mostly transanal approach by colorectal surgeons.

The symptomatic relief and anatomical success noted in the medium term is overall more pronounced than pooled analyses of either of the two approaches individually (2)(19)(20).

The spectrum of pre-operative symptoms are in keeping with literature and emphasize the difficulty in limiting a rectocele to specific symptomatology (21)(22)(23). This unfortunately also creates doubt in regards to proposed management and the decision if and when to perform surgery and subsequently to select the optimal procedure for the affected individual (8) (24). This concern and uncertainty are shared by other authors (25) (26) (27). A further confounding factor is the multiple disorders in the posterior compartment that might present with defecatory complaints and it can be perplexing to discern the contribution of concomitant processes in the cause or effect of the presenting symptoms (28).

The anticipated symptoms of vaginal bulge (52.5%) and obstructed defecation (35.3%) were observed in this population with posterior prolapse. A symptom group that was however prominent both as a presenting symptom (52.5%) and in relief obtained after surgery (28.5%) was the overactive bladder symptoms. This specific finding has been alluded to in literature, but never before well described for the posterior compartment

(29)(30). The explanation for this observation requires further research and the hypothesis is that it might be related to the creation of urinary outflow obstruction by the posterior compartment prolapse in a similar fashion as that of an enlarged prostate in the male.

Posterior transvaginal repairs have been associated with dyspareunia and this was particularly observed when levator plication was performed (50%) (31). It is seen less often with site-specific repair (18%) and with midline fascial repair (18%) (2). A reduction in overall dyspareunia from 18% to 12.2% was observed in our population, although this was not statistically significant (p=0.25). A possible explanation for this finding is the avoidance of routine vaginal trimming as well as the maintenance of vaginal caliber by focusing the repair on the rectal defect, rather than on the rectovaginal fascia.

The anatomic success was significantly evident in the posterior compartment for all stages of prolapse and similarly reflected in both the POP-Q staging as well as the digital rectal evaluation. There was no observed increase in anterior compartment prolapse as was reported recently (32). Significantly more stage 1 apical compartment prolapse was however detected after surgery. An accurate explanation for this finding was not possible. The TPUS findings were furthermore in keeping with the anatomic observations and confirmed efficacy of the rectocele plication in addressing the rectal defect. The role of TPUS in the posterior compartment is gathering more prominence of late (33) (34). There was a congruently significant correction of rectal intussusception seen by way of ultrasound evaluation. Rectal intussusception is in most cases not resolved with traditional transvaginal rectocele repairs and often requires either mucosal resection or abdominal rectopexy (35)(36)(37).

The limitations of this study were its retrospective nature and the acknowledged bias accompanying these trials. The data was however captured in a database in a prospective fashion which limits recall bias. A further reduction in bias was achieved by avoiding post-operative clinical assessment by the operating surgeon. The clinicians were however not consistent during this period due to the rotation of residents during their training. The strength of this study lies in its description of a novel surgical approach for rectocele repair and the limitation of the operating surgeons to two clinicians. This series was one of the largest reported on for transvaginal rectocele repairs and the follow up period was more than two years. The data reported on is furthermore structured and robust and it provides a reassuring report on the outcomes of a rectocele plication.

Conclusion

A rectocele plication is a transvaginal procedure in which the focus of repair is the anterior rectal wall defect. This procedure allows the clinician the ability to perform concomitant vaginal reconstructive procedures. It is conceptually a philosophical fusion of the traditional gynecologic and colorectal approaches to the repair of a rectocele. The symptomatic and anatomic outcomes were satisfactory in the medium term with an acceptably low complication rate. Of note was the significant improvement in overactive bladder symptoms in this patient group. Further research should focus on comparing this technique with established vaginal procedures in a randomized setting and to explore the underlying mechanism for the high prevalence of overactive bladder symptoms seen in women presenting with rectoceles.

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CHAPTER 9

REPAIR OF THE PERINEAL BODY AT THE TIME OF A POSTERIOR REPAIR

9.1 INTRODUCTION

This chapter will follow a narrative approach for the description of a procedure for reconstruction of the female perineal body. Narrative essays or descriptions are reflective in nature and it is encourage to form part of scholarly discourse (Pollock & Bono 2013). Often the emphasis of scientific academic writing is on purely conveying the facts whilst neglecting or eliminating the story behind these. Reflective writing is not a new concept in the health sciences, and along with the close reading of literary publications, has carved out a well-deserved place in medical training for nurturing professional growth and providing a therapeutic platform for clinician well-being (Baruch 2013). Narrative writing provides the author with the freedom to compose text without much of the limitations of formal academic writing. It can be used in the simple transfer of knowledge, but is also a modality though which to impart the synthesis of new knowledge in the health sciences (Hirvela & Du 2013).

The anatomy of the female perineum and perineal body has been established. It emphasizes the complexity of an area that is often not appreciated for its functional contribution. Injuries to the perineum mostly occur during vaginal childbirth, but perineal abnormality has been proven to reflect abnormalities in the levator muscle function. There is little controversy for the acute management of perineal injuries, although a Cochrane review found that first and second degree lacerations can be

managed surgically or conservative without evidence of alternate outcomes (Elharmeel et al. 2011). The dispute arises with the management of chronic perineal dysfunction. A perineal repair (perineorrhaphy or perineoplasty) is often performed along with procedures to correct POP. The indication for this procedure is often vague and entails decreasing the genital hiatus, correcting perineal descent, improving sexual function, or strengthening level 3 vaginal support. A recent survey confirmed this heterogeneity in indication and surgical technique used for a perineorrhaphy (Kanter et al. 2015). The importance of perineal support – and underlining its function – has been illustrated with the finding that perineal descent is the common denominator in nulliparous women with rectoceles and in the reported outcomes after the TFS procedure, which provides a mechanism to normalize the support which is required of the functional perineal body (Dietz & Clarke 2005)(Wagenlehner et al. 2013a)(Wagenlehner et al. 2013b).

Karram describes a perineorrhaphy as the third part of a posterior repair and Baggish alluded to the lack of evidence supporting improved sexual function after a perineal repair (Baggish 2016). He specifically raised his concern that picking up of lateral muscle mass and placating it across the midline might create an unnatural vaginal hump, produce and excessive inflammatory response and result in gross scar formation. He describes a technique which consist of an inverted pyramidal excision of perineal skin, the suturing of underlying fascia and the advancement of the vaginal epithelium prior to closure of the incision.

9.2 SURGICAL PHILOSOPHY AND TECHNIQUE

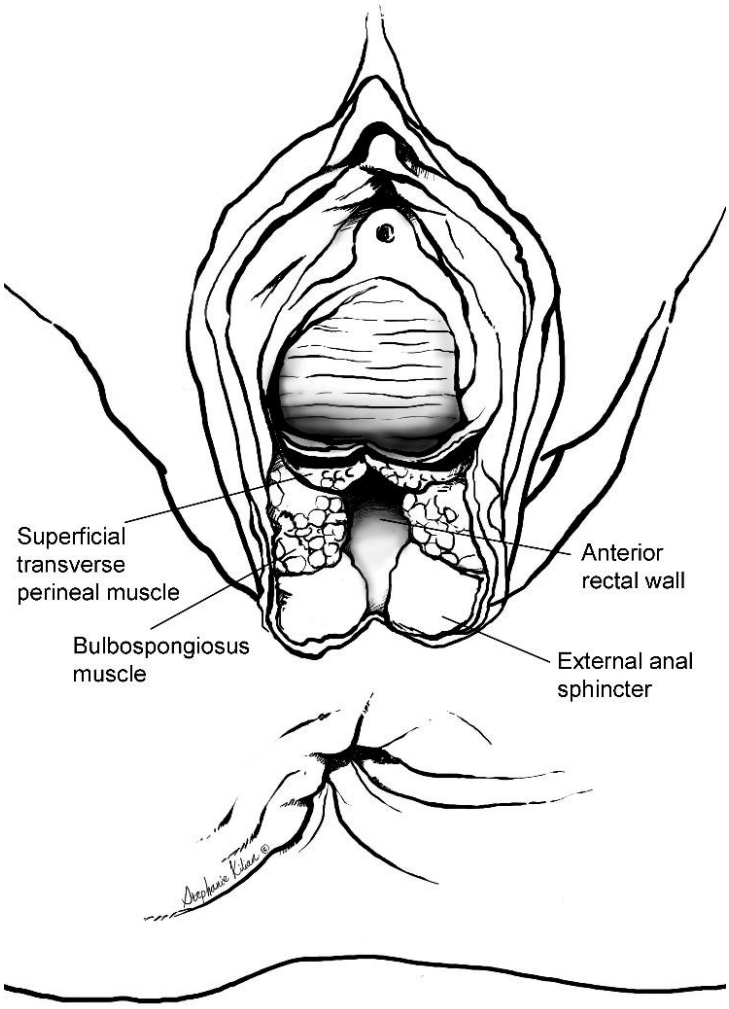
The procedure followed for a perineal body repair in the urogynecology unit at UAH was in accordance with anatomic reconstruction of this structure. The clinical observation that perineal abnormalities in women with pelvic floor disorders were often associated with a midline attenuation or disruption of the EAS and bulbospongiosus muscle was the impetus for the development of this procedure. The perineal repair is mostly performed in conjunction with a posterior vaginal repair, but can be an independent procedure to correct perineal dysfunction.

The procedure starts with the patient receiving a single prophylactic dose of intravenous antibiotic, which was mostly 2g of Cefazolin, prior to anesthesia. Anesthesia could be either general or regional, depending on the individual patient profile and the assessment of the anesthetist. She is then positioned with her legs in lithotomy poles, buttocks on the edge of the operating table and hips flexed to approximately 70^0. After cleaning and draping of the patient, a transurethral catheter is inserted and left in-situ for the remainder of the procedure to allow free drainage of urine. The catheter is required due to the use of a vaginal pack at the end of the procedure and if this was not done, the patient would not be able to void adequately after surgery. An examination of the vaginal calibre and anatomy is performed to confirm the planned surgical approach prior to the first incision. Four 2/0 black silk sutures are inserted into the labia minora to provide retraction. These are loosely tied so that there is no resulting labial ischaemia with a risk of subsequent necrosis. An alternate option would be to use a retractor system, but the suture approach has been deemed optimal in our setting. A 20 millilitre solution consisting of a

vasoconstrictor and saline is injected under the posterior vaginal wall and also lateral of the anus on either side. The hymenal remnants are identified. The diamond-shaped ellipse of skin that will be excised are marked and the goal is to reconstruct the hymenal ring distally without narrowing the vaginal calibre. A Kocher's forceps is applied in the midline posterior vaginal wall and elevates it. A midline posterior vaginal incision is made which extends from the posterior fourchette to this forceps. An Alice forceps is attached each side of the incision and secured to the surgical drapes by means of artery forceps (or similar). The surgeon grasps the Alice forceps on the patient's right side with his left hand and with the index finger on the outer vaginal surface. Sharp dissection is then used to distally separate the perineal membrane and underlying fascia from the vagina. This dissection is limited to the distal 2-3 centimetres of the vagina in cases of an isolated perineal repair. The surgeon then inserts his double-gloved left index finger in the distal anorectum. The lateral spaces are opened on both sides of the rectum with sharp dissection and the EAS is dissected laterally, i.e. the intersphincteric space is entered (Figure 9).

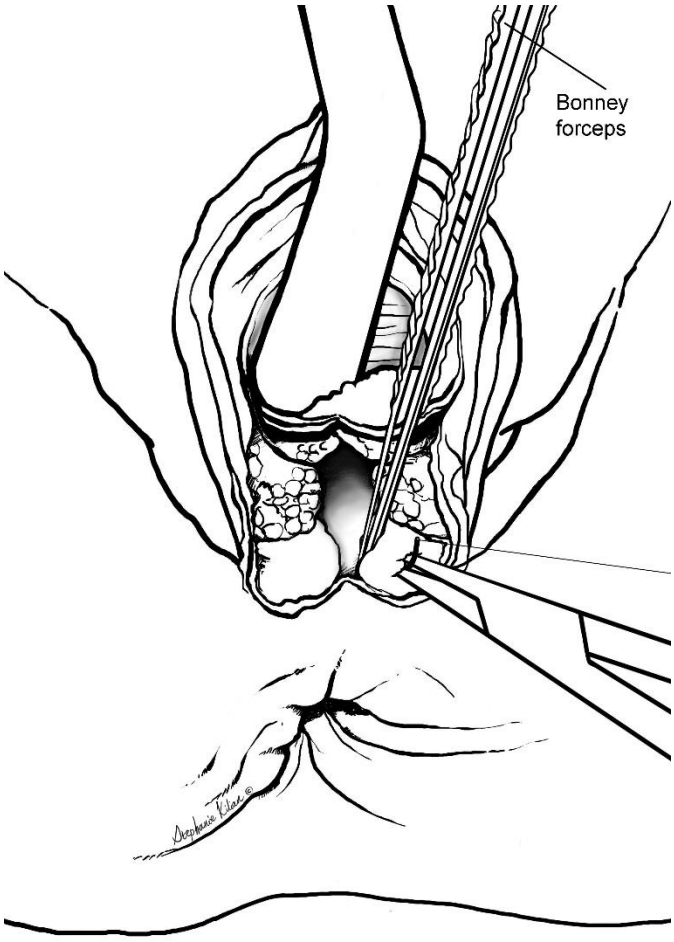
Care is taken not to inadvertently cause an anal mucosal laceration. This is prevented by ensuring control over the dissection at all times and to continuously evaluating the position and direction of the tip of the scissors in relation to the anal canal. The surgeon removes his finger on completion of this dissection.

Figure 9: Illustration of the prepared surgical field.



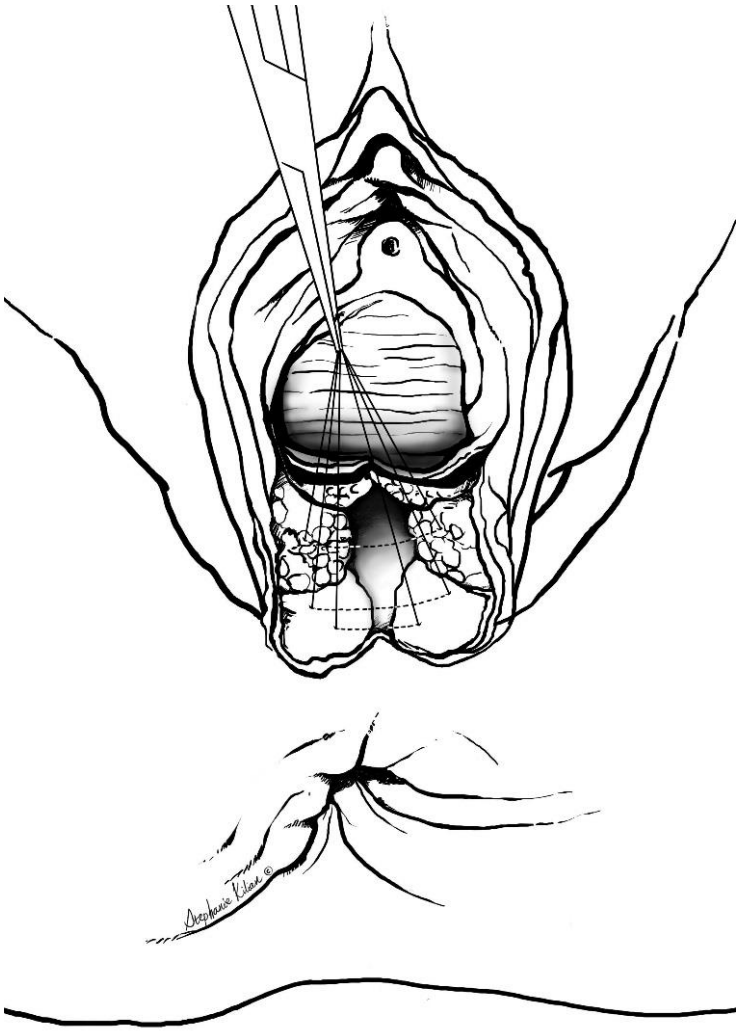
A Bonney's forceps is positioned vertically alongside the anorectum and in the dissected space, to protect it at the time of suture placement (Figure 10).

Figure 10: Protection of rectum and insertion of first suture.



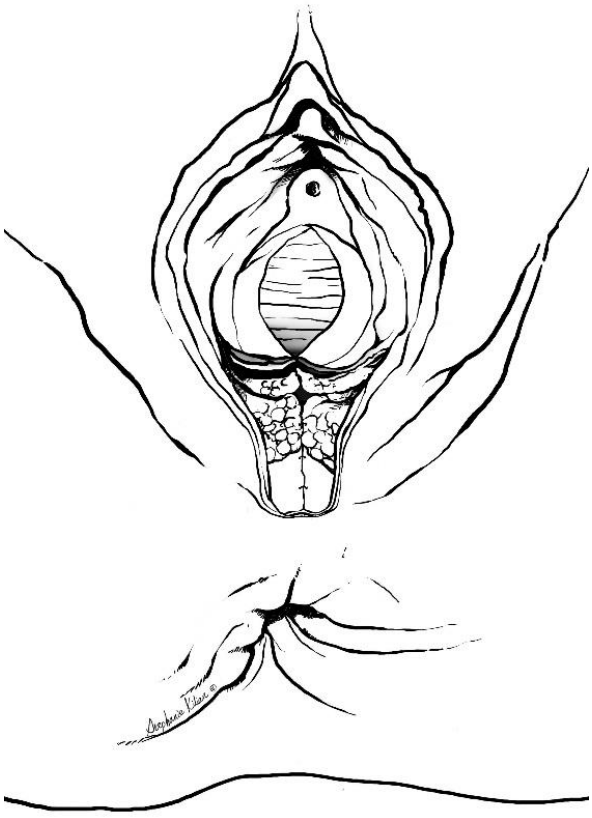
Three polydioxanone 0 sutures are then inserted. The first suture is inserted in the EAS, distal to the puborectalis muscle, from the patient's left to right. Care must be taken not to start proximal to this level, otherwise visceral parts of the pubococcygeus muscle (puboanalis and/or pubovaginalis) might be included, resulting in a levator plication. This will manifest as excessive post-operative pain and has been established to be a cause of post-operative urinary retention and long term risk for dyspareunia. The second suture, inserted in a similar way, includes the EAS just distal to the first suture. The third suture incorporates the superficial part of the EAS and the bulbospongiosus muscle at the level of reattachment to the perineal body (Figure 11).

Figure 11: Illustration of the inserted sutures.



The sutures are then individually tied, starting with the last one inserted. This results in an end-end approximation of the sphincter and midline approximation of the bulbospongiosus muscle (Figure 12).

Figure 12: End-result of perineal body repair prior to closure of vaginal epithelium.



A rectal examination is performed to ensure no mucosal injury occurred during suture placement. The last layer incorporates closure of the vaginal epithelium and superficial transverse perineal muscles with the use of a polyglycolic acid 2/0 running suture. An acriflavine impregnated vaginal pack is inserted and removed the next morning and all patients receives a stool softener for four weeks after surgery. No additional antibiotic treatment is prescribed.

9.3 PREPARED ARTICLE: THE CONTRIBUTION OF A PERINEAL BODY REPAIR IN COMBINATION WITH A POSTERIOR REPAIR IN WOMEN WITH A RECTOCELE (ADDENDUM 18)

The effect of a concomitant perineal body repair at the time of a posterior vaginal repair: Does it provide a superior clinical outcome?

Abstract

INTRODUCTION AND HYPOTHESIS*:* The female perineal body is a relatively small, but complex anatomical structure due to the sum of its components. It plays an often underrated role in pelvic floor function. The term perineorrhaphy is used to reflect the surgical repair of this structure. This term does however not define a specific procedure, but is a general description for an assortment of techniques. A perineorrhaphy is often combined with a posterior vaginal repair. The aim of this retrospective study was to describe a specific surgical technique for the repair of the perineal body and explore the clinical contribution of this procedure to that of a posterior vaginal repair.

METHODS*:* This is a retrospective case-control study. Records were retrieved for all cases who underwent a perineal body repair in combination with a posterior vaginal repair (PBPV) for the period January 2010 until December 2015 in a referral urogynecology unit. The control group, identified in the same time period, were made up of all women who received only a posterior vaginal repair (PV). This repair

comprised a rectocele plication. Pre- and post-operative symptoms, clinical findings and quality of life (QOL) metrics were evaluated and reported on. A minimum follow-up period of 12 months was a prerequisite for inclusion.

RESULTS: 139 Women met the initial inclusion criteria with full data available for 123 women. There were 45 (36.6%) PBPV cases and 78 (63.4%) PV controls. The respective presenting symptoms were similar for both groups. There was no significant difference in the severity of posterior vaginal prolapse. The mean follow-up period was 30 ± 15 months for the cases and 25 ± 15 months for the controls. The post-operative assessment confirmed significant symptomatic improvement in all pelvic floor domains. There was no significant difference in symptomatic improvement between the two groups. An anatomically successful outcome at follow-up was present in 41 (91.1%) of PBPV cases and in 68 (87.2%) of PV cases (p 0.57). The overall peri-operative complication rate was 25.5% vs 12.5% (p 0.06), none of which required additional surgical intervention.

CONCLUSION: The benefit of adding of a perineal body repair at the time of a rectocele plication remains elusive as do the specific indication for women undergoing a posterior compartment repair.

Keywords*:* Perineum, perineal repair, posterior repair, rectocele plication, perineorrhaphy

Introduction

Pelvic organ prolapse (POP) is a prevalent condition and nearly 1 in 5 women will require a pelvic floor reconstructive surgical procedure in their lifetime (1). A posterior vaginal repair with or without a perineorrhaphy is frequently combined with repairs in the anterior or apical vaginal compartments (2). The female perineal body is a relatively small, but complex anatomical structure due to the sum of its components. It plays an often undervalued role in pelvic floor function. It contributes to level 3 vaginal support, plays a role in sexual function, anal and urinary continence and genital cosmesis (3)(4)(5). The term perineorrhaphy or perineoplasty is used to reflect the surgical repair of this structure for miscellaneous indications. This term does not define a specific procedure, but is a rather general description for a variety of techniques (6). Vague terminology are often used with little specific reference to the anatomical structures repaired, nor the specific suture material used (7)(8) (4). Gynecologists will frequently add a perineal repair at the time of a posterior vaginal repair, whereas colorectal surgeons would repair the posterior prolapse mostly without performing a perineal repair (9)(10)(11)(12)(13).

An abnormal perineal body is frequently observed as part of posterior vaginal prolapse, although the exact cause and effect relationship has not been determined (5)(14) (15).There is however little evidence of the specific benefit which a perineal repair might add to POP surgery in general and none for the value which it might contribute in combination with isolated posterior vaginal prolapse repairs.

The purpose of this manuscript was to describe a specific surgical technique used for the reconstruction of the perineal body and to examine the clinical contribution which

the addition of a perineal body repair at the time of correcting a posterior vaginal wall defect might have.

Methods

This is a retrospective report on the surgical outcomes of a series of women who underwent a rectocele plication with or without a perineal body repair in the Urogynecology unit of Universitas Academic Hospital in Bloemfontein, South Africa. This is a tertiary referral unit in a teaching hospital. Reporting is according to the Strobe guidelines (16) and ethics committee approval was obtained (ECUFS 116/04). Clinical information was extracted from an electronic database for the period January 2010 until December 2015. The inclusion criteria were all patients who underwent a posterior vaginal repair (PV) with or without a perineal body repair (PBPV) and who had followed up for a minimum period of 12 months. The case group was therefore the PBPV women and the control group the women who received a rectocele plication without a perineal body repair (PV). Exclusion criteria were patients who underwent associated pelvic floor procedures, those where mesh was used in the posterior compartment and where the follow-up period was less than 12 months. The initial data as well as follow-up clinical data were captured in the Urogynecology unit's database. Definitions used in regards to pelvic floor symptoms were based on the International Urogynecological Association (IUGA) / International Continence Society (ICS) joint report on the terminology for female POP and pelvic floor dysfunction(17). The quality of life (QOL) assessment and scoring was obtained from a locally used abbreviated pelvic floor questionnaire compiled from internationally validated questionnaires and consisting of 10 questions (3 on POP, 3 on urinary distress, 3 on colorectal symptoms

and 1 on sexual function impact). Each question could be scored from 1-5, with 5 carrying the most weight and a higher score thus reflecting less dysfunction. Data collected included basic demographic information, clinical symptoms, the QOL questionnaire, clinical examination and a transperineal ultrasound (TPUS) evaluation. A standard digital rectal examination was performed as part of the clinical examination during which the patient was asked to perform a Valsalva maneuver with the ensuing rectal bulge size noted in centimeters above the posterior fourchette. A perineal body defect was diagnosed as either a bulging perineum during Valsalva or where the anatomic integrity of the perineal body was abnormal on rectovaginal palpation. The 2-dimensional (2D) TPUS was performed according to the technique described by Dietz (18). Follow-up occurred at 6 weeks, 3 months, 6 months and then annually after surgery. Successful primary surgery was anatomically defined as a posterior compartment pelvic organ prolapse quantification (POP-Q) stage of < 2. Surgical complications were classified by means of the Dindo classification system (19). The clinical findings at the latest visit were retrieved from the database and reported on. Variables were limited by excluding patients who underwent concomitant procedures and a surgical team consisting of two consultants either performing the surgery themselves or supervising a trainee. The indication for surgery was a symptomatic vaginal bulge, obstructed defecation (Rome III criteria), sexual discomfort due to the bulge, or obstructive urinary symptoms in women with a rectocele ≥ stage 2. Bias was limited by ensuring that the operating surgeon did not perform the post-operative examinations. All quantitative data were recorded in a similar and structured fashion pre-operatively as well as during the post-operative visits and analyzed accordingly. The qualitative metrics were compared and analyzed with the Chi-square and Fisher's exact tests and the continuous variables with the student-t test with statistical

significance set at a value of $p < 0.05$. Patients with incomplete data and those lost to follow-up were excluded from the final reporting.

Surgical technique

The surgical technique for the plication of a rectocele is described in detail in a preceding publication. After tying of the rectocele plication sutures, the surgeon replaced his finger in the distal anorectum. The pararectal spaces were opened on both sides with sharp dissection and the external anal sphincter (EAS) was mobilized laterally. A midline perineal body anatomical disruption that includes a portion of the EAS was often observed. Care was taken not to inadvertently cause an anal mucosal laceration. The surgeon removed his finger on completion of this dissection. A Bonney's forceps were positioned vertically alongside the anorectum to protect it at the time of suture placement. Three polydioxanone 0 sutures were inserted. The first suture was inserted in the EAS, distal to the puborectalis muscle, from the patient's left to right. The second suture, placed in a similar way, included the EAS just distal to the first suture. The third suture incorporated the superficial EAS and bulbospongiosus muscle at the level of reattachment to the perineal body. The sutures were then individually tied, resulting in an end-end approximation of the sphincter. A rectal examination was performed to exclude mucosal injury during suture placement. A final layer incorporated closure of the vaginal epithelium and superficial transverse perineal muscles with the use of a continuous 2/0 polyglycolic acid suture. An acriflavine impregnated vaginal pack was inserted and removed the next morning. All patients received a stool softener for four weeks after surgery.

Results

There were 1349 pelvic floor reconstruction procedures performed during this period. Of these, 849 (59.6%) included a posterior vaginal repair and of these, 139 (10.3%) had only a posterior vaginal repair with/without a perineal body repair. This group was then divided into 51 PBPV cases and 88 PV controls. Complete follow-up data of ≥ 12 months were available for 45 cases and 78 controls. Of the 16 cases not included in the final report, 3 did not attend any follow-up, 8 attended until 3 months, and 5 only until the 6-month visit. There were no significant differences in those not included in the final report compared to the rest of the study population.

The women in the PBPV group were significantly younger than those in the PV group (p=0.02). The basic demographic characteristics were otherwise similar between the two groups and are displayed in Table 1.

Table 1: Baseline demographic characteristics of study population.

Characteristics	PBPV (n=51)	PV (n=88)	p-value
Age[a]	53.9 ± 13.1	59.2 ± 12.7	**0.02**[†]
BMI[a]	28.4 ± 5	28 ± 4.4	0.62
Parity[b]	3 (0;8)	3 (0;7)	0.83
Menopausal[c]	34 (66.7%)	67 (76.1%)	0.22
HRT[c]	13 (25.5%)	25 (28.4%)	0.70
Previous hysterectomy[c]	24 (47.1%)	33 (37.5%)	0.27
Previous POP surgery[c]	11 (21.6%)	18 (20.4%)	0.87
Previous UI surgery[c]	5 (9.8%)	11 (12.5%)	0.62
Smoker[c]	9 (17.6%)	6 (6.8%)	0.08
Diabetes mellitus[c]	7 (13.7%)	11 (12.6%)	0.85
Hypertension[c]	11 (12.6%)	25 (28.4%)	0.37

BMI: Body mass index, HRT: Hormone replacement therapy, POP: Pelvic organ prolapse, UI: Urinary incontinence. [a]mean ± standard deviation; [b] median (range); [c] n (%); [†]significance p <0.05.

Pre- and post-operative pelvic floor symptoms are summarized in Table 2. The mean PBPV follow-up period was 30 ± 15 months compared to 25 ± 15 months for the PV group (p 0.02). There was a significant improvement in the symptoms of a vaginal bulge, overactive bladder (OAB) (wet), obstructed defecation (OD) and overall QOL within both groups, but no significant differences between the two groups. The mean procedure time was 31 ± 8 minutes for the PBPV group compared to 31 ± 7 minutes for the PV group (p 0.65) and the operative blood loss 62 ± 25 milliliters compared to 60 ± 27 milliliters respectively (p 0.70). Peri-operative complications according to the Dindo grading system were identified in 13 (25.5%) women in the PBPV group versus 11(12.5%) in the PV group (p 0.06), none of which required post-operative surgical intervention. This correspondingly consisted of surgical site infection (SSI) in 2 (3.9%) versus 0 (0%) (p= 0.13), urinary tract infection in 2 (3.9%) versus 5 (5.7%) (p =1.00), hematoma in 5 (9.8%) versus 2 (2.3%) (p 0.09), rectal injury in 6 (11.7%) versus 0 (0%) (p 0.001) and excessive pain (pain score > 5/10 on discharge) in 4 (7.8%) versus 6 (6.8%) (p 1.00). The rectal injuries occurred during the pararectal dissection for the perineal body repair and all befell the trainee surgeon. The injuries were repaired during the initial procedure and there were no incidences of fistula formation in these women. The median hospital stay for the PBPV group was 3 (2; 5) days compared to 3 (2; 9) days in the PV group (p 0.16).

Table 2: Pre- and post-operative pelvic floor symptoms

Symptom	PBPV: Pre- vs Post-op	p	PV: Pre- vs Post-op	p	p†
Bulge	24 (47.1) *vs* 3 (6.7)	**<0.001**	49 (55.7) *vs* 7 (8.9)	**<0.001**	0.75
OAB (wet)	18 (35.3) *vs* 6 (13.3)	**0.02**	12 (13.6) *vs* 7 (8.9)	**0.04**	0.45
OAB (dry)	13 (25.5) *vs* 6 (13.3)	0.20	30 (34.1) *vs* 16 (20.5)	0.06	0.32
SUI	9 (17.6) *vs* 5 (11.1)	0.40	9 (10.2) *vs* 6 (7.7)	0.60	0.52
RUTI	11 (21.6) *vs* 5 (11.1)	0.27	15 (17) *vs* 3 (3.9)	**0.01**	0.14
Constipation	21 (41.2) *vs* 12 (26.7)	0.19	36 (40.9) *vs* 23 (29.5)	0.27	0.74

OD	15 (29.4) *vs* 4 (8.9)	**0.02**	34 (38.6) *vs* 13 (16.7)	**0.002**	0.23
AI	11 (21.6) *vs* 7 (15.6)	0.60	24 (27.3) *vs* 18 (23.1)	0.59	0.32
Sexual					
Dyspareunia	13 (25.5) *vs* 8 (17.8)	0.61	12 (13.6) *vs* 7 (8.9)	0.22	0.14
Not active	10 (19.6) *vs* 13 (28.9)	0.34	28 (31.8) *vs* 21 (26.9)	0.50	0.84
QOL score*	52 ± 17.9 *vs* 77.4 ± 15	**<0.001**	51.4 ± 14.8 *vs* 72.3 ± 15.2	**<0.001**	0.08

OAB: Overactive bladder, SUI: Stress urinary incontinence, RUTI: Recurrent urinary tract infection, OD: Obstructed defecation, AI: anal incontinence. PBPV: Pre-op n=51, post-op n=45 (%), PV: Pre-op n=88, post-op n=78 (%), * mean %; ± standard deviation, † Post-op p-value for PBPV compared to PV.

The pre- and post-operative clinical examination findings are displayed in Table 3. The primary indication for surgery was a symptomatic rectocele. The 7 patients with a POP-Q stage 1 rectocele all had a larger defect on digital rectal examination which was consistent with a stage 2-3 posterior prolapse.

Table 3: Pre- and post-operative clinical findings

Measurement	**PBPV: Pre- vs Post-op**	**p**	**PV: Pre- vs Post-op**	**p**	**p†**
Posterior:					
Stage 0	O (0) *vs* 24 (53.3)	**<0.001**	0 (0) *vs* 24 (30.8)	**<0.001**	**0.02**
Stage 1	4 (7.8) *vs* 17 (37.8)	**0.005**	3 (3.4) *vs* 44 (56.4)	**<0.001**	0.06
Stage 2	20 (39.2) *vs* 3 (6.7)	**0.002**	40 (45.5) *vs* 8 (10.3)	**<0.001**	0.74
Stage 3	24 (47.1) *vs* 1 (2.2)	**<0.001**	40 (45.5) *vs* 2 (2.6)	**<0.001**	1.00
Stage 4	3 (5.9) *vs* 0 (0)	0.24	5 (5.7) *vs* 0 (0)	0.06	1.00
Rectal examination (defect size)					
0 cm	0 (0) *vs* 28 (62.2)	**<0.001**	0 (0) *vs* 38 (48.7)	**<0.001**	0.19
1 cm	1 (2) *vs* 13 (28.9)	**0.0002**	4 (4.5) *vs* 31 (39.7)	**<0.001**	0.25
2 cm	17 (33.3) *vs* 4 (8.9)	**0.006**	35 (39.8) *vs* 3 (3.8)	**<0.001**	0.26
3 cm	31 (60.8) *vs* 0 (0)	**<0.001**	46 (52.3) *vs* 5 (6.4)	**<0.001**	0.16
≥ 4 cm	2 (3.9) *vs* 0 (0)	0.49	3 (3.4) *vs* 1 (1.2)	0.62	1.00
Anterior:					
Stage 0	6 (11.8) *vs* 7 (15.6)	0.76	12 (13.6) *vs* 15 (19.2)	0.40	0.80
Stage 1	37 (72.6) *vs* 28 (62.2)	0.38	59 (67.1) *vs* 47 (60.3)	0.41	0.85
Stage 2	8 (15.7) *vs* 10 (22.2)	0.44	17 (19.3) *vs* 16 (20.5)	0.85	0.82
Apical:					
Stage 0	44 (86.3) *vs* 34 (75.6)	0.20	76 (86.4) *vs* 54 (69.2)	**0.008**	0.54
Stage 1	7 (13.7) *vs* 11 (24.4)	0.20	12 (13.6) *vs* 24 (30.8)	**0.009**	0.53

Perineal body defect	41 (80.4) *vs* 5 (11.1)	**<0.001**	1 (1.1) *vs* 7 (8.9)	**0.03**	0.76

. PBPV: Pre-op n=51, post-op n=45 (%), PV: Pre-op n=88, post-op n=78 (%), * mean %; ± standard deviation, † Post-op p-value for PBPV compared to PV.

The transperineal ultrasound findings are illustrated pre- and post-operatively in Table 4.

Table 4: Pre- and post-operative transperineal ultrasound findings

Measurement	**PBPV: Pre- vs Post-op**	**p**	**PV: Pre- vs Post-op**	**p**	**p†**
Rectocele	46 (90.2) *vs* 3 (6.7)	**<0.001**	80 (90.9) *vs* 6 (7.7)	**<0.001**	1.00
Enterocele	6 (11.8) *vs* 4 (8.9)	0.75	5 (5.7) *vs* 6 (7.7)	0.76	1.00
Rectal intussusception	8 (15.7) *vs* 3 (6.7)	0.21	12 (13.6) *vs* 2 (2.6)	**0.01**	0.35
Paradoxical puborectalis	4 (7.8) *vs* 4 (8.9)	1.00	9 (10.2) *vs* 5 (6.4)	0.42	0.72

PBPV: Pre-op n=51, post-op n=45 (%), PV: Pre-op n=88, post-op n=78 (%), * mean %; ± standard deviation, † Post-op p-value PBPV compared to PV.

An anatomically successful outcome was achieved in 41 (91.1%) of PBPV cases and in 68 (87.2%) of PV cases (p 0.57) and a repeat procedure was respectively performed in 3 (6.7%) compared to 4 (5.1%) women (p 0.71).

Discussion

The addition of a perineal repair in combination with a posterior vaginal repair did not result in any observed benefit in this population. The routine addition of a perineal repair to that of a posterior vaginal repair creates controversy due to a lack of evidence. A concomitant perineal repair has been reported in approximately 50-80% of posterior vaginal wall repairs (9)(4) and in this series, this was the case in 36.6% of posterior repairs. The question that needs answering is whether this procedure adds benefit or harm to the prolapse repair.

The anticipated outcomes include correction of level 3 defects, narrowing of the genital hiatus, and increasing the functional vaginal length (10)(4). We were able to report on prolapse staging, but not on specific POP-Q measurements, such as TVL and GH, in this series. Significantly less stage 0 posterior prolapse was observed when a PB repair was added to the posterior repair (p=0.02). This was likely due to the supportive shelf effect that the corrected perineal body added in the distal vagina. A concern with traditional posterior colporrhaphy with perineorrhaphy was the high rate of de novo dyspareunia of nearly 50% in some series ((20)(21)(9). This is a concern when an indication for perineorrhaphy includes an expected improvement in sexual function (4). There was no significant deterioration or improvement in sexual function between the two groups in this series. A plausible explanation for the absence of de novo dyspareunia was a restrictive approach towards trimming of the vaginal epithelium and the avoidance of incorporating the puborectalis muscle in the perineal body or posterior vaginal repair.

Obstructed defecation and anal incontinence were significantly improved within both groups, but there was no difference between the two groups (p=0.23 and 0.32 respectively). A comparable improvement was noted in overall bladder function and recurrent urinary tract infection respectively, but once again with no difference between the cases and controls (p=0.14 to 0.52). The improvement in bowel symptoms were similar to those reported in the colorectal literature as seen with transanal approaches (22)(23)(13)(24). The addition of a perineal body repair particularly in case of large rectoceles has furthermore been shown to be associated with improved defecatory symptoms (25), a difference which we did not observe in this series.

There is very little objective indication for a perineal body repair. Some authors recommend it in cases of large rectoceles, rectal intussusception and obstructed defecation due to the association of pudendal neuropathy and chronic straining with perineal descent (26). Others recommend it for low, symptomatic rectoceles where the technique described consists of a diamond shaped excision of the distal vaginal and perineal skin and re-approximation of the superficial perineal and bulbospongiosus muscles (27). A pertinent part of the ambiguity in regards to indication and technique has been the lack of terminology for anorectal dysfunction. This has recently been addressed by a comprehensive document with multidisciplinary input jointly compiled by IUGA and ICS (28).

There are however limitations to this study. It is retrospective in nature and there is acknowledged bias that accompanies these reports. The data was however captured in a database in a prospective way which limits recall bias. An additional reduction in bias was achieved by avoiding post-operative clinical evaluation by the operating surgeon. The clinicians were also not constant during this period due to the rotation of residents during their training. We did not include specific POP-Q measurements in our report and were not able to identify an objective indication for a perineal body repair, other than a perceived deficient perineum. This is however in accordance with current literature and emphasizes a shortcoming in the existing literature. A confounding variable is furthermore that the PV group initially presented with an adequate perineal body and therefore not offered a PVPB repair. The strength of this study lies in its description of a novel surgical approach for reconstruction of the perineal body, the limitation of the operating surgeons to two clinicians, and a follow-up period of more than two years.

The value that the addition of a perineal repair might add to a posterior vaginal repair has not been specifically addressed in the literature as far as could be identified. The data reported on is furthermore structured and robust and it provides a reassuring report on the subjective and objective clinical outcomes. It does however indicate that there was little clinical benefit in this population with the addition of a perineal body repair to that of a posterior vaginal repair.

Conclusion

A perineal body repair as described in this manuscript, is an anatomically accurate transvaginal procedure in those patients diagnosed with a perineal body defect. The symptomatic and anatomic outcomes seen with this procedure demonstrated significant clinical improvement with a low complication rate in experienced hands. Of note is the absence of de novo dyspareunia in these women. Further research is however required and this should incorporate the newly released IUGA/ICS anorectal terminology (28), consist of an adequately powered randomized trial and attempt to identify the indications for a perineal body repair.

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CHAPTER 10

RECTOCELE PLICATION COMPARED TO A DEFECT-SPECIFIC REPAIR FOR THE CORRECTION OF A RECTOCELE

10.1 INTRODUCTION

The surgical options for repair of a rectocele have been discussed in Chapter 6. The technique and outcomes of a rectocele plication have been discussed in Chapter 8. This chapter deals with the results of a randomized controlled trial comparing two transvaginal procedures for the repair of a rectocele. The procedures compared are a rectocele plication and a defect-specific rectocele repair.

10.2 STATISTICAL DESIGN

The standard RCT is designed with the purpose to determine whether one intervention is superior to another. Alternative randomized designs are equivalence and non-inferiority trials. Equivalence trials aim to determine whether an intervention is similar to another existing treatment or procedure (Piaggio et al. 2012). Non-inferiority trials aim to determine whether an intervention is not worse than an existing treatment or procedure. To achieve this, a predetermined margin defining non-inferiority needs to be set. The procedure or treatment can then be recommended if it is similar to or better than the comparative procedure, but not if it is worse by more than the predetermined margin. It is therefore designed to show that the new treatment or procedure is similarly effective to an existing one and that it might have some additional advantages hypothesized by the investigator.

There are specific features that are essential in the design of a non-inferiority trial. The efficacy of the reference procedure has to be known and the participants and outcome measure should be similar to those in which the efficacy was determined. The sample size can then be calculated based on the expected outcomes and taking into account the predetermined margin of non-inferiority. Non-inferiority trials seem to be common from an objective point of view, but infrequent from the point of correct design for a trial of such nature when reviewing the literature. The potential advantage of a non-inferiority RCT design is firstly for the introduction of a new procedure in comparison to an existing intervention and secondly in the required number of participants, which is less than that required in a standard superiority RCT design. Reporting of non-inferiority RCTs follow the same CONSORT guidelines applicable to any other RCT (Lesaffre 2008).

10.3 CLINICAL OUTCOMES AFTER POSTERIOR COMPARTMENT SURGERY

10.3.1 ANATOMIC SUCCESS

The reported anatomic success rates are generally high after rectocele repairs, but the functional success varies (Beck & Allen 2010). This is the case irrespective of the route of repair. Arezzo et al. noted that most rectal surgical procedures for evacuatory disorders did not show superiority over the others in part due to a lack of prospective trials. The outcome is usually good in the short term, but long term follow-up showed that most procedures carried a high recurrence rate. They deemed that this was possibly due to a lack of identifying the underlying functional problem. (Arezzo & Pescatori 2009). A gradual deterioration in clinical outcome was noted for both transanal and transvaginal (levatorplasty) repairs (Chung et al. 2012).

The concern that a defect-specific repair with or without levator plication does not address the rectal defect and only masks it with overlying tissue was clearly demonstrated in a study comparing the transanal to the transvaginal route with the aid of post-operative defecography. By means of post-operative defecography evaluation, Chung et al. demonstrated that superior long term outcomes were present in patients in whom the rectal wall defect were successfully corrected (Chung et al. 2012). Abdominal repair of a rectocele with mesh extending down to the perineum exhibited good anatomic results, but functional results were not agreeable with 50% of patients complaining of constipation and 36% of incomplete bowel emptying (Fox & Stanton 2000). This suggested that the mesh had a propensity for covering the bulge, but not to correct the rectal defect. This could also be observed in a Russian study of posterior vaginal mesh in patients with ODS. At a mean follow-up of 19 months, there was an anatomic failure rate of only 10%, i.e. a clinically detected vaginal bulge. This however did not correlate with the functional outcome as determined from validated questionnaires. The authors commented that this was suggestive of a persistent disorder affecting bowel function, in the absence of a vaginal bulge. (Tsar'kov et al. 2012). Leanza et al. indicated that better anatomic results were assured after vaginal surgery, while better rectal function prevailed after the transanal approach (Leanza, Intagliata, Leanza, M. A. Cannizzaro, et al. 2013). In the largest retrospective study of posterior compartment repairs (n=307), prolapse recurrence rates beyond the hymeneal ring were 4% for traditional colporrhaphy versus 11% for site-specific defect repair, with no observed differences in postoperative dyspareunia, constipation, or fecal incontinence (Abramov et al. 2005).

It is thus relevant to question this variation in reported outcome for a specific condition. Certain authors stated that the correct patient selection for surgical repair was

associated with a success rate of up to 82% after 12 months (Khubchandani et al. 1983) (Sommai Sehapayak 1985) whilst others hardly ever observed failures. Cespedes stated: “I have not seen a symptomatic recurrence in more than 225 rectocele repairs” and was of the opinion that rectoceles rarely recur after a well-performed rectocele repair (Cespedes 2011). Sloots et al. were of the opinion that selection of patients for rectocele repair should be performed based on evacuation and protrusion complaints, but that anorectal function or colonic transit time measurements had a limited role to play (Sloots et al. 2003).Strict inclusion criteria were used by Hall et al., who included patients with a rectocele and ODS, but excluded those with associated slow-transit constipation form surgical repair. Their strict inclusion criteria resulted in a 5.8% recurrence rate with a statistically significant improvement in QOL (p=0.04) (G. Hall et al. 2014).

Rectocele recurrence requires a thorough evaluation in regards to the possible predisposing factors. This should be corrected as much as possible before a repeat procedure is attempted. When it comes to the repeat repair itself, some advocate a perineal approach for a failed abdominal repair and an abdominal approach for a failed perineal repair (Berman et al. 2005). The long-term recurrence after transanal rectocele repair in 71 women followed up for a mean of 74 months was 40.8%. The optimal predictive factor for rectocele recurrence in this series was the persistence of initial symptoms two months after surgery. (Roman & Michot 2005).

It can therefore be seen that the anatomic success rate varies, irrespective of the procedure or technique chosen. It is not yet clear which specific pre-operative factors are indicative of a superior anatomic outcome, but what is apparent is that patients should be selected for a surgical repair only after a comprehensive review of their anatomical defect(s) and associated functional impairment(s).

10.3.2 FUNCTIONAL SUCCESS

The traditional posterior colporrhaphy resulted in a variety of post-operative pain-related disorders due to the non-anatomical suturing of the pubococcygeus components of the levator ani muscle in the midline. Dyspareunia was initially emphasized, but the described pain disorders consisted of more than only that (Weber et al. 2000). It was reflected amongst others with higher rates of postoperative urinary retention, which was probable due to the inability to void normally as a result of levator dysfunction associated with the plication of the muscle. (Book et al. 2012). Where a levatorplasty was not included, there was often an improved functional outcome. This could be seen in an improved functional levator muscle and decreased rates of dyssynergic defecation after such surgical repairs (Liang et al. 2015). Results from a prospective combined transvaginal and transanal approach where levatorplasty was performed, found that after rectocele repair 8.6% of patients experienced deterioration in fecal continence, and dyspareunia developed in 41% of the sexually active patients (J. van Dam, Huisman, et al. 2000). It has however been acknowledged that there was a poor correlation between symptoms and anatomic measures for the posterior compartment (C L Grimes et al. 2014). Bowel symptoms often persist to an extent after rectocele repairs and it is important to counsel patients accurately in order to avoid creating unrealistic expectations. In an ancillary analysis of a RCT for rectocele repair, the authors found that the overall prevalence of bowel symptoms decreased, but did not resolve completely after transvaginal posterior compartment repairs. Splinting decreased from 56% to 23%, straining from 74% to 37%, and incomplete evacuation from 85% to 19% ($p < 0.001$ for all). Nearly half of the women however still had persistent symptoms (V. W. Sung et al. 2012).

Polin et al. evaluated QOL symptoms after a transvaginal rectocele repair alone in a retrospective series of 66 women followed up for a mean period of 31 months. They showed that the PFDI-20 and PFIQ-7 scores were significantly improved following surgery, with a median pre- and post-operative difference of 35.4 ($p<0.001$) and 31.0 ($p=0.002$), respectively. The bowel symptoms, specifically, often persisted to a lesser degree (Polin et al. 2012).

Gustilo-Ashby et al. reported on bowel symptoms one year after surgery in a further analysis of the Paraiso RCT of rectocele repairs (Gustilo-Ashby et al. 2007) (Paraiso et al. 2006). They found that these symptoms were on average significantly improved one year after surgery. A reduction in postoperative straining and incomplete emptying were specifically associated with anatomic cure in the posterior compartment. New bothersome bowel symptoms however occurred in 11% of participants. Similar improvements were reported by Sloots et al. after posterior colporrhaphy. They additionally demonstrated that anorectal function was unaltered after this type of rectocele repair (Sloots et al. 2003). The failure to reduce postoperative constipation and manual disimpaction rates remained a problem in nearly 50% of patients (C. Maher et al. 2004) (Kenton, Shott, et al. 1999). The outcome for AI was varied in surgical reports. Anal incontinence improved after transperineal repair of rectocele, but very few patients were fully symptom free. Ayabaca et al. very importantly recommended that pelvic floor rehabilitation was also needed to achieve better sphincter function in women after surgical repair of a rectocele (Ayabaca et al. 2002).

The colorectal literature contains numerous reports documenting defecatory improvement through a transanal approach using, as an alternative, endorectal plication to reduce rectal lumen size and restore anatomy of the anterior rectal wall musculature. Over the past decade, these studies have shown improvements in

bowel- related symptoms and sexual function in up to 50% of patient (Davis & Kumar 2005).

10.4 CHOICE OF PROCEDURE

A concern of dyspareunia after posterior colporrhaphy was initially highlighted by Jeffcoate et al. (Jeffcoate 1959). This consequence after posterior colporrhaphy was associated with levator muscle plication and was confirmed in subsequent reviews of this technique (Beck & Allen 2010). The traditional posterior colporrhaphy with levator ani plication was consequently largely replaced by fascial repairs with similar anatomic success rates but more favorable functional outcomes. The fascial repairs were either defect-specific repairs or midline plication of rectovaginal fascia.

The defect-specific repair was chosen to be compared to the rectocele plication in the trial reported in this chapter. The choice of procedure was based on the theory of discrete rectovaginal fascial breaks being responsible for the development of a rectocele as was described by Richardson, but also supported by other authors more recently (Richardson 1993)(Cundiff et al. 1998)(DH Nichols 1991)(Guzmán Rojas, Kamisan Atan, et al. 2015). In a large RCT evaluating the effect of porcine dermis, further evidence supporting the outcome and selection of this procedure was obtained. Sung et al. randomized 160 women with posterior compartment prolapse. The native tissue repairs consisted of a midline fascial repair as described by Maher et al. or a defect-specific repair as described by Cundiff et al. (C. Maher et al. 2004)(Cundiff et al. 1998). The 12-month follow-up evaluation found no difference between the two procedures in regards to anatomical failure (V. Sung et al. 2012). The Cochrane review stated that a midline fascial plication as described by Maher et al. is superior to a

defect-specific repair (C. Maher et al. 2004)(Maher et al. 2013). The reported outcomes for a midline fascial plication was a mean anatomic success rate of 83% (76-96%) and 26% of women experienced post-operative obstructed defecation. The reported outcomes for a defect-specific repair showed a mean anatomic success rate of 83% (56-100%) and 18% of women experienced post-operative obstructed defecation. The comparative trials however incorporated variations in surgical technique, definitions of anatomic success and evaluation of post-operative functional outcome. This resulted in a lower level of evidence being available (Karram & Maher 2013). Lastly, the choice of procedure was based on the familiarity of the researchers with a specific procedure. This element is of vital importance in a surgical trial of this nature, for an inferior surgical technique will invalidate any findings made.

10.5 SUMMARY

This chapter incorporates all the preceding elements of this thesis in the research report that follows. It consists of a comparison of two transvaginal techniques for the surgical repair of a rectocele in symptomatic women. This includes the elements of QOL determination through South African-validated QOL questionnaires, standardised clinical examination by means of the ICS POP-Q, pelvic floor imaging with 2D TPUS, functional investigations limited to that which are feasible in a resource limited setting, and surgical procedures with their focus of repair based on the prevailing theories of the pathogenesis of a rectocele.

The statistical design is that of a non-inferiority randomized trial according to the CONSORT guidelines. The sample size and rationale for this design is based on the findings of efficacy from retrospective procedural analysis of a rectocele plication and

literature reported outcomes of a defect-specific repair within the specific pragmatic constraints of the healthcare setting in which this research will take place.

The anatomic and functional outcomes reported in the literature is varied and reflective of a range of procedures which involve different anatomical corrections. This trial will compare the correction of the vaginal defect to that of the rectal defect, which in essence is the belief along which the current literature is divided.

The motivation for the selection of the defect-specific repair as the comparator is that of the available evidence and practical implementation of this technique. A finer dissection of the defect-specific fascial repair and the midline fascial plication techniques, nonetheless indicates different descriptions of similarly principled anatomic approaches.

10.6 PREPARED ARTICLE: A RANDOMMIZED TRIAL OF TWO SURGICAL TECHNIQUES FOR THE TRANSVAGINAL REPAIR OF A RECTOCELE (ADDENDUM 19)

A double-blind, non-inferiority randomized controlled trial of transvaginal procedures for the repair of a rectocele

Abstract

BACKGROUND: Posterior compartment prolapse is a prevalent condition. It is mostly due to a rectocele and often accompanied by defecatory disorders. A large number of surgical procedures have been described to correct a rectocele. There are very few randomized trials to assess these procedures.

OBJECTIVE: To randomly evaluate a defect-specific posterior repair (DSR) to a rectocele plication repair (RPR) in regards to objective and subjective outcomes.

DESIGN: A non-inferiority randomized trial design was followed and participants who required a surgical repair of a rectocele were enrolled to either a RPR or a DSR after consenting. A non-inferiority margin of 15% was identified, based on the reviewed literature. A pragmatic approach was followed in regards to participant assessment and follow-up due to limited healthcare resources. Assessors and participants were blinded to the allocated treatment. Data were analyzed and reported on after 12 months of follow-up.

RESULTS: 27 Participants were randomized to DSR and 28 to RPR. The 12-month follow-up was completed by 26 participants in each group. There was no difference in

operative parameters or complications. Anatomic success was present in 20 (76.9%) participants in the DSR group and in 24 (92.3%) of those in the RPR group (p=0.2485, 95% CI -13.6; 42.5). Symptomatic improvement was significantly greater in the RPR group for awareness of a vaginal bulge (p=0.0226), obstructed voiding (p=0.0238) and overactive bladder (dry) (p=0.0266). Quality of life outcomes were furthermore significantly greater among the RPR participants in regard to the questionnaire scores of the PFDI-20 (p=0.0160) and the PFIQ-7 (p=0.0041). There was no difference in the PISQ-12 questionnaire scores or in reported sexual function between the two groups.

CONCLUSIONS: The rectocele plication procedure was not inferior to a defect-specific posterior repair for women with a rectocele. There were however significant differences in subjective outcome which favored a rectocele plication.

TRIAL REGISTRATION: South African National Clinical Trials Registry. NHREC #4529.

KEY WORDS: Rectocele, defect-specific, randomized, voiding dysfunction, obstructed defecation, non-superiority.

INTRODUCTION

A rectocele is defined as a bulge in the posterior vaginal wall that is associated with herniation of the anterior rectal wall (1). The prevalence of a rectocele has been documented in up to 76% of women presenting with pelvic organ prolapse (POP), but also in 12-81% of asymptomatic nulliparous volunteers (2)(3)(4)(5). Moreover, a posterior vaginal procedure is performed in 40-85% of cases in women undergoing

surgical repairs for POP. Isolated rectoceles are however less common and observed in only approximately 7% of women presenting for surgical repair (6)(7)(8).

The recognized symptoms associated with a clinically significant rectocele are obstructed defecation (OD) with splinting and the awareness of a vaginal bulge (9)(10). It has furthermore been stated that the majority of women with an isolated rectocele have no defecatory symptoms and that such cases can be regarded as not in need of interventional measures (11). The complexity of OD has been illustrated using the "iceberg diagram" to describe the potential attendant disorders that need to be considered prior to surgery (12). This has resulted in the recommendation of an expansive workup of such patients (13). Such evaluations are often not possible in resource limited healthcare environments where there are a lack of human resources as well as access to specialized diagnostic equipment (14). The mindfulness of defecatory disorders is the traditional divide between the colorectal and gynecologic approaches and is reflected as such in the literature.

A multitude of surgical approaches and procedures has been described to correct a rectocele (6). The defect-specific posterior repair (DSR) was originally described by Richardson and has been used universally by gynecologists with good reported outcomes (15)(16)(17). Colorectal surgeons on the other hand prefer to correct the rectal disorder by means of transanal or abdominal procedures (18)(19). The anatomic success rate of all procedures is generally good, but there is significant variation in the quality of reporting and levels of evidence. This limit comparative analyses of procedures. There is furthermore a lack of randomized trials, with only four having been reported in the literature (20)(21)(22)(23).

A rectocele plication has been performed in the local urogynecology unit for the past 8 years. This is a vaginal procedure, but the focus of repair is on the anterior rectal wall defect, which is similar in philosophy to the transanal procedures. The observed clinical outcomes have been encouraging, but it has never been prospectively assessed. The aim of this study was thus to randomly assess a rectocele plication repair (RPR) compared to a DSR in regards to objective and subjective outcomes. A non-inferiority randomized trial design was selected. The healthcare setting was a resource limited environment and the study design concentrated on a frugal, yet pragmatic approach to these women in reflection of this environment (24)(25).

MATERIALS AND METHODS

Study design

This was a prospective non-inferiority, randomized controlled trial comparing two surgical techniques for the repair of a rectocele. The trial was conducted in a referral urogynecology unit in a teaching hospital in Bloemfontein, South Africa between December 2014 and December 2016. Institutional ethics committee approval was obtained (ECUFS 222/2014) and the trial was registered with the South African National Clinical Trials Registry (NHREC 4529). All participants provided written informed consent at the time of recruitment. The primary objective was to evaluate the anatomic success 12 months after surgical repair of a rectocele. This was defined as an International Continence Association (ICS) Pelvic Organ Prolapse Quantification (POP-Q) stage < 2 in the posterior compartment (26). Secondary end points included comparison of quality of life (QOL), uroflow and transperineal ultrasound (TPUS) measurements. Participants were evaluated by a blinded assessor at 8 weeks, 6

months and 12 months after surgery. Terminology used was in accordance with the joint reports of the International Urogynecological Association (IUGA) / International Continence Society (ICS) (27)(1) All evaluations included both objective and subjective outcome measures. The objective assessment consisted of clinical examination by means of the POP-Q system (26), free uroflowmetry (27), and 2-dimensional TPUS examination (28). All these were technically performed in accordance with the referenced literature. The subjective outcomes were assessed through three validated, condition-specific QOL questionnaires, the Pelvic Floor Distress Inventory-20 (PFDI-20), the Pelvic Floor Impact Questionnaire-7 (PFIQ-7) and the Pelvic Organ Prolapse/Incontinence Sexual Questionnaire-12 (PISQ-12) (29)(30). A numeric pain scale was used to assess post-operative pain and the Patient Global Impression of Improvement (PGI-I) was used to explore individual perceptions after surgery (31). The PGI-I was dichotomized for coding into two categories. An answer of any improvement (options 1-3) was classified as “improved” and no improvement or any deterioration (options 4-7) was classified as “not improved”.

Patients

Adult women who were seen at the urogynecology outpatient department and considered to require a surgical repair of a rectocele were approached to participate by the researcher. Exclusion criteria included the following: previous POP surgery with mesh, previous rectocele repair, concomitant pelvic floor procedures, current anticoagulant therapy, chronic pelvic pain syndrome or fibromyalgia and undiagnosed rectal bleeding.

Randomization, allocation, and blinding

Consenting participants were randomly assigned (1:1) to either a DSR or a RPR. Randomization was by means of a sequence provided by the Department of Biostatistics, University of the Free State, South Africa. Sequentially numbered sealed envelopes were drawn in theatre prior to surgery by the scrub nurse to indicate group allocation. Participants and staff members who performed the post-operative assessments remained blinded to the group assignments.

Surgical technique

The surgery was performed by a single urogynecology consultant with experience of > 50 cases for each procedure. A transvaginal approach was used for both procedures with the participant in the lithotomy position. A vasoconstrictor-containing solution was used prior to the vaginal incision (32). The DSR technique consisted of a posterior midline vaginal incision with dissection of the rectovaginal space to the apex of the vagina. Fascial defects were identified and individually repaired with interrupted 2/0 polydioxanone sutures. Superior transverse defects were sutured to the pubocervical fascia or to the attachment of the uterosacral ligaments at the apex of the vaginal vault in cases with a prior hysterectomy.

The technique of dissection for the RPR consisted of a full thickness mobilization of the vagina off the rectum to the apex of the defect. Care was taken to avoid injury to the puborectalis muscle fibers. The index finger of the surgeon was introduced transanal and interrupted 2/0 polydiaxonone sutures were inserted in the rectal muscularis. The rectal finger guided the depth of suture placement and prevents mucosal penetration. Sutures were inserted longitudinally in a zig-zag pattern from the

apex of the defect to the level of the perineal membrane and positioned approximately 10 mm apart. They were individually tied. A perineal body repair could be performed with either procedure if indicated. An acriflavine impregnated vaginal pack was inserted and removed the following day.

Statistical analysis

The sample size calculation was for a non-inferiority randomized clinical trial with a binary outcome. The success of DSRs identified in the literature was approximately 80%. A non-inferiority limit of 15% was deemed to be of clinical significance and centered on the expected difference in anatomical outcome of 10% between the two procedures. Transanal procedures described in literature for the correction of a rectocele generally have a lesser anatomic success rate (approximately 75%) to those performed vaginally (approximately 80%) (17). The functional outcomes however report improvement in both the transanal and vaginal categories for anatomic success rates ≥ 75%(17)(33). A non-inferiority limit of 15% (delta value) less than the anticipated anatomic outcome of 90% for the RPR was thus projected to be clinically accurate. Based on this model, a sample size of 54 participants (25 per arm, assuming 8% will be lost to follow-up) was calculated to provide a significance level of 0.05 (α) with a power of 80% to identify non-inferiority for the rectocele plication technique. The data of this study were summarized descriptively. Inferential statistics were based on the Kruskal-Wallis test for quantitative data, and the Freeman-Halton test for qualitative data. Sequential non-inferiority and superiority analyses with hierarchical end-point testing were used with the calculation of 95% confidence intervals (CI). This

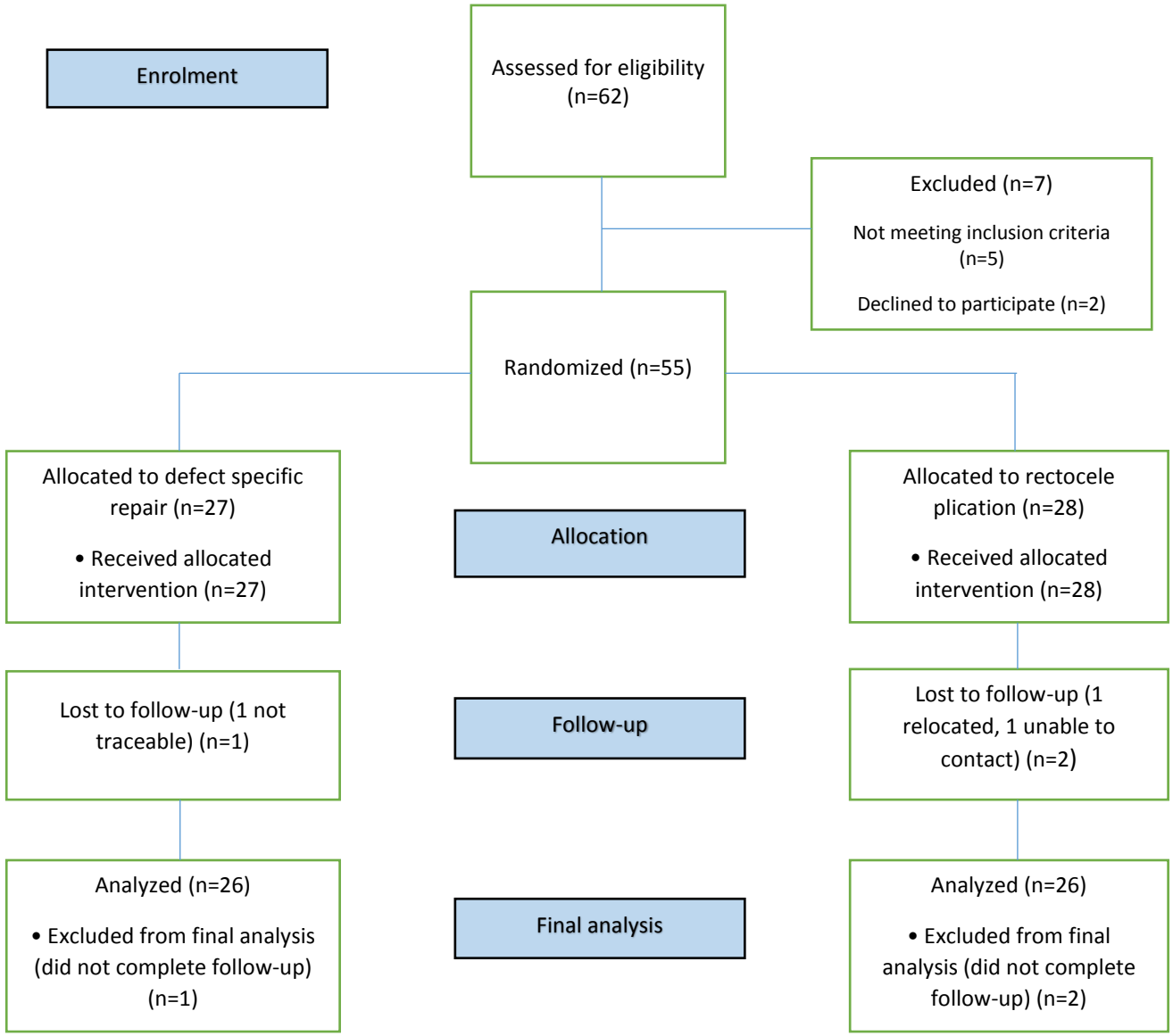
was by means of the Hodges-Lehman method for quantitative data and the Exact unconditional method for qualitative data.

RESULTS

Participants were recruited from 1 December 2014 until 15 December 2015. A total of 52 participants (26 controls and 26 RPR) completed the 12 months follow-up. The study population is presented in Figure 1.

There was no significant difference between the groups in terms of the baseline characteristics (Table 1). The mean age was 60 years and the mean parity was 3. The mean body mass index (BMI) of > 30 kg/m^2 documented in both groups, categorized the study population as obese (34). The majority of participants in the RPR group (67.9%) had prior pelvic floor surgery.

Figure 1: Flow of study participants and randomization.



Prominent baseline symptoms in the DSR and RPR groups respectively (Table 2) were that of a vaginal bulge (88.9% and 82.1%), obstructed defecation (44.4% and 67.9%) and obstructed voiding (51.9% and 42.9%). These were also the leading indications to proceed with surgery after failed conservative treatment. The mean baseline POP-Q measurements in both groups (Table 3) for the posterior compartment, Ap and Bp, were in keeping with a Stage 3 rectocele. The mean of the average flow during uroflowmetry at baseline was 7.93 (±3.41) ml/sec among the

participants randomized to a DSR and 8.39 (±3.54) ml/sec among those of the RPR group (p=0.7288). The size of the rectocele was measured by TPUS. The mean height of the rectocele was 26.22 (±7.71) mm among the DSR participants and 24.68 (±8.65) mm among those assigned to RPR (p=0.5835).

Table 1: Baseline demographic characteristics of participants.

Metric	Defect-specific repair (N=27)	Rectocele plication (N=28)	P-value
Age, years	60.04 (10.64)	60.18 (8.91)	0.8927
BMI, kg/m^2	30.15 (6.34)	31.53 (6.41)	0.2700
Race			0.5162
Black	11 (40.7)	8 (28.6)	
White	13 (48.1)	14 (50.0)	
Other	3 (11.1)	6 (21.4)	
Parity	3.15 (1.20)	3.29 (1.18)	0.8591
Vaginal delivery	2.93 (1.36)	2.86 (1.38)	0.5914
Cesarean section	0.22 (0.51)	0.50 (0.75)	0.1309
Menopausal	21 (77.8)	22 (78.6)	1.0000
HRT	4 (14.8)	4 (14.3)	1.0000
Previous hysterectomy	14 (51.9)	14 (50.0)	1.0000
Previous POP surgery	7 (25.9)	15 (53.6)	0.0543
Previous UI surgery	1 (3.7)	4 (14.3)	0.3516
Smoker	3 (11.1)	3 (10.7)	1.0000
Chronic cough	4 (14.8)	7 (25.0)	0.5027
Family history POP/UI	15 (55.6)	13 (46.4)	0.8569

BMI = Body mass index, HRT = Hormone replacement therapy, POP = Pelvic organ prolapse, UI = Urinary incontinence. Data are presented as number of participants (%) or as mean (±Standard deviation).

Table 2: Subjective outcomes at baseline and after 12 months

Measurement	Defect-specific repair (N=27)	Rectocele plication (N=28)	P-value
Vaginal bulge			
Baseline	24 (88.9)	23 (82.1)	0.7049
12 Months	5 (18.5)	0 (0.0)	**0.0226***
Constipation			
Baseline	12 (44.4)	20 (71.4)	0.0577
12 Months	16 (59.3)	8 (28.6)	0.0505

Obstructed defecation			
Baseline	12 (44.4)	19 (67.9)	0.1060
12 Months	6 (22.2)	1 (3.6)	0.0993
Anal Incontinence			
Baseline	8 (29.6)	8 (28.6)	1.0000
12 Months	6 (22.2)	4 (14.3)	0.7265
Obstructed voiding			
Baseline	14 (51.9)	12 (42.9)	0.5932
12 Months	8 (29.6)	1 (3.6)	**0.0238***
RUTI			
Baseline	7 (25.9)	8 (28.6)	1.0000
12 Months	3 (11.1)	0 (0.0)	0.2353
OAB (dry)			
Baseline	11 (40.7)	10 (35.7)	0.7848
12 Months	11 (40.7)	3 (10.7)	**0.0266***
OAB (wet)			
Baseline	4 (14.8)	7 (25.0)	0.5027
12 Months	1 (3.7)	0 (0.0)	1.0000
SUI			
Baseline	3 (11.1)	7 (25.0)	0.2955
12 Months	2 (7.4)	0 (0.0)	0.4902
Dyspareunia			
Baseline	8 (29.6)	6 (21.4)	0.6985
12 Months	0 (0.0)	0 (0.0)	1.0000
Not sexually active	10 (37.0)	13 (46.4)	1.0000
Baseline	11 (40.7)	10 (35.7)	1.0000
12 Months			
PFDI-20			
Baseline	129.30 (55.35)	133.18 (43.01)	0.4588
12 Months	38.62 (48.26)	14.12 (30.83)	**0.0160***
PFIQ-7			
Baseline	101.52 (68.52)	111.25 (66.75)	0.5784
12 Months	28.75 (40.87)	9.15 (27.34)	**0.0041***
PISQ-12			
Baseline	20.59 (9.86)	22.93 (8.16)	0.4162
12 Months	32.56 (5.19)	30.40 (5.03)	0.2573
PGI-I (12 Months)			
Improved	19 (70.4)	25 (89.3)	**0.0496***

RUTI= recurrent urinary tract infection, OAB= overactive bladder, SUI= stress urinary incontinence. Data are presented as number of participants (%), PFDI-20 and PFIQ-7 data are presented as score/300 and PISQ-12 data as score/48. ***** P-value ≤ 0.05.

Table 3: Objective assessments at baseline and at 12 months follow-up.

Measurement	Defect-specific repair (N=27)	Rectocele plication (N=28)	P-value
POP-Q			
Aa (baseline)	-1.76 (0.58)	-1.63 (0.75)	0.4403
Aa (12 months)	-1.46 (0.66)	-1.62 (0.36)	0.2568
Ba (baseline)	-1.89 (0.67)	-1.80 (0.58)	0.4521
Ba (12 months)	-1.50 (0.68)	-1.69 (0.32)	0.1589
GH (baseline)	4.32 (1.74)	4.54 (1.03)	0.8885
GH (12 months)	4.14 (0.36)	4.15 (0.61)	0.9069
PB (baseline)	2.89 (0.56)	3.00 (0.62)	0.4652
PB (12 months)	3.31 (0.38)	3.31 (0.49)	0.9690
TVL (baseline)	9.67 (1.36)	9.98 (1.06)	0.7136
TVL (12 months)	9.37 (0.87)	8.94 (3.87)	0.3454
C (baseline)	-6.41 (2.99)	-7.48 (1.00)	0.1060
C (12 months)	-6.98 (0.78)	-6.67 (2.87)	0.4333
D (baseline)	-7.62 (1.45)	-8.50 (1.16)	0.1914
D (12 months)	-7.58 (1.24)	-7.60 (2.23)	0.4438
Ap (baseline)	1.41 (0.87)	1.64 (0.87)	0.3276
Ap (12 months)	-1.31 (1.05)	-2.04 (0.63)	**0.0009***
Bp (baseline)	1.35 (0.91)	1.48 (0.92)	0.7415
Bp (12 months)	-1.31 (1.08)	-1.89 (1.00)	**0.0064***
Uroflow			
Average (baseline)	7.93 (3.41)	8.39 (3.54)	0.7288
Average (12 months)	9.35 (3.69)	11.50 (3.58)	**0.0208***
Peak flow (baseline)	17.89 (7.13)	17.54 (7.11)	0.8397
Peak flow (12 months)	27.35 (35.11)	24.57 (7.25)	0.0725
PVR urine volume (baseline)	30.22 (48.48)	27.57 (31.85)	0.7680
PVR urine volume (12 months)	17.96 (18.66)	18.08 (27.84)	0.3740
TPUS			
Rectocele height (baseline)	26.22 (7.71)	24.68 (8.65)	0.5835
Rectocele height (12 months)	12.50 (6.57)	8.31 (3.25)	**0.0006***
Rectocele length (baseline)	22.93 (8.69)	19.75 (6.79)	0.1855
Rectocele length (12 months)	13.08 (5.97)	9.85 (5.30)	**0.0201***
Intussusception (baseline)	7 (25.9)	7 (25.0)	1.0000
Intussusception (12 months)	6 (22.2)	1 (3.6)	0.0993

POP-Q = Pelvic organ prolapse quantification (cm), DRE= Digital rectal examination, PVR = Post void residual urine volume (ml), TPUS = Transperineal ultrasound. Data are presented as number of participants (%) or as mean (±Standard deviation).***** P-value ≤ 0.05.

There was no significant difference (p=0.2961) in the type of anesthesia given to the participants. Concomitant posterior compartment procedures included an enterocele and perineal body repair in the DSR (3.7% and 18.5% respectively) and RPR (10.7%

and 28.6% respectively) groups. The mean procedure time was 30.79 (±6.34) minutes for a DSR and 33.19 (±8.22) minutes for a RPR (p=0.3459) and the mean operative blood loss was 73.56 (±43.06) ml and 68.64 (±27.43) ml respectively (p=0.7617). There was one intra-operative complication (palpitations after injection of the vasoconstrictor solution) in the DSR group and none in the RPR group. Apical fascial defects were the leading type of defect (n=19, 70.4%) among the DSR participants.

The pain score and analgesia used is summarized in Table 4. The RPR participants experienced significantly higher post-operative pain scores, but this was not reflected in the analgesia usage. The first bowel motion after surgery was after 28.49 (±6.53) hours in the DSR group and after 29.25 (±7.93) hours in the RPR group (p=0.6673). The mean hospital stay was 2.52 (±0.58) days for the DSR group and 2.74 (±0.54) days for the RPR group (p=0.1687).

Table 4: Post-operative pain score and analgesia use.

Measurement	Defect-specific repair (N=27)	Rectocele plication (N=28)	P-value
Pain score			
6 hours	3.96 (1.95)	5.11 (2.30)	0.0337*
12 hours	3.07 (1.69)	4.32 (2.15)	0.0210*
24 hours	1.70 (1.14)	3.39 (1.64)	0.0001*
36 hours	0.70 (0.91)	1.86 (1.38)	0.0012*
Analgesia doses post-op			
Parenteral analgesia	1.82 (1.00)	2.04 (1.55)	0.66225
Compound oral analgesia	1.22 (1.34)	1.82 (1.54)	0.1429
Simple oral analgesia	3.19 (1.14)	3.50 (1.77)	0.4291
Post-operative pain score			
8 Weeks	0.48 (1.12)	0.82 (1.16)	0.1580
12 Months	0.42 (0.81)	0.15 (0.46)	0.2263

Pains score/10, values 0-10. Data are mean (± standard deviation) * P-Value ≤ 0.05

Post-operative complications occurred in 6 (21.4%) of the RPR participants and in 2 (7.4%) from the DSR group (p=0.2516). This included one Dindo Grade 3 complication

(wound hematoma) in the RPR group which required surgical evacuation. The rest were all Dindo Grades 1-2 and resolved with symptomatic treatment.

The subjective outcomes are summarized in Table 2. The majority of symptoms assessed, showed improvement after either surgical procedure. Significant differences were however calculated in favor of the RPR procedure for that of awareness of a vaginal bulge (p=0.0226), obstructed voiding (p=0.0238) and for OAB (dry) (p=0.0266). There was no de novo dyspareunia recorded in either group. The QOL questionnaires were in keeping with the reported improvement in symptoms. Participants in the RPR group had significantly better scores for the POPDI-20 (p=0.0160) and the PFIQ-7 (p=0.0041) after 12 months than those in the DSR group.

Table 3 summarizes the objective outcome measurements. The RPR group had significantly superior posterior compartment POP-Q measurements after 12 months for both points Ap (p=0.0009) and Bp (p=0.0064). There were also significant differences detected in the uroflowmetry and TPUS measurements 12 months after surgery. The mean of the average uroflow was significantly higher in the RPR group (p=0.0208) and the mean height of the rectocele was significantly lower among the RPR participants (p=0.0006).

Anatomic success, defined as a POP-Q stage < 2 in the posterior compartment, was present in 24 (92.3%) participants form the RPR group and in 20 (76.9%) participants from the DSR group after 12 months (p=0.2485, 95% CI -13.6; 42.5). This margin confirmed non-inferiority of the RPR. The patient reported PGI-I closely matched this number. In the DSR group, 19 (70.4%) participants described themselves as improved and this was the case amongst 25 (89.3%) participants of the RPR group. A repeat

procedure was necessary in 3 (11.1%) participants in the DSR group after a mean period of 12.33 (±0.58) months.

DISCUSSION

This research confirmed that a rectocele plication is not inferior in comparison to a defect-specific repair for women with symptomatic rectoceles. The overall anatomic success rate was not significantly different for the two procedures after 12 months. The patient's perception of improvement, the PGI-I, however favored the RPR procedure one year after surgery (p=0.0496).

It is however when we evaluate the finer details one year after surgery that the difference in improval becomes more evident between the two procedures. The objective measurements showed a significant difference for POP-Q points Ap (p=0.0009) and Bp (p=0.0064), for the height (p=0.0006) and length (p=0.0201) of the rectocele as measured by means of a TPUS examination and for the average uroflow speed (p=0.0208) in favor of the RPR participants. The RPR participants did report significantly higher pain scores immediately after surgery, but this observation was absent at the post-operative assessments. The QOL questionnaires displayed similar findings for the PFDI-20 (p=0.0160) and the PFIQ-7 (p=0.0041) questionnaires in favor of the RPR participants. There was however no difference in the PISQ-12 questionnaire scores or in reported sexual function between the two groups. There was specifically no cases of de novo dyspareunia documented in either group.

The results should be interpreted with appreciation of the constraints of the study design and setting. A non-inferiority design was chosen to allow for the evaluation of a new surgical technique in a single center. The sample size calculation of this design

will differ in respect to the defined margin of non-inferiority. A margin (delta-value) of 15% was selected based on literature reviewed. This might not be the case if other authors wish to repeat this research and could hence have an effect on the conclusions. The procedures were furthermore performed by a single surgeon, which results in the limitation of surgical variables, but does restrict the generalizability of the findings of this study in clinical practice.

The strengths lie with the randomization of the surgical procedures, the structured clinical and QOL evaluations, the blinded post-operative assessments and the limitation of participants to only those that underwent posterior compartment reconstructive procedures.

The RPR procedure was objectively shown to be non-inferior to a DSR for women requiring a surgical repair of a rectocele, but there was a significantly improved subjective outcome among women who underwent this novel procedure after 12 months.

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CHAPTER 11

CONCLUSION AND RECOMMENDATIONS

11.1 INTRODUCTION

Current medical care of all patients should have its origins in evidence-based medicine. New evidence has been documented with regards to the clinical approach of women with rectoceles. This was the first compilation of studies for the evaluation and management of a rectocele in a resource limited healthcare environment. It is the first to linguistically and culturally validate the PFDI-20, PFIQ-7 and PISQ-12 condition-specific QOL questionnaires in a South African population and specifically for the Afrikaans and Sesotho languages. It is the first to empirically demonstrate the influence that pelvic floor imaging has on clinical decision making through the integration of information obtained from a 2D TPUS with that of the clinical assessment. It is furthermore the first study to report on a randomized evaluation of the effect of a rectopexy when added to a sacrocolpopexy in women with advanced POP. The report of a novel surgical technique for the repair of a rectocele and its associated outcomes is the first that integrates the philosophical approaches of gynecologists and coloproctologists. The specific benefit of a perineal body repair at the time of a posterior compartment repair has not been reported in the literature, nor the surgical technique described for this repair. Lastly, the first report of a randomized trial of a rectocele plication compared to a defect-specific repair provided novel scientific data for the surgical approach to a rectocele repair and the observed clinical outcomes in a resource limited environment.

It is evident form the literature that posterior compartment prolapse is often underestimated, its symptoms often misunderstood and its treatment outcomes often unsatisfactory. This research has emphasized the importance of a multimodal approach to this condition. This should consist of a thorough clinical evaluation aided by validated OQL questionnaires, the integration of a pelvic floor imaging modality and the selection of the optimal surgical procedure for an individual when surgery becomes indicated. The evidence obtained from this research will be summarized in this chapter within the context of the initially stated objectives.

11.2 EVALUATION OF RECTOCELES

A rectocele can be expected in approximately 11-19% of women and is present in 40-85% of women requiring pelvic floor surgery for other disorders. There is currently no epidemiological data for the South African population, but there is no plausible reason to suspect that it would be less prevalent. The demographic profile of the patients with isolated rectoceles seen in this population corresponded with that of the published literature. The average age was 58 years, parity 3 and 75% of the patients were menopausal. Overweight and obesity were documented in the majority of patients.

11.2.1 SYMPTOMS

Many symptoms have been described in association with a rectocele, but few have been pertinently associated with this condition. The symptoms that women with isolated rectoceles presented with in this population were (in order of decreasing prevalence):

1. Vaginal bulge (62%)
2. Obstructed voiding (47%)

3. Constipation (46%)
4. Obstructed defecation (41%)
5. Overactive bladder (dry) (33%)
6. Anal incontinence (26%)
7. Recurrent urinary tract infection (21%)
8. Overactive bladder (wet) (21%)

It is relevant to emphasize that these symptoms were the presenting complaints in women with isolated rectoceles, although many of the symptoms would similarly be expected in other pelvic floor disorders. The correlation of rectocele size to symptoms were not performed and this requires further analysis in this population. It is acknowledged that rectoceles are often associated with defecatory disorders, and particularly with ODS. The most consistent component of ODS in rectoceles is the need to perform vaginal or perineal splinting. Sexual dysfunction was not observed to be any more prevalent in this population than in the general population. What has been mostly obscured in the literature is the association of rectoceles with urinary dysfunction. Obstructed voiding was the second most frequent symptom encountered among this population of women with isolated rectoceles. The co-existing urinary symptoms in this population were OAB (dry), RUTI and OAB (wet). These are all part of the irritative lower urinary tract symptom group. It is described as potential prolapse-related lower urinary tract symptoms in the most recent IUGA/ICS terminology paper, but not specifically mentioned to occur in relation to isolated posterior compartment prolapse. The symptomatic improvement after surgery contributes additional information to the symptoms associated with a rectocele in this population (in order of most improvement):

1. Vaginal bulge ($p < 0.0001$)

2. Obstructed defecation ($p < 0.0001$)
3. Recurrent urinary tract infection ($p < 0.0001$)
4. Overactive bladder (wet) ($p= 0.0004$)
5. Obstructed voiding ($p= 0.0011$)
6. Overactive bladder (dry) ($p= 0.0070$)
7. Constipation ($p= 0.0147$)
8. Anal incontinence ($p= 0.1409$)

This provides us with invaluable information to include in the counseling and management plans of patients.

The most significant new finding in relation to the symptoms experienced in this population of women with an isolated rectocele was that of voiding dysfunction and recurrent urinary tract infection. It is apparent form this observation that any woman who experiences obstructive voiding symptoms needs to be assessed for the presence of a rectocele and this information needs to be included in her counseling and management.

11.2.2 CLINICAL EVALUATION

The severity of any POP is staged according to the ICS POP-Q system. In women who present with defecatory disorders or the suspicion of a rectocele it is imperative to perform a DRE. The inclusion of this technique allows one to determine the extent of the rectocele pocket, i.e. size of the defect, to evaluate for any concomitant anorectal disease, to evaluate for anorectal intussusception, to assess the presence and quality of stool, to evaluate the anal sphincter function, to assess the integrity of the perineal body and to assess for the presence of puborectalis dyssynergia. It has

been shown in literature to provide good correlation with anorectal manometry and rectal balloon expulsion tests. It is furthermore an invaluable assessment modality in an environment without access to specialized equipment to evaluate anorectal function.

The identification of the size of a rectocele is through a DRE and not through POP-Q staging alone. The colorectal literature is clear on this aspect and the underestimation of posterior compartment prolapse by means of the POP-Q system has emerged in the urogynecology literature as well. Additional information on rectal sensitivity can be obtained with rectal balloon testing. This is normally a test performed with a calibrated barostat, but often not accessible in many clinical environments. Further research is required on the contribution of this modality in the management of women with rectoceles in a limited resource environment.

11.2.3 QUALITY OF LIFE ASSESSMENT

The application of patient assessed measures of health outcome has become increasingly important for the evaluation of health care. The use of individualized measures to plan treatment additionally allows patients to include different aspect of their lives which might have been influenced by the specific pelvic floor disorder. The instrument(s) chosen for this evaluation has to be psychometrically validated in the specific population. The validity of any findings are otherwise questionable. The condition-specific QOL questionnaires selected for use in this population fulfilled the scientific and practical criteria that was identified beforehand. The validation of the PFDI-20, PFIQ-7 and PISQ-12 questionnaires in the South African languages of Afrikaans, Sesotho and English followed recommended guidelines in regards to the

psychometric properties, sample size and composition. It was furthermore demonstrated that these instruments were responsive in this population. This information provides objective data on patient-reported symptoms at any stage of interaction and should therefore be incorporated in all clinical decisions. The bothersomeness of pelvic floor disorders in specifically black African women in this population was identified for the first time. It became apparent that there was no difference in this ethnic group's experience of their symptoms as compared to any other population group. The higher than expected prevalence of pelvic floor symptoms in the control group among the Sesotho population additionally requires further exploration.

11.2.4 TRANSPERINEAL ULTRASOUND IMAGING OF THE PELVIC FLOOR

Imaging of the posterior compartment is a recommended component of the clinical assessment due to the number of disorders that can lead to the symptoms encountered. The options available are 2D TPUS, 3D TPUS, endorectal ultrasound, endovaginal ultrasound, MRI, MR defecography, conventional defecography and colpocystodefecography. The intention should be to achieve dynamic (functional) imaging which allows for the identification and differentiation of the spectrum of disorders that might be present. The incorporation of imaging of the pelvic floor has been endorsed in the IUGA/ICS terminology papers on POP and anorectal dysfunction. The integration of ultrasound findings in the clinical management has not been described before. It was observed that the integration of the imaging findings altered the initial management plan in 37.6% of women in this population. It was additionally found that the addition of imaging findings may accommodate for a lack of

clinician experience in the clinical assessment of these women. The clinical value of the 2D TPUS findings were most pronounced for those women who were found to have posterior compartment disorders. Most healthcare settings do have access to a basic 2D ultrasound machine, which will allow for a comprehensive pelvic floor assessment. It must be mentioned that a 2D TPUS is not envisaged to replace more specific imaging modalities such as defecography or endorectal / endoanal ultrasound. It is however expected that the majority of women will be sufficiently evaluated with this modality by a skilled operator.

11.2.5 UROFLOWMETRY

A urodynamic investigation is recommended for the functional evaluation of the lower urinary tract in women with voiding dysfunction. Cystometry is the urodynamic investigation mostly performed in women referred to urogynecology departments. This invasive procedure requires specific disposable catheters to allow for the accurate measurement of pressure / volume relationships and clinical interpretation. These disposables are frequently not available in the healthcare setting of this research. Free uroflowmetry was selected due to these factors and the observation of voiding dysfunction possibly associated with posterior compartment prolapse. Uroflowmetry findings are however not absolute and can be influenced by the voided volume and therefore need to be repeated to obtain a more accurate interpretation in cases with initial abnormal results. This was addressed with repeated uroflowmetry at each post-operative visit in the participants randomized to a RPR or a DSR. The uroflowmetry improved significantly after the successful correction of a rectocele among all participants. This was most apparent in the flow speed and it correlated with the

symptomatic improvement of urinary symptoms that the participants reported. This finding suggests that the basis for urinary dysfunction in women with a rectocele is that of an outflow obstruction that is created. Once the rectocele is repaired and the posterior compartment bulge corrected, the urinary symptoms as well as the uroflow improved. This novel information is the first that explains the likely pathogenesis of voiding dysfunction in women with a rectocele.

11.3 MANAGEMENT OF RECTOCELES

Numerous surgical procedures have been proposed for the repair of a rectocele. The underlying pathogenesis can be at any of the three levels of vaginal support and this needs to be considered in the selection of both the surgical procedure and candidate. Surgery can be performed via vaginal, transanal, abdominal or combined approaches.

11.3.1 SACROCOLPOPEXY FOR A RECTOCELE

A rectocele can be corrected through the distal insertion of the posterior mesh during a sacrocolpopexy. This is thought to act as a reinforcement of the defective RVF. The literature does however not support the assumption that this technique will correct a rectocele. The extension of posterior mesh to the level of the perineal body can still result in rectocele persistence or recurrence in 33 – 57% of women. This limitation of a sacrocolpopexy was not evident in the group of women who only underwent a PCSS procedure in our population. The most likely explanation for this was that a concomitant rectocele plication was performed in 57.6% and a perineal body repair in 48.5% of this group, resulting in the introduction of to many variables in the smaller subgroup to test this hypothesis. A sacrocolpopexy however remains the procedure of

choice for women with generalised POP where the apical compartment support is compromised and this suspensory procedure can simultaneously address the presence of perineal descent. Based on the literature studied, a concomitant posterior repair is recommended in the presence of a rectocele.

11.3.2 RECTOPEXY FOR A RECTOCELE

A rectopexy, mostly performed by colorectal surgeons, can be considered for certain rectal disorders. The VMR is the current technique with the best functional outcomes, mostly due to its nerve sparing approach. It is infrequently used for isolated rectoceles. A rectopexy can however be combined with a sacrocolpopexy in women with generalized POP. The main correctional benefit with this combined suspensory approach is in its effect on the levator plate. The risk for surgical failure is increased in women with levator avulsion, even in the presence of extensive suspensory pelvic floor reconstructive procedures. The randomized addition of a VMR in a group of women with severe and generalized POP undergoing a PCSS procedure did not demonstrate any overall anatomic benefit. There was significantly less enteroceles identified with post-operative TPUS in the women who underwent a rectopexy (p 0.0495), but these were all asymptomatic at 1 year after surgery and clinically non-detectable. It was observed that the post-operative CRADI-8 score was however significantly higher in the group of women who had a rectopexy as was the rate of dyspareunia. It is not apparent what the reason was for this and further exploration of this observation was limited due to the number of variables in a small sample size. This was the first report of the randomized addition of a rectopexy in combination with a sacrocolpopexy in women with multi-compartment POP. It was unable to show any

clear value of adding a rectopexy in this population, but has to be interpreted within the limitations of this analysis. Further research is thus required to establish the specific indication(s) and potential value of a rectopexy concomitant with a sacrocolpopexy and to observe the long-term significance of the asymptomatic enteroceles detected with post-operative imaging.

11.3.3. RECTOCELE PLICATION

The rectocele plication procedure was founded on the belief that a rectocele is primarily a rectal defect and not a vaginal defect. This is also the general divide between the colorectal and gynecologic literature and thus reflective of the philosophies of these two disciplines. This procedure is aimed at correcting the anterior rectal wall defect. The retrospective review of the rectocele plication technique provided reassuring results in regards to both anatomic and functional outcomes among women who underwent it and furthermore in relation to its safety. This report included a large number of women with isolated posterior compartment prolapse and a mean post-operative follow-up period of 27 months. Anatomic success was observed in 88.6% of women with an associated significant improvement in QOL and symptoms. This was the first report of a novel surgical technique and the first which combined the philosophical approaches of the different disciplines involved in the surgical correction of a rectocele.

11.3.4 PERINEAL BODY REPAIR IN COMBINATION WITH A RECTOCELE REPAIR

The pathogenesis of low rectoceles are believed to be due to a disruption at the level of the perineal membrane. Perineal descent is additionally a marker of more severe pelvic floor disorders and associated with a levator plate abnormality which in turn is a reflection of levator avulsion and/or dysfunction. A perineal body repair (perineorrhaphy or perineoplasty) is often performed in combination with a posterior compartment repair. This is principally done to correct an enlarged genital hiatus and to provide additional level III vaginal support. A specific technique for the reconstruction of the perineal body was reported. The analysis of those women who underwent a perineal body repair with a rectocele plication compared to those who only had a rectocele plication showed that no significant benefit was conferred with the addition of a perineal repair. A possible explanation for this observation might lie in the population studied and the concomitant procedure. The population comprised women with isolated posterior compartment prolapse and not those with specific complaints of perineal disorders or previous injuries. The indications and potential benefits of a perineal repair is therefore likely to be altered in a different population. The concomitant procedure of a rectocele plication incorporates the perineal membrane with the distal placement of each individual suture. The perineal body is thus inevitably included in the repair, although to a lesser extent than the technique described for a formal perineal body repair. The evidence in this population is hence that the addition of a perineal body repair to that of a rectocele plication does not offer any clear benefit to the patient with isolated posterior compartment prolapse.

11.3.5 RECTOCELE PLICATION COMPARED TO A DEFECT-SPECIFIC REPAIR

The rectocele plication was shown to be effective in a retrospective report over the medium term. A prospective evaluation was subsequently indicated to provide additional information on its safety and clinical outcomes and to allow for the exploration of other observations made in the lead-up to this research. The defect-specific repair was selected as the comparative procedure due to the extensive published outcomes of this procedure as well as the technique employed. The surgeon involved was furthermore familiar with this specific procedure, which is an essential component in limiting variation and bias in a proposed surgical trial. The statistical design and reporting was for that of a non-inferiority RCT in order to evaluate whether a rectocele plication was not inferior to a defect-specific repair. The outcomes after 12 months showed that a rectocele plication was firstly not inferior to a defect-specific repair in regards to the anatomic outcome. It furthermore showed that a rectocele plication resulted in superior functional outcomes. It has thus been proven that a rectocele plication is an effective procedure for women requiring surgical repair of a rectocele.

11.4 INTEGRATION IN A RESOURCE LIMITED ENVIRONMENT

The environment in which this research was performed could be classified as a limited resource setting. Limited resources denote human resources (healthcare workers), access to diagnostic equipment and availability of medical and surgical consumables, all of which are compounded by bureaucratic inefficiency.

This research proved that women in this population who present with posterior compartment disorders can be effectively evaluated and treated. The lack of access

to more advanced investigations were overcome with innovative approaches. Free uroflowmetry, DRE, rectal balloon sensitivity testing and 2D TPUS were used to add information to a detailed clinical history and examination. Conservative therapy was often not practically feasible in this population and surgery was mostly utilized. The introduction of a novel surgical technique for the repair of a rectocele proved efficient. The observed anatomic and functional outcomes in this population were not inferior to those reported in the literature. The feasibility of such a minimalistic approach in this healthcare environment was thus proven.

11.5 CONCLUSION

11.5.1 SUMMARY

This research has shown that a rectocele often presents with not only defecatory complaints, but also with voiding dysfunction. It has underlined the importance of a digital rectal examination in women with posterior compartment disorders and illustrated the value of using validated condition-specific QOL questionnaires in the assessment of these women. Imaging of the posterior pelvic floor was shown to contribute significantly to clinical decision making with the integration of 2D TPUS findings. The surgical treatment of a rectocele was extensively explored and it was observed that a neither a rectopexy, nor a perineal body repair routinely added any clear benefit in these women. A novel surgical technique for the repair of a rectocele and its associated outcomes were reported and it was found to be very encouraging. Lastly, a rectocele plication was prospectively compared in a RCT to a defect-specific repair. It was found that a rectocele plication was not inferior to a defect-specific repair, but that after 12 months it resulted in superior functional outcomes.

11.5.2 RECOMMENDATIONS FOR FUTURE RESEARCH

There are numerous questions that remain to be answered and which justifies further research. The epidemiology of pelvic floor disorders in the ethnic black population requires further exploration as does the impact of these disorders on their QOL. The effect of altered decision making with the integration of 2DTPUS findings need to be explored in the context of its effect on eventual clinical outcomes. The potential benefit of a perineal body repair needs to be researched in women with general POP and in those with specific perineal disorders. This would ideally require a RCT design in a large group of participants. The place and benefit of special investigations in regards to clinical outcome should be studied and compared to a minimalistic approach followed in a resource limited healthcare environment. Lastly, the participants of the rectocele plication and defect-specific repair RCT requires to be followed up and assessed over a longer term with regards to their anatomic and functional outcomes.

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ADDENDA

ADDENDUM 1: QOL DATA COLLECTION

Study number: **Date 1st visit:**

1st Visit	
Data 1. Age (years) 2. Education level (1=primary school; 2=high school; 3=matric; 4=post-matric) 3. Parity 4. Pelvic organ prolapse (1=yes ; 2=no) 5. Urinary incontinence (1=yes ; 2=no) 6. Fecal incontinence (1=yes ; 2=no) 7. Baseline PFDI-20 score (0-300) 8. Baseline POPDI-6 score (0-100) 9. Missing values (0-6) 10. Baseline CRADI-8 score (0-100) 11. Missing values (0-8) 12. Baseline UDI-6 score (0-100) 13. Missing values (0-6) 14. Baseline PFIQ-7 score (0-300) 15. Baseline POPIQ-7 score (0-100) 16. Missing values (0-7)	

17. Baseline CRAIQ-7 score (0-100) 18. Missing values (0 – 7) 19. Baseline UIQ-7 score (0-100) 20. Missing values (0-7) 21. Baseline dyspareunia (1=yes; 2=no; 3= not sexually active) 22. Baseline PISQ-12 score (0-48) (NP = no partner) 23. Missing values (0-12) (NA = not applicable) 24. Language (1= English ; 2= Afrikaans ; 3= Sesotho)	

2nd Round **Date:** **Data** 25. 1st Follow up PFDI-20 score (0-300) 26. 1st Follow up POPDI-6 score (0-100) 27. Missing values (0-6) 28. 1st Follow up CRADI-8 score (0-100) 29. Missing values (0-8) 30. 1st Follow up UDI-6 score (0-100) 31. Missing values (0-6)	

32. 1st Follow up PFIQ-7 score (0-300)

33. 1st Follow up POPIQ-7 score (0-100)

34. Missing values (0-7)

35. 1st Follow up CRAIQ-7 score (0-100)

36. Missing values (0-7)

37. 1st Follow up UIQ-7 score (0-100)

38. Missing values (0-7)

39. 1st Follow up PISQ-12 score (0-48) (NP = no partner)

40. Missing values (0-12) (NA = not applicable)

3rd Visit (STUDY GROUP ONLY) **Date:**

41. 3rd Follow up PFDI-20 score (0-300)

42. 3rd Follow up POPDI-6 score (0-100)

43. Missing values (0-6)

44. 3rd Follow up CRADI-8 score (0-100)

45. Missing values (0-8)

46. 3rdt Follow up UDI-6 score (0-100)

47. Missing values (0-6)

48. 3rd Follow up PFIQ-7 score (0-300)

49. 3rd Follow up POPIQ-7 score (0-100)

50. Missing values (0-7)

51. 3rd Follow up CRAIQ-7 score (0-100)

52. Missing values (0-7) 53. 3rd Follow up UIQ-7 score (0-100) 54. Missing values (0-7) 55. 3rd Follow up PISQ-12 score (0-48) (NP=no partner) 56. Missing values (0-12) (NA = not applicable) 57. PGI-I value (1= improved ; 2= not improved)	

ADDENDUM 2: PATIENT GLOBAL IMPRESSION OF IMPROVEMENT (PGI-I) SCALE

Circle the number that best describes how your condition is now, compared with how it was before you had the treatment:

1. Very much better
2. Much better
3. A little better
4. No change
5. A little worse
6. Much worse
7. Very much worse

Scoring: Items 1-3 is classified as “improved”. An answer for items 4-7 is classified as “not improved”.

ADDENDUM 3: PFDI-20 QUESTIONNAIRES

PFDI-20 VRAELYS

Instruksies: Antwoord asseblief al die volgende vrae. Hierdie vrae handel oor sekere derm, blaas of bekkenvloer klagtes, en indien jy dit het, oor hoeveel dit jou pla. Antwoord deur 'n **X** in die toepaslike boksie te maak. Terwyl jy hierdie vrae beantwoord, dink oor hoe hierdie klagtes jou oor die laaste **3 maande** gepla het.

Die PFDI-20 het 20 items en 3 skale. ***Alle items*** *gebruik die volgende formaat met 'n respons skaal van* ***1 tot 4***.

Patient:
Datum:

Het jy? O ***Nee*** ; O ***Ja***

***********Indien Ja****, hoeveel pla dit vir jou? *********

01	***02***	***03***	***04***
Glad nie	*Effens*	*Redelik*	*Baie*

Pelvic Organ Prolapse Distress Inventory 6 (POPDI-6):

	Het jy?	**Nee**	**Ja**	**Ja: 1 - 4**
1	Gewoonlik 'n *drukkende* gevoel in die onderbuik of bekken?			1 / 2 / 3 / 4
2	Gewoonlik 'n *swaar* of *dowwe* gevoel in die vaginale area?			1 / 2 / 3 / 4
3	Gewoonlik 'n uitbulting of iets wat uitkom, wat jy kan voel of sien in die vaginale area?			1 / 2 / 3 / 4
4	Ooit met jou vingers moes druk in die vagina of rondom jou agterwêreld om jou opelyf heeltemal uit te kry?			1 / 2 / 3 / 4
5	Gewoonlik die ervaring van onvolledige leegmaak van jou blaas?			1 / 2 / 3 / 4
6	Ooit moes druk op 'n uitbulting in die vagina met jou vingers om uriene te laat begin of daarmee klaar te kan maak?			1 / 2 / 3 / 4

Colorectal-Anal Distress Inventory 8 (CRADI-8):

	Het jy?	**Nee**	**Ja**	**Ja: 1 - 4**
7	Die gevoel dat jy te hard moes druk om 'n opelyf te kan hê?			1 / 2 / 3 / 4
8	Die gevoel dat jou derm nog nie heeltemal leeg is aan die einde van 'n opelyf nie?			1 / 2 / 3 / 4
9	Gewoonlik beheer oor jou maag verloor as jou poef goed gevorm is?			1 / 2 / 3 / 4
10	Gewoonlik beheer oor jou maag verloor as jou poef waterig is?			1 / 2 / 3 / 4
11	Gewoonlik beheer verloor oor winde van agter af?			1 / 2 / 3 / 4
12	Gewoonlik pyn wanneer jy opelyf het?			1 / 2 / 3 / 4
13	Die ervaring van 'n sterk drang sodat jy badkamer toe moet haas om 'n opelyf te hê?			1 / 2 / 3 / 4
14	Enige deel van jou derm voel uitkom en na buite uitbult gedurende of na 'n opelyf?			1 / 2 / 3 / 4

Urinary Distress Inventory 6 (UDI-6):

	Het jy?	**Nee**	**Ja**	**Ja: 1 - 4**
15	Gewoonlik die ervaring dat jy gereeld jou blaas moet ledig?			1 / 2 / 3 / 4

16	Gewoonlik uriene wat lek as jy 'n sterk behoefte ervaar om jou blaas te moet ledig?			1 / 2 / 3 / 4
17	Gewoonlik uriene wat lek as jy hoes, nies, of lag?			1 / 2 / 3 / 4
18	Gewoonlik klein bietjies uriene (druppels) wat lek?			1 / 2 / 3 / 4
19	Gewoonlik 'n gevoel dat jy jou blaas nie heeltemal leeg maak nie?			1 / 2 / 3 / 4
20	Gewoonlik 'n gevoel van *pyn* of *ongemak* in die onderbuik of vrouedele?			1 / 2 / 3 / 4

Skaal punte: Verkry die *gemiddelde* waarde van al die *beantwoorde* items binne die spesifieke skaal (0 tot 4) en vermenigvuldig dit dan met 25 om die skaal punt (0 tot 100) te kry. Vir onbeanwoorde items word die gemiddeld van die ander vrae in daardie skaal gebruik.

PFDI-20 Gemiddelde punt: Voeg die punte van die 3 skale saam om die gemiddelde PFDI-20 punt te kry (0-300).

PUNTE: POPDI: …….. CRADI: …… UDI: …… TOTAL: ……

PFDI – 20 QUESTIONNAIRE: SESOTHO

Ka kopo araba dipotso tsohle tse latelang mabapi le diteko tse ntseng di etswa. Dipotso tsena di botswa haeba o na le mathata ka senya, mala kapa bohloko bo itseng dithong tse itseng tsa hao tsa sesadi.

O tla raba potso ka nngwe ka ho beha letshwao la **X** lebokoseng le tshwanetseng. Ha o araba dipotso tsena nahana ka matshwao ao o bileng le ona kgweding tse tharo (3) tse fetileng.

PATIENT

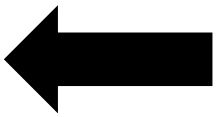
DATE

Ditekong tsena dipotso di 20, mme ho tsona o ka kgetha hoya ka matshwao a hao.

Mohlala: E kaba… O Tjhe / E

********** *Haeba karabo ke **e**, e be e o tshwenya jwang*: *********

1 Ho hang **2** Tje-the **3** Haholonyane **4** Haholo



DIPOTSO

(POPDI-6) Pelvic Organ Prolapse Distress Inventory 6

	Na?	**Tjhe**	**E**	**E: 1-4**
1	Ho na le hore o utlwe kgatello tlase mpeng?			1 / 2 / 3 / 4
22	Ho na le hore o utlwe boima bo itseng tlase mpeng?			1 / 2 / 3 / 4
3	Ho na le hore o utlwe e kare ho na le ntho ekareng e tla tswa ka pele?			1 / 2 / 3 / 4
4	Ho na le nako tseo o sututsang kapele kapa ka morao ho thusa hore mantle a tswe kaofela?			1 / 2 / 3 / 4
5	Ha o sesa o ye utlwe ekare mosese (metsi) ha o wa tswa kaofela ha o se o qetile?			1 / 2 / 3 / 4
6	Ho nne ho etsahala hore o tlamehe ho sututsa ntho e nyehlileng kapele ka menwana hore o kgone ho ntsha metsi?			1 / 2 / 3 / 4

Colorectal-Anal Distress Inventory 8 (CRADI-8)

	Na?	**Tjhe**	**E**	**E: 1-4**
7	O tlameha ho kokomosa ka thata hore o kgone ho ithusa?			1 / 2 / 3 / 4
8	O ke o utlwe eka ha a tswa kaofela ha o qeta ho ithusa kaofela?			1 / 2 / 3 / 4
9	Ho na le hore mantle a hantle a itswele feela a sa rerisa?			1 / 2 / 3 / 4
10	Ho na le hore letshollo le itswele feela pele o ka fihla ntlwaneng?			1 / 2 / 3 /4
11	Na moya o itswela feela o sa kgone ho o laola?			1 / 2 / 3 / 4
12	Na ho na le bohloko bo itseng bo o bo utlwang ha o ithusa?			1 / 2 / 3 / 4
13	Ha o tshwarehile na o tlameha ho mathela ka pele-pele ntlwaneng o utlwa eka ha o nah o kgona ho itshwara?			1 / 2 / 3 / 4
14	Ho na le hore lela le tswele ka ntle pele kapa ka mora hoba o ithuse?			1 / 2 / 3 / 4

Urinary Distress Inventory 6 (UDI -6)

	Na?	**Tjhe**	**E**	**E: 1-4**
15	O sesa kgafetsa?			1 / 2 / 3 / 4
16	Ho na le hore mosese o intshe ebile o utlwa hore o tlameha h oho mathela ntlwaneng?			1 / 2 / 3 / 4
17	Ha o kgohlela,o thimula kapa o tsheha ho na le hore mosese o intshe?			1 / 2 / 3 / 4
18	Ho na le marothodi a mosese a intshang?			1 / 2 / 3 / 4
19	Ebe o sesa ka thata?			1 / 2 / 3 / 4
20	Ho na le bohloko bo o bo utlwang ha o sesa?			1 / 2 / 3 / 4

Scale scores: Obtain the *mean* value of all of the *answered* items within the corresponding scale (possible value 0 to 4) and then multiply by 25 to obtain the scale score (range 0 to 100).Missing items are dealt with by using the mean from answered items only.***PFDI-20 Summary Score***: Add the scores from the 3 scales together to obtain the summary score (range 0 to 300).

SCORE: POPDI:……. CRADI:……. UDI:…….

TOTAL:……..

PFDI-20 QUESTIONNAIRE ENGLISH

Instructions: Please answer all of the questions in the following survey. These questions will ask you if you have certain bowel, bladder, or pelvic symptoms and, if you do, how much they bother you. Answer these by putting an **X** in the appropriate box or boxes. While answering these questions, please consider your symptoms over the last **3 months**.

The PFDI-20 has 20 items and 3 scales. **All items** use the following format with a response scale from **1 to 4**.

Patient: ***Date:***	→	Do you? O **No** ; O **Yes** ******** **If yes**, how much does it bother you? ******** **01** Not at all **02** Somewhat **03** Moderately **04** Quite a bit

Pelvic Organ Prolapse Distress Inventory 6 (POPDI-6):

	Do you?	**No**	**Yes**	**If yes: 1 - 4**
1	Usually experience *pressure* in the lower abdomen?			1 / 2 / 3 / 4
2	Usually experience *heaviness or dullness* in the pelvic area?			1 / 2 / 3 / 4
3	Usually have a bulge or something falling out that you can see or feel in your vaginal area?			1 / 2 / 3 / 4
4	Ever have to push on the vagina or around the rectum to have or complete a bowel movement?			1 / 2 / 3 / 4
5	Usually experience a feeling of incomplete bladder emptying?			1 / 2 / 3 / 4
6	Ever have to push up on a bulge in the vaginal area with your fingers to start or complete urination?			1 / 2 / 3 / 4

Colorectal-Anal Distress Inventory 8 (CRADI-8):

	Do you?	**No**	**Yes**	**If yes: 1 - 4**
7	Feel you need to strain too hard to have a bowel movement?			1 / 2 / 3 / 4
8	Feel you have not completely emptied your bowels at the end of a bowel movement?			1 / 2 / 3 / 4
9	Usually lose stool beyond your control if your stool is well formed?			1 / 2 / 3 / 4
10	Usually lose stool beyond your control if your stool is loose?			1 / 2 / 3 / 4
11	Usually lose gas from the rectum beyond your control?			1 / 2 / 3 / 4
12	Usually have pain when you pass your stool?			1 / 2 / 3 / 4
13	Experience a strong sense of urgency and have to rush to the bathroom to have a bowel movement?			1 / 2 / 3 / 4
14	Does part of your bowel ever pass through the rectum and bulge outside during or after a bowel movement?			1 / 2 / 3 / 4

Urinary Distress Inventory 6 (UDI-6):

	Do you?	**No**	**Yes**	**If yes: 1 - 4**
15	Usually experience frequent urination?			1 / 2 / 3 / 4
16	Usually experience urine leakage associated with a feeling of urgency that is a strong sensation of needing to go to the bathroom?			1 / 2 / 3 / 4
17	Usually experience urine leakage related to coughing, sneezing, or laughing?			1 / 2 / 3 / 4
18	Usually experience small amounts of urine leakage (that is, drops)?			1 / 2 / 3 / 4
19	Usually experience difficulty emptying your bladder?			1 / 2 / 3 / 4

20	Usually experience *pain* or *discomfort* in the lower abdomen or genital region?			1 / 2 / 3 / 4

Scale scores: Obtain the *mean* value of all of the *answered* items within the corresponding scale (possible value 0 to 4) and then multiply by 25 to obtain the scale score (range 0 to 100).Missing items are dealt with by using the mean from answered items only.***PFDI-20 Summary Score***: Add the scores from the 3 scales together to obtain the summary score (range 0 to 300).

SCORE: POPDI: …… CRADI: …….. UDI: …… TOTAL: ……

ADDENDUM 4: PFIQ-7 QUESTIONNAIRES

PFIQ-7 VRAELYS: AFRIKAANS

Patient:

Datum:

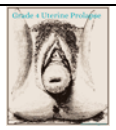
Instruksies: Sommige vroue vind dat hul blaas, derm of vaginale simptome hulle aktiwiteite, verhoudings en gevoelens affekteer. Vir elke vraag moet u 'n **X** in die blokkie plaas wat die beste beskryf in hoe 'n mate u aktiwiteite, verhoudings en gevoelens affekteer is deur u blaas, derm of vaginale probleme oor **die laaste 3 maande**.

Merk asseblief u 'n antoord merk in **al 3** dele vir elke vraag. *Selfs as u geen klagte het nie! – merk dan die "Glad nie" blokkie)*.

	Hoe affekteer simptome of probleme verwant aan die volgende afdelings u:	 ***Blaas of uriene***
1	Vermoë om huishoudelike take te doen (kos kook, huis skoonmaak, wasgoed was, ens.)?	D Glad nie D Effens D Redelik D Baie
2	Vermoë om fisiese aktiwiteite of oefeninge te doen (stap, hardloop, swem, of ander oefeninge)?	D Glad nie D Effens D Redelik D Baie
3	Uitgaan aktiwiteite by te woon (fliek, konserte, ens.)?	D Glad nie D Effens D Redelik D Baie
4	Vermoë om met 'n bus of taxi of kar te ry vir meer as 30 minute weg van die huis af?	D Glad nie D Effens D Redelik D Baie
5	Deelname aan sosiale aktiwiteite buite die huis (kerk, vriende kuier, winkels toe gaan, ens.)?	D Glad nie D Effens D Redelik D Baie
6	Emosionele gesondheid (gespannendheid, depressiewe gemoed, angstigheid, ens.)?	D Glad nie D Effens D Redelik D Baie
7	Gevoel van frustrasie?	D Glad nie D Effens D Redelik D Baie

	Hoe affekteer simptome of probleme verwant aan die volgende afdelings u:	 ***Derm of rektum***

1	Vermoë om huishoudelike take te doen (kos kook, huis skoonmaak, wasgoed was, ens.)?	D Glad nie D Effens D Redelik D Baie
2	Vermoë om fisiese aktiwiteite of oefeninge te doen (stap, hardloop, swem, of ander oefeninge)?	D Glad nie D Effens D Redelik D Baie
3	Uitgaan aktiwiteite by te woon (fliek, konserte, ens.)?	D Glad nie D Effens D Redelik D Baie ***BLAAI OM ASSEBLIEF***
4	Vermoë om met 'n bus of taxi of kar te ry vir meer as 30 minute weg van die huis af?	D Glad nie D Effens D Redelik D Baie
5	Deelname aan sosiale aktiwiteite buite die huis (kerk, vriende kuier, winkels toe gaan, ens.)?	D Glad nie D Effens D Redelik D Baie
6	Emosionele gesondheid (gespannendheid, depressiewe gemoed, angstigheid, ens.)?	D Glad nie D Effens D Redelik D Baie
7	Gevoel van frustrasie?	D Glad nie D Effens D Redelik D Baie

	Hoe affekteer simptome of probleme verwant aan die volgende afdelings u:	 ***Prolaps of Uitsakking***
1	Vermoë om huishoudelike take te doen (kos kook, huis skoonmaak, wasgoed was, ens.)?	D Glad nie D Effens D Redelik D Baie
2	Vermoë om fisiese aktiwiteite of oefeninge te doen (stap, hardloop, swem, of ander oefeninge)?	D Glad nie D Effens D Redelik D Baie
3		D Glad nie

	Uitgaan aktiwiteite by te woon (fliek, konserte, ens.)?	D Effens D Redelik D Baie
4	Vermoë om met 'n bus of taxi of kar te ry vir meer as 30 minute weg van die huis af?	D Glad nie D Effens D Redelik D Baie
5	Deelname aan sosiale aktiwiteite buite die huis (kerk, vriende kuier, winkels toe gaan, ens.)?	D Glad nie D Effens D Redelik D Baie
6	Emosionele gesondheid (gespannendheid, depressiewe gemoed, angstigheid, ens.)?	D Glad nie D Effens D Redelik D Baie
7	Gevoel van frustrasie?	D Glad nie D Effens D Redelik D Baie

PFIQ-7 punte toekenning: Al die items maak gebruik van die volgende respons skaal: **0**, Glad nie ; **1**, Effens ; **2**, Redelik ; **3**, Baie.

Skaal punte: Verkry die *gemiddelde* waarde van die die *beantwoorde* items in die korresponderende skaal (waarde 0 – 3) en vermenigvuldig dit dan met (100/3) om die skaal punt te kry (reikwydte 0 – 100). Vir onvolledige items word die gemiddeld van die beantwoorde items gebruik.

PFIQ-7 Samevattende punt: Voeg die punte van die 3 skale bymekaar om die samevattende punt te kry (reikwydte 0 – 300).

PUNTE: UIQ-7:…… CRAIQ-7:……. POPIQ-7:…… PFIQ7 TOTAL:……

PFIQ-7 Questionnaire: Sesotho

Melawana: Basadi ba bang ba fumana hore mathata a senya, mala le botenga tlisa ditlamaroa tse seng molemo ho bophelo ba letsatsi, dikamano tsa bona le maikutlo a bona. Bakeng sa potso e ngoe le e ngoe, taka ka **X** ho karabo e hlalosang hantle hore bophelo ba letsatsi le letsatsi, dikamano tsa hao le maikutlo a hao a fetotswe jwang ke mathata a hao.

Patient:

Date

Etsa bonnete ba hore o araba dipotso tsohle mabokosaneng a mararo, potsong ka ngoe (***le ha mathata a se teng, taka "ha ho mathata")***

	Mathata a amanang le tse latelang a fetotse bophelo ba hao jwang:	 ***Senya kapa ho rota***
1	Ho etsa mesebetsi ea ntlong (ho apea, ho hlwekisa le ho hlatswa)?	[ ] Ha ho jwalo [ ] Ha se ha ngata [ ] Ha ngata [ ] Ha ngata haholo
2	Ho etsa dintho tse hlokang matla jwalo ka ho tsamae, ho sesa le ho ithapolla?	[ ] Ha ho jwalo [ ] Ha se ha ngata [ ] Ha ngata [ ] Ha ngata haholo
3	Ho ya dibakeng tsa boithapello/boithabiso, joaloka ditshoanto kopa mokete o mmimo?	[ ] Ha ho jwalo [ ] Ha se ha ngata [ ] Ha ngata [ ] Ha ngata haholo
4	Ho tsamae ka koloi kapa bese lebaka la ho metsotso e 30 o se ntlong?	[ ] Ha ho jwalo [ ] Ha se ha ngata [ ] Ha ngata [ ] Ha ngata haholo
5	Ho nka karolo ditabeng tsa boithapollo ka ntle ho ntlong (kereke, metswalle, hoy a mabenkeleng)?	[ ] Ha ho jwalo [ ] Ha se ha ngata [ ] Ha ngata [ ] Ha ngata haholo
6	Maikutlong a hao (o dula o tshohile, o tetebetse kapa o sena botsitso)?	[ ] Ha ho jwalo [ ] Ha se ha ngata [ ] Ha ngata [ ] Ha ngata haholo
7	O utlwa o sa thabela boemo boo o leng ho bona?	[ ] Ha ho jwalo [ ] Ha se ha ngata [ ] Ha ngata [ ] Ha ngata haholo

	Mathata a amanang le tse latelang a fetotse bophelo ba hao jwang:	 ***Ho ithusa (mantle)***
1	Ho etsa mesebetsi ea ntlong (ho apea, ho hlwekisa le ho hlatswa)?	[ ] Ha ho jwalo [ ] Ha se ha ngata [ ] Ha ngata [ ] Ha ngata haholo
2	Ho etsa dintho tse hlokang matla jwalo ka ho tsamae, ho sesa le ho ithapolla?	[ ] Ha ho jwalo [ ] Ha se ha ngata [ ] Ha ngata [ ] Ha ngata haholo

3	Ho ya dibakeng tsa boithapello/boithabiso, joaloka ditshoanto kopa mokete o mmimo?	[ ] Ha ho jwalo [ ] Ha se ha ngata [ ] Ha ngata [ ] Ha ngata haholo **<u>Phetla leqephe o ee ho le latelang…</u>**
4	Ho tsamae ka koloi kapa bese lebaka la ho metsotso e 30 o se ntlong?	[ ] Ha ho jwalo [ ] Ha se ha ngata [ ] Ha ngata [ ] Ha ngata haholo
5	Ho nka karolo ditabeng tsa boithapollo ka ntle ho ntlong (kereke, metswalle, hoy a mabenkeleng)?	[ ] Ha ho jwalo [ ] Ha se ha ngata [ ] Ha ngata [ ] Ha ngata haholo
6	Maikutlong a hao (o dula o tshohile, o tetebetse kapa o sena botsitso)?	[ ] Ha ho jwalo [ ] Ha se ha ngata [ ] Ha ngata [ ] Ha ngata haholo
7	O utlwa o sa thabela boemo boo o leng ho bona?	[ ] Ha ho jwalo [ ] Ha se ha ngata [ ] Ha ngata [ ] Ha ngata haholo

	Mathata a amanang le tse latelang a fetotse bophelo ba hao jwang:	 ***Ho ithusa (mantle)***
1	Ho etsa mesebetsi ea ntlong (ho apea, ho hlwekisa le ho hlatswa)?	[ ] Ha ho jwalo [ ] Ha se ha ngata [ ] Ha ngata [ ] Ha ngata haholo
2	Ho etsa dintho tse hlokang matla jwalo ka ho tsamae, ho sesa le ho ithapolla?	[ ] Ha ho jwalo [ ] Ha se ha ngata [ ] Ha ngata [ ] Ha ngata haholo
3	Ho ya dibakeng tsa boithapello/boithabiso, joaloka ditshoanto kopa mokete o mmimo?	[ ] Ha ho jwalo [ ] Ha se ha ngata [ ] Ha ngata [ ] Ha ngata haholo
4	Ho tsamae ka koloi kapa bese lebaka la ho metsotso e 30 o se ntlong?	[ ] Ha ho jwalo [ ] Ha se ha ngata [ ] Ha ngata [ ] Ha ngata haholo
5	Ho nka karolo ditabeng tsa boithapollo ka ntle ho ntlong (kereke, metswalle, hoy a mabenkeleng)?	[ ] Ha ho jwalo [ ] Ha se ha ngata [ ] Ha ngata [ ] Ha ngata haholo
6	Maikutlong a hao (o dula o tshohile, o tetebetse kapa o sena botsitso)?	[ ] Ha ho jwalo [ ] Ha se ha ngata [ ] Ha ngata [ ] Ha ngata haholo
7	O utlwa o sa thabela boemo boo o leng ho bona?	[ ] Ha ho jwalo [ ] Ha se ha ngata [ ] Ha ngata [ ] Ha ngata haholo

<u>Scoring the PFIQ-7:</u> **0**, Ha ho jwalo ; **1**, Ha se ha ngata ; **2**, Ha ngata ; **3**, Ha ngata haholo.

Scale scores: Obtain the *mean* value for all of the *answered* items within the corresponding scale (possible value 0 to 3) and then multiply by (100/3) to obtain the scale score (range 0 to 100). Missing items are dealt with by using the mean from answered items only.

PFIQ-7 Summary Score: Add the scores from the 3 scales together to obtain the summary score (range 0 to 300).

UIQ-7: …… CRAIQ-7: …….. POPIQ-7: …….. TOTAL: ……/300

PFIQ-7 Questionnaire: English

Patient:

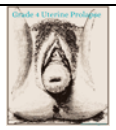
Date:

Instructions: Some women find that bladder, bowel, or vaginal symptoms affect their activities, relationships, and feelings. For each question place an **X** in the block that best describes how much your activities, relationships, or feelings have been affected by your bladder, bowel, or vaginal symptoms or conditions **over the last 3months**.Please make sure you mark an answer in **for each question**. *(Even if you have no complaints! - Then mark the "Not at all" block)*

	How do symptoms or conditions related to the following usually affect your:	 ***Bladder or urine***
1	Ability to do household chores (cooking, house cleaning, laundry, etc.)?	D Not at all D Somewhat D Moderately D Quite a bit
2	Ability to do physical activities such as walking, swimming, or other exercise?	D Not at all D Somewhat D Moderately D Quite a bit
3	Attending entertainment activities (movie, concert, etc.)?	D Not at all D Somewhat D Moderately D Quite a bit
4	Ability to travel by car or bus for a distance greater than 30 minutes away from home?	D Not at all D Somewhat D Moderately D Quite a bit
5	Participating in social activities outside your home (church, friends, shopping, etc.)?	D Not at all D Somewhat D Moderately D Quite a bit
6	Emotional health (nervousness, depression, anxiety, etc.)?	D Not at all D Somewhat D Moderately D Quite a bit
7	Feeling frustrated?	D Not at all D Somewhat D Moderately D Quite a bit

	How do symptoms or conditions related to the following usually affect your:	 ***Bowel or rectum***
1	Ability to do household chores (cooking, house cleaning, laundry, etc.)?	D Not at all D Somewhat D Moderately D Quite a bit
2	Ability to do physical activities such as walking, swimming, or other exercise?	D Not at all D Somewhat D Moderately D Quite a bit
3		D Not at all

	Attending entertainment activities (movie, concert, etc.)?	D Somewhat D Moderately D Quite a bit ***PLEASE TURN PAGE***
4	Ability to travel by car or bus for a distance greater than 30 minutes away from home?	D Not at all D Somewhat D Moderately D Quite a bit
5	Participating in social activities outside your home (church, friends, shopping, etc.)?	D Not at all D Somewhat D Moderately D Quite a bit
6	Emotional health (nervousness, depression, anxiety, etc.)?	D Not at all D Somewhat D Moderately D Quite a bit
7.	Feeling frustrated?	D Not at all D Somewhat D Moderately D Quite a bit

	How do symptoms or conditions related to the following usually affect your:	 ***Prolapse or Pelvis***
1	Ability to do household chores (cooking, house cleaning, laundry, etc.)?	D Not at all D Somewhat D Moderately D Quite a bit
2	Ability to do physical activities such as walking, swimming, or other exercise?	D Not at all D Somewhat D Moderately D Quite a bit
3	Attending entertainment activities (movie, concert, etc.)?	D Not at all D Somewhat D Moderately D Quite a bit
4	Ability to travel by car or bus for a distance greater than 30 minutes away from home?	D Not at all D Somewhat D Moderately D Quite a bit
5	Participating in social activities outside your home (church, friends, shopping, etc.)?	D Not at all D Somewhat D Moderately D Quite a bit
6	Emotional health (nervousness, depression, anxiety, etc.)?	D Not at all D Somewhat D Moderately D Quite a bit
7	Feeling frustrated?	D Not at all D Somewhat

		D Moderately D Quite a bit

Scoring the PFIQ-7: All of the items use the following response scale: **0**, Not at all ; **1**, Somewhat ; **2**, Moderately ; **3**, Quite a bit.

Scale scores: Obtain the *mean* value for all of the *answered* items within the corresponding scale (possible value 0 to 3) and then multiply by (100/3) to obtain the scale score (range 0 to 100). Missing items are dealt with by using the mean from answered items only.

UIQ-7: ……. CRAIQ-7: …… POPIQ-7: ……. PFIQ-7 TOTAL:

……/300

ADDENDUM 5: PISQ-12 QUESTIONNAIRES

PISQ-12 VRAELYS: AFRIKAANS

PASIENT:

DATUM:

Instruksies: Die volgende **12** vrae handel oor jou en jou maat se seksuele lewe.

Alle inligting is streng vertroulik. Jou antwoorde sal slegs gebruik word sodat jou dokter die effek van jou toestand op jou seksuele lewe beter kan verstaan. Maak 'n **X** in die blokkie wat die vraag die beste beskryf *vir jou*. Terwyl jy die vrae antwoord, dink aan jou seksuele lewe oor die laaste **6** maande.

Watter van die volgende beskryf jou die beste:

Glad nie seksueel aktief nie — 1 ☐ → Gaan na vraag P1

Seksueel aktief met of sonder 'n maat — 2 ☐ → Gaan na vraag Q2

P1: Het u 'n maat (man/vriend)? ☐ Ja ☐ Nee (*Indien NEE: vraelys is voltooi. DANKIE*)

Q1 Hoe gereeld voel jy 'n seksuele drang? Dit sluit die gevoel in om seksueel te wil verkeer, beplanning om seks te hê of frustrasie as gevolg van die tekort aan seks. .

4 ☐ Altyd 3 ☐ Dikwels 2 ☐ Partykeer 1 ☐ Min 0 ☐ Nooit

Q2 Bereik jy 'n klimaks (orgasme) wanneer jy *seksuele omgang* met jou maat het?

4 ☐ Altyd 3 ☐ Dikwels 2 ☐ Partykeer 1 ☐ Min 0 ☐ Nooit

Q3 Voel jy seksueel opgewek (fisies opgewonde of seksueel aangetrokke) tot jou maat gedurende seksuele aktiwitieit?

4 ☐ Altyd 3 ☐ Dikwels 2 ☐ Partykeer 1 ☐ Min 0 ☐ Nooit

Q4 Hoe tevrede is jy met die verskeidenheid van seksuele aktiwiteite in jou huidige seksuele lewe?

4 ☐ Altyd 3 ☐ Dikwels 2 ☐ Partykeer 1 ☐ Min 0 ☐ Nooit

Q5 Voel jy pyn tydens seksuele omgang?

0 ☐ Altyd 1 ☐ Dikwels 2 ☐ Partykeer 3 ☐ Min 4 ☐ Nooit

Q6 Lek jy enige uriene tydens seksuele aktiwiteite (penetrasie of met klimaks)?

0 ☐ Altyd 1 ☐ Dikwels 2 ☐ Partykeer 3 ☐ Min 4 ☐ Nooit

BLAAI OM ASSEBLIEF

Q7 Het jy minder of geen seks omdat jy bang is dat jy dalk gaan lek (uriene of opelyf) tydens seks?

0 ☐ Altyd 1 ☐ Dikwels 2 ☐ Partykeer 3 ☐ Min 4 ☐ Nooit

Q8 Vermy jy seks as gevolg van 'n uitsakking of uitbulting in jou vagina?

0 ☐ Altyd 1 ☐ Dikwels 2 ☐ Partykeer 3 ☐ Min 4 ☐ Nooit

Q9 Ervaar jy emosies soos vrees, skaamte, afgryse of skuld wanneer jy seks het met jou maat?

0 ☐ Altyd 1 ☐ Dikwels 2 ☐ Partykeer 3 ☐ Min 4 ☐ Nooit

Q10 Sukkel jou man met *ereksies* sodat dit julle seksuele lewe affekteer?

0 ☐ Altyd 1 ☐ Dikwels 2 ☐ Partykeer 3 ☐ Min 4 ☐ Nooit

Q11 Sukkel jou man met *vroeë ejakulasie* sodat dit julle seksuele aktiwiteite affekteer?

0 ☐ Altyd 1 ☐ Dikwels 2 ☐ Partykeer 3 ☐ Min 4 ☐ Nooit

Q12 Hoe intens is jou orgasmes (klimaks) oor die laaste 6 maande in vergelyking met hoe dit in die verlede was?

0 ☐ Baie minder intens 1 ☐ Minder intens 2 ☐ Dieselfde 3 ☐ Meer intens 4 ☐ Baie meer intens

Baie dankie dat u hierdie vraelys voltooi het

Punte berekening:

Punte word bereken deur die totaal (0-4) vir elke vraag bymekaar te tel. Hierdie vraelys kan gebruik word met tot 2 antwoorde onvoltooid. Vir onvoltooide vrae word die gemiddeld van die beantwoorde vrae gebruik en toegevoeg tot die totale punt.

TELLING PISQ-12: …… / 48

PISQ-12 QUESTIONNAIRE: SESOTHO

MELAWANA: Ho latela lipotso tse **12** ka wena le molekane wa hao, bophelong ba lona ba thobalano. Ditaba tsohle ke lekunutu.

Dikarabo tsohle tsa hao di tla thusa dingaka ho utluisisa bophelo ba hao ba thobalano le hore boemo ba hao ba bokulo bo na le ditlamorao di fe thobalanong pakeng tsa hao le molekane wa hao tswaea ka **X** lebokosaneng ho araba dipotso dikaraba tsa hao di ipapise le bophelo ba thobalano dikgweding tse **6** tse fetileng.

PATIENT:
DATE:

Q1 Ke ka nako e kae kapo makgetlo a makae o ikutloa o na le maikutlo a ho etsa thobalano? Sena se ka kenyelletsa ditakatso tsa thobalano, ho itukisetsa ho etsa thobalano kapo maikutlo a ho khathala matla hobane o sa kgone ho etsa thabalano.

4 ☐ Nako tsohle 3 ☐ Hangata 2 ☐ Ka nako tse ding 1 ☐ E seng ha ngata 0 ☐ Ha e etsahale

Q2 Na o ee o fihlele boemo ba kgotsofalo ha o etsa thobalano le molekane wa hao?

4 ☐ Nako tsohle 3 ☐ Hangata 2 ☐ Ka nako tse ding 1 ☐ E seng ha ngata 0 ☐ Ha e etsahale

Q3 Na o ee ikutlwe o thabela ho etsa thobalano le molekane wa hao?

4 ☐ Nako tsohle 3 ☐ Hangata 2 ☐ Ka nako tse ding 1 ☐ E seng ha ngata 0 ☐ Ha e etsahale

Q4 O kgotsofetse hakae ke mokgwa oo le etsang thobalano ka ona?

4 ☐ Nako tsohle 3 ☐ Hangata 2 ☐ Ka nako tse ding 1 ☐ E seng ha ngata 0 ☐ Ha e etsahale

Q5 Na o na le ho utlwa bohloko/sehlabi ha o etsa thobalano?

0 ☐ Nako tsohle 1 ☐ Hangata 2 ☐ Ka nako tse ding 3 ☐ E seng ha ngata 4 ☐ Ha e etsahale

Q6 Na o ee ho etsahale hore moroto o tswe feela ha o etsa thobalano?

☐

0 ☐ Nako tsohle 1 ☐ Hangata 2 ☐ Ka nako tse ding 3 E seng ha ngata 4 ☐ Ha e etsahale

Phetla leqephe o ee ho le latelang…

Q7 Na o dula o tshohile hore moroto kappa mantle a tla tswa feela ho o sitisa ho etsa thobalano?

0 ☐ Nako tsohle 1 ☐ Hangata 2 ☐ Ka nako tse ding 3 ☐ E seng ha ngata 4 ☐ Ha e etsahale

Q8 Na o baleha/qoba thobalano hobane ho na le seo o se utloang ka bothong ba hao?

0 ☐ Nako tsohle 1 ☐ Hangata 2 ☐ Ka nako tse ding 3 ☐ E seng ha ngata 4 ☐ Ha e etsahale

Q9 Ha le etsa thobalano le molekane wa hao, na o ikutlwa o sa thaba, o tshohile, o na le maikutlo a seng monate?

0 ☐ Nako tsohle 1 ☐ Hangata 2 ☐ Ka nako tse ding 3 ☐ E seng ha ngata 4 ☐ Ha e etsahale

Q10 Na molekane wa hao o na le mathata a botona bah ae (ka ho se phahame hantle)?

0 ☐ Nako tsohle 1 ☐ Hangata 2 ☐ Ka nako tse ding 3 ☐ E seng ha ngata 4 ☐ Ha e etsahale

Q11 Na molekane wa hao o na le bothata ba ho felloa ke matla kapele, e stsang hore thobalano e se ke ea le kgotsofatso bobedi?

0 ☐ Nako tsohle 1 ☐ Hangata 2 ☐ Ka nako tse ding 3 ☐ E seng ha ngata 4 ☐ Ha e etsahale

Q12 Ha o bapisa thabo eo o neng o e fumana thobalanong pele, thabo ea hao dikgoeding tse 6 tse fetileng e joang?

0 ☐ E fokotsehile haholo 1 ☐ E fokotsehile 2 ☐ E ntse e tswana 3 ☐ E feta pele 4 ☐ E feta pele haholo

Rea leboha ha o nkile nako ho araba dipotso

Scoring: Scores are calculated by totaling the scores for each question as indicated (0-4). This questionnaire can be used with up to 2 missing responses. To handle missing values the sum is calculated by multiplying the number of items by the means of the answered items.

SCORE: ……/48

PISQ-12 QUESTIONNAIRE: ENGLISH

PATIENT:

DATE:

Instructions: Following are **12** questions about you and your partner's sex life. All information is strictly confidential. Your confidential answers will be used only to help your doctor understand the impact of your condition on your sex life better. Please mark (**X)** the block that best answers the question for you. While answering the questions, consider your sex life over the past **SIX** months.

Which of the following best describes you:

Not sexually active at all 1 ☐ → Go to item PQ1
Sexually active with or without a partner 2 ☐ → Skip to item Q2

P1 Do you have a partner (husband/friend)? ☐ Yes ☐ No (If NO: questionnaire is completed. ***THANK YOU***)

Q1 How frequently do you feel sexual desire? This may include wanting to have sex, planning to have sex or feeling frustrated due to lack of sex.

4 ☐ Always 3 ☐ Usually 2 ☐ Sometimes 1 ☐ Seldom 0 ☐ Never

Q2 Do you climax (orgasm) when having *sexual intercourse* with your partner?

4 ☐ Always 3 ☐ Usually 2 ☐ Sometimes 1 ☐ Seldom 0 ☐ Never

Q3 Do you feel sexually excited (turned on) when having sexual activity with your partner?

4 ☐ Always 3 ☐ Usually 2 ☐ Sometimes 1 ☐ Seldom 0 ☐ Never

Q4 How satisfied are you with the variety of different sexual activities in your current sex life?

4 ☐ Always 3 ☐ Usually 2 ☐ Sometimes 1 ☐ Seldom 0 ☐ Never

Q5 Do you feel pain during sexual intercourse?

0 ☐ Always 1 ☐ Usually 2 ☐ Sometimes 3 ☐ Seldom 4 ☐ Never

Q6 Do you notice that you sometimes leak urine with sexual activity (penetration or climax)?

0 ☐ Always 1 ☐ Usually 2 ☐ Sometimes 3 ☐ Seldom 4 ☐ Never

Q7 Does the fear that you might leak urine or stool (poop) restrict your sexual activity?

4 ☐ Always 3 ☐ Usually 2 ☐ Sometimes 1 ☐ Seldom 0 ☐ Never

Q8 Do you avoid sexual intercourse because of bulging or prolapse in the vagina?

4 ☐ Always 3 ☐ Usually 2 ☐ Sometimes 1 ☐ Seldom 0 ☐ Never

PLEASE TURN PAGE OVER

Q9 When you have sex with your partner, do you have negative emotional feelings such as fear, disgust, shame or guilt?

4 ☐ Always 3 ☐ Usually 2 ☐ Sometimes 1 ☐ Seldom 0 ☐ Never

Q10 Does your partner have a problem with *erections* that affects your sexual activity?

4 ☐ Always 3 ☐ Usually 2 ☐ Sometimes 1 ☐ Seldom 0 ☐ Never

Q11 Does your partner have a problem with *premature ejaculation* that affects your sexual activity?

4 ☐ Always 3 ☐ Usually 2 ☐ Sometimes 1 ☐ Seldom 0 ☐ Never

Q12 Compared to orgasms you have had in the past, how intense are the orgasms you have had in the past 6 months?

4 ☐ Much less intense 3 ☐ Less intense 2 ☐ Same intensity 1 ☐ More intense 0 ☐ Much more intense

Thank you for completing this questionnaire

Scoring: Scores are calculated by totaling the scores for each question as indicated (0-4). This questionnaire can be used with up to 2 missing responses. To handle missing values the sum is calculated by multiplying the number of items by the means of the answered items.

SCORE: ……/48

ADDENDUM 6: THE IMPACT OF TRANSLABIAL ULTRASOUND ON CLINICAL DECISION MAKING AND OUTCOMES IN PELVIC FLOOR SURGERY – DATA FORM

Patient Study Number:

1. Randomisation: (1 = consultant , 2 = registrar)	
Clinical assessment:	
2. Anterior POP (Stage 0 – 4)	
3. Apical POP (Stage 0 – 4)	
Specify (1 = cervix , 2 = vault)	
4. Posterior POP (stage 0 – 4)	
Specify (1 = rectocele, 2= enterocele, 3 = both)	
5. Perineal descent (1 = yes , 2 = no)	
Ultrasound assessment:	
6. Anterior POP (Stage 0 – 4)	
7. Apical POP (stage 0 – 4)	
Specify (1= cervix, 2 = vault)	
8. Posterior POP (Stage 0 – 4)	
Specify (1 = rectocele, 2= enterocele, 3 = both)	
9. Perineal descent (1 = yes, 2 = no)	
10. Did U/S change clinical management (1 = yes, 2 = no)	
11. Notes (If yes, in which way was it changed):	
Patient demographic information	
12. Age	
13. Parity	
14. BMI	
15. Previous hysterectomy (1 = yes; 2 = no)	

16. Previous pelvic floor surgery (1 = yes; 2 = no)	
17. Menopausal status (1=premenopause, 2=postmenopause)	
18. HRT use (1=yes, 2=no)	
19. Prior continence surgery (1=yes, 2=no)	
20. QOL score	

ADDENDUM 7: UNIVERSITAS UROGYNECOLOGY QUALITY OF LIFE QUESTIONNAIRE

UROGYNAECOLOGY UNIT
QUALITY OF LIFE QUESTIONNAIRE

Patient name: _____

_

File number: _____ **Date:** _____

		Please mark one block for each question: **1= very bad; unacceptable** **5= excellent; no problem**
1.	To what extent does your problem affect you?	1☐ 2☐ 3☐ 4☐ 5☐
2.	To what extent does your problem affect your relationship to the people nearest to you?	1☐ 2☐ 3☐ 4☐ 5☐
3.	How would you rate the condition of your bladder?	1☐ 2☐ 3☐ 4☐ 5☐
4.	To what extent can you hold up your urine when you feel a need to pass urine?	1☐ 2☐ 3☐ 4☐ 5☐
5.	To what extent do you wet yourself?	1☐ 2☐ 3☐ 4☐ 5☐
6.	How do you feel about your bowel movements?	1☐ 2☐ 3☐ 4☐ 5☐
7.	Are you constipated and if so, how severe would you rate it? (1=very severe; 5= not constipated)	1☐ 2☐ 3☐ 4☐ 5☐
8.	How well can you empty your bowel?	1☐ 2☐ 3☐ 4☐ 5☐
9.	If you are sexually active how do you rate the quality of your sexual experience? (leave open if not sexually active).	1☐ 2☐ 3☐ 4☐ 5☐
10.	How would you rate your general well-being?	1☐ 2☐ 3☐ 4☐ 5☐

If you have something to add, you may do it here:

_____

_____

_____

_____

ADDENDUM 8: RECTOPEXY AT THE TIME OF A SACROCOLPOPEXY – DATA FORM

SACROCOLPOPEXY-RECTOPEXY STUDY

Study number:

Randomization: (1 = with rectopexy; 2 = without rectopexy)	
DEMOGRAPHIC DATA Age (yr) Race (1= White, 2 = Coloured, 3 = Black, 4 = Other) Parity Body mass index (kg/m^2)	
PREVIOUS HISTORY Previous surgery for prolapse (1=yes, 2=no, 3=?) If yes, vaginally (=1) or abdominally (=2) (3=?) Previous surgery for urinary incontinence (1=yes, 2=no, 3=?)	
CURRENT HISTORY (1= yes, 2=no) Hysterectomy Menopause HRT Bulge PV Lower abdominal pain Lower back pain	

Dyspareunia (3= no coitus) Urinary urge (OAB dry) Urinary urge incontinence (OAB wet) Stress urinary incontinence Obstructive voiding Constipation (< once every 3 days) Obstructed defecation AI (1=yes, 2=no) IBS Anal incontinence	
CO-MORBIDITY (1=yes, 2-no, 3=?) Diabetes Smoker	
CLINICAL EXAMINATION *POP-Q values (cm)* Aa Ba Ap Bp C Vaginal length Perineal body length	

Genital hiatus length Pyramid length (cm) Levator avulsion (1=yes, 2=no) Which side (1=L, 2=R, 3=both, 4=NA)	
SONAR Residual urine volume (ml) Bladder neck mobility (mm) Anterior compartment prolapsed (mm) Internal cystocele (1=yes, 2=no, 3=?) Paravaginal defect (1=yes, 2=no, 3=?) Rectocele (height in mm) Rectal intussusceptions (1=yes, 2=no, 3=?) Enterocele (1=yes, 2=no) Puborectalis movement (mm) Paradoxical PR movement (1=yes, 2=no) Apex (mm) External sphincter defect (1=yes, 2=no, 3=?)	
OTHER SPECIAL INVESTIGATIONS Urine MCS (1=pos, 2=neg, 3=?/not done) Pre-op Hb level (g/dl)	
SIGMOIDOSCOPY (PRE-OP) Normal (1=yes, 2=no, 3=?)	

SURGERY Date Duration (min) Blood loss (ml) Rectocele plication (1=yes, 2=no) Perineal repair (1=yes, 2=no) Complications (1=yes, 2= no, 3=?) Dindo Grade Detail: _____ _____ _____ _____	
POSTOPERATIVE COURSE Postoperative complications (1=yes, 2= no, 3=±) Dindo Grade Details: ……. Days in hospital Hb on day 2 (g/dl)	

3 MONTHS POSTOP VISIT Urine MCS (1=pos, 2=neg, 3= not done) Vaginal bulge (1=yes, 2=no)	

Constipation (<1x/3 days) (1=yes, 2=no) Obstructed defecation (1=yes, 2= no) AI (1=yes, 2=no) Lower abdominal pain (1=yes, 2=no, 3=?) Low back pain (1=yes, 2=no, 3=?) Dyspareunia (1=yes, 2=no, 3=NA) Urinary urge (OAB dry)(1=yes, 2=no, 3=?) Urinary urge incontinence (1=yes, 2=no, 3=?) Stress urinary incontinence (1=yes, 2=no, 3= ?) Obstructed voiding (1=yes, 2=no) *POP-Q values (cm)* Aa Ba Ap Bp C Vaginal length Perineal body length Genital hiatus length Pyramid length Perineal body defect (< 5mm) (1=yes, 2=no)	

Mesh complication (1=yes, 2=no) Time to complication CTS classification Management (1=conservative, 2=medical, 3=surgical)	

SONAR AT 3 MONTHS Residual urine volume (ml) Bladder neck mobility (mm) Anterior compartment prolapsed (mm) Internal cystocele (1=yes, 2=no, 3=?) Paravaginal defect (1=yes, 2=no, 3=?) Rectocele (height in mm) Rectal intussusceptions (1=yes, 2=no, 3=?) Enterocele (1=yes, 2=no) Puborectalis movement (mm) Paradoxical PR movement (1=yes, 2=no) Apex (mm) External sphincter defect (1=yes, 2=no, 3=?) **Anatomy** Success at 3 months (1=yes, 2=no)	

6 MONTHS POSTOP VISIT Urine MCS (1=pos, 2=neg, 3= not done) Vaginal bulge (1=yes, 2=no) Constipation (<1x/3 days) (1=yes, 2=no) Obstructed defecation (1=yes, 2= no) AI (1=yes, 2=no) Lower abdominal pain (1=yes, 2=no, 3=?) Low back pain (1=yes, 2=no, 3=?) Dyspareunia (1=yes, 2=no, 3=NA) Urinary urge (OAB dry)(1=yes, 2=no, 3=?) Urinary urge incontinence (1=yes, 2=no, 3=?) Stress urinary incontinence (1=yes, 2=no, 3= ?) Obstructed voiding (1=yes, 2=no) *POP-Q values (cm)* Aa Ba Ap Bp C Vaginal length Perineal body length	

Genital hiatus length Pyramid length Perineal body defect (< 5mm) (1=yes, 2=no) Mesh complication (1=yes, 2=no) Time to complication CTS classification Management (1=conservative, 2=medical, 3=surgical)	
SONAR AT 6 MONTHS Residual urine volume (ml) Bladder neck mobility (mm) Anterior compartment prolapsed (mm) Internal cystocele (1=yes, 2=no, 3=?) Paravaginal defect (1=yes, 2=no, 3=?) Rectocele (height in mm) Rectal intussusceptions (1=yes, 2=no, 3=?) Enterocele (1=yes, 2=no) Puborectalis movement (mm) Paradoxical PR movement (1=yes, 2=no) Apex (mm) External sphincter defect (1=yes, 2=no, 3=?) **Anatomy**	

Success at 6 months (1=yes, 2=no)	

12 MONTHS POSTOP VISIT Urine MCS (1=pos, 2=neg, 3= not done) Vaginal bulge (1=yes, 2=no) Constipation (<1x/3 days) (1=yes, 2=no) Obstructed defecation (1=yes, 2= no) AI (1=yes, 2=no) Lower abdominal pain (1=yes, 2=no, 3=?) Low back pain (1=yes, 2=no, 3=?) Dyspareunia (1=yes, 2=no, 3=NA) Urinary urge (OAB dry)(1=yes, 2=no, 3=?) Urinary urge incontinence (1=yes, 2=no, 3=?) Stress urinary incontinence (1=yes, 2=no, 3= ?) Obstructed voiding (1=yes, 2=no) *POP-Q values (cm)* Aa Ba Ap Bp	

C Vaginal length Perineal body length Genital hiatus length Pyramid length Perineal body defect (< 5mm) (1=yes, 2=no) Mesh complication (1=yes, 2=no) Time to complication CTS classification Management (1=conservative, 2=medical, 3=surgical)	
SONAR AT 12 MONTHS Residual urine volume (ml) Bladder neck mobility (mm) Anterior compartment prolapsed (mm) Internal cystocele (1=yes, 2=no, 3=?) Paravaginal defect (1=yes, 2=no, 3=?) Rectocele (height in mm) Rectal intussusceptions (1=yes, 2=no, 3=?) Enterocele (1=yes, 2=no) Puborectalis movement (mm) Paradoxical PR movement (1=yes, 2=no) Apex (mm)	

External sphincter defect (1=yes, 2=no, 3=?) **Anatomy** Success at 12 months (1=yes, 2=no)	
SURGERY Repeat procedure (1=yes, 2=no) Time to procedure Different procedure (1=yes, 2=no) Time to different procedure Operation for complications (1=yes, 2=no) Surgery for UI (1=yes, 2=no) Follow-up Success at last FU	
QUALITY OF LIFE QUESTIONNAIRES **PRE-OPERATIVE SCORE** PFIQ-7 UIQ-7 CRAIQ-7 POPIQ-7 PFDI-20 POPDI-6 CRADI-8	

UDI-6 PISQ-12 **3 MONTHS POST-OPERATIVE SCORE** PFIQ-7 UIQ-7 CRAIQ-7 POPIQ-7 PFDI-20 POPDI-6 CRADI-8 UDI-6 PISQ-12 **6 MONTHS POST-OPERATIVE SCORE** PFIQ-7 UIQ-7 CRAIQ-7 POPIQ-7 PFDI-20 POPDI-6 CRADI-8 UDI-6	

PISQ-12 **12 MONTHS POST-OPERATIVE SCORE** PFIQ-7 UIQ-7 CRAIQ-7 POPIQ-7 PFDI-20 POPDI-6 CRADI-8 UDI-6 PISQ-12	

ADDENDUM 9: RECTOCELE PLICATION AND PERINEAL BODY REPAIR

REVIEW DATA

Rectocele plication and perineal body repair – data extraction

STUDY FILE NUMBER:……

Demographics: Age Parity Race (1=black, 2=white, 3=other) BMI Menopausal (1=yes, 2=no) HRT (1=yes, 2=no) Hysterectomy (1=yes, 2=no) Previous POP surgery (1=yes, 2=no) Previous UI surgery (1=yes, 2=no) Smoker (1=yes, 2=no) DM (1=yes, 2=no) Hypertension (1=yes, 2=no)	
Symptoms: Bulge (1=yes, 2=no) OAB (wet) (1=yes, 2=no) OAB (dry) (1=yes, 2=no) SUI (1=yes, 2=no) Recurrent UTI (1=yes, 2=no) Constipation (1=yes, 2=no) Obstructed defecation (1=yes, 2=no)	

AI (1=yes, 2=no) Dyspareunia (1=yes, 2=no, 3=NA) QOL score Urine MCS (1=yes, 2=no, 3=not available)	
Examination: Posterior POP (1=yes, 2=no) Posterior stage Pyramid (cm) Anterior POP (1=yes, 2=no) Anterior stage Apical POP (1=yes, 2=no) Apical stage Perineal defect (1=yes, 2=no)	
Ultrasound Rectocele (1=yes, 2=no) Enterocele (1=yes, 2=no) Intussusception (1=yes, 2=no) Paradoxical puborectalis movement (1=yes, 2=no)	
Surgery: Op time (min) EBL (ml) Dindo complications Grade (0-5) SSI (1=yes, 2=no) UTI (1=yes, 2=no) Hematoma (1=yes, 2=no) Antibiotic use (1=yes, 2=no) Text: ……..	

Hospital stay (days) Perineal repair (1=yes, 2=no)	
Follow-up: FU period (months) Bulge (1=yes, 2=no) OAB (wet) (1=yes, 2=no) OAB (dry) (1=yes, 2=no) SUI (1=yes, 2=no) Recurrent UTI (1=yes, 2=no) Constipation (1=yes, 2=no) Obstructed defecation (1=yes, 2=no) AI (1=yes, 2=no) Dyspareunia (1=yes, 2=no, 3=NA) QOL score Urine MCS (1=yes, 2=no, 3=not available)	
Examination: Posterior POP (1=yes, 2=no) Posterior stage Pyramid (cm) Anterior POP (1=yes, 2=no) Anterior stage Apical POP (1=yes, 2=no) Apical stage Perineal defect (1=yes, 2=no)	
Ultrasound Rectocele (1=yes, 2=no) Enterocele (1=yes, 2=no)	

Intussusception (1=yes, 2=no) Paradoxical puborectalis movement (1=yes, 2=no)	
Other: Success at last visit (1=yes, 2=no) Different operation (1=yes, 2=no) Repeat operation (1=yes, 2=no) Op for complication (1=yes, 2=no)	

ADDENDUM 10: RECTOCELE PLICATION COMPARED TO DEFECT-SPECIFIC REPAIR – DATA FORM

Study number: Date 1st visit:

1st Visit **Demographics** 1. Age (years) 2. BMI 3. Race (1=black; 2=white; 3=coloured; 4=other) 4. Parity 5. Vaginal deliveries 6. Cesarean sections 7. Menopausal (1=yes; 2=no; 3= unknown) 8. HRT use: Oral/Dermal (1=yes; 2=no; 3= unknown) 9. HRT use: Vaginal (1=yes; 2=no; 3= unknown) 10. Smoking (1=yes; 2=no; 3= unknown) 11. Chronic cough (≥6 months) (1=yes; 2=no; 3= unknown) 12. Chronic constipation (≥6 months) (1=yes; 2=no; 3= unknown) 13. Prior hysterectomy (1=yes; 2=no; 3= unknown) 14. Prior POP surgery (1=yes; 2=no; 3= unknown) 15. Prior incontinence surgery (1=yes; 2=no; 3= unknown) 16. Family history (1st degree) – POP/UI (1=yes; 2= no; 3= unknown) 17. Other medical disorders (1=yes; n=no)	

Details: ……..	
Questionnaire Scores 18. PFDI-20 (score= 0-300) 19. POPDI-6 (score= 0-100) 20. CRADI-8 (score= 0-100) 21. UDI-6 (score= 0-100) 22. PFIQ-7 (score= 0-300) 23. UIQ-7 (score= 0-100) 24. CRAIQ-7 (score= 0-100) 25. POPIQ-7 (score= 0-100) 26. PISQ-12 (score = 0-48)	
Presenting complaints: 27. Bulge (1=yes; 2=no; 3= unknown) 28. Obstructed defecation (1=yes; 2=no; 3= unknown) 29. Obstructive voiding (1=yes; 2=no; 3= unknown) 30. Position-dependent voiding (1=yes; 2=no; 3= unknown) 31. Recurrent UTI (1=yes; 2=no; 3= unknown) 32. Nocturia (1=yes; 2=no; 3= unknown) 33. Detrusor overactivity (1=yes; 2=no; 3= unknown) 34. UUI (1=yes; 2=no) 35. SUI (1=yes; 2=no) 36. Lower back pain(1=yes; 2=no; 3= unknown) 37. Lower abdominal pain(1=yes; 2=no; 3= unknown)	

Clinical examination: 38. Aa(-3 to +3 cm) 39. Ba(-3 to +3 cm) 40. GH (cm) 41. PB (cm) 42. TVL (cm) 43. C (cm) 44. D (cm) 45. Ap(-3 to +3 cm) 46. Bp(-3 to +3 cm) 47. Pyramid (cm) 48. DRE (rest) (0-5) 49. DRE (squeeze) (0-5) 50. Levator avulsion (1=left; 2=right; 3=bilateral; 4=none) 51. Demonstrable SUI (1=yes; 2=no; 3=empty bladder) 52. Trigger points puborectalis (1=yes; 2=no; 3=not known) 53. Trigger points obturator internus (1=yes; 2=no; 3=not known) 54. Trigger points coccygeus (1=yes; 2=no; 3=not known) 55. Hemorrhoids (0=none;1=grade1; 2=grade2; 3=grade3; 4=grade4)	
Uroflow: 56. Uroflow – average flow (ml/sec) 57. Uroflow – peak flow rate (ml/sec) 58. Uroflow – time to maximum flow rate (sec)	

59. Uroflow – voiding time (sec) 60. Uroflow – flow time (sec) 61. Uroflow – volume voided (ml) 62. Uroflow – stream (1=continuous;2=intermittent) 63. Uroflow – postvoid residual (ml)	
Rectal balloon testing: 64. First sensation (ml) 65. First desire (ml) 66. Normal desire (ml) 67. Rectal urgency (ml) 68. Maximum capacity (ml) 69. Urinary voiding desire (ml) 70. No sensation at maximum volume (1=yes; 2=no; 3=not applicable)	
Transperineal ultrasound: 71. Levator hiatus – rest (mm) 72. Levator hiatus – contraction (mm) 73. Levator hiatus – Valsalva (mm) 74. UVJ – rest (mm) 75. UVJ – Valsalva (mm) 76. Anterior prolapse (mm) 77. Uterine prolapse (mm) 78. Vault prolapse (mm) 79. Enterocele prolapse (mm)	

80. Rectocele depth (mm) 81. Rectocele length (mm) 82. Rectovaginal septum intact (1=yes; 2=no; 3=unsure) 83. Rectovaginal septum defect size (mm) 84. Rectal intussusception (1=yes; 2=no; 3=not known) 85. Rectal ampulla at rest (mm) 86. Rectal ampulla at Valsalva (mm) 87. Peak rectocele – UVJ (mm) 88. Peak rectocele – mid-urethra (mm) 89. Peak rectocele – distal urethra (mm) 90. Perineal position at rest (mm) 91. Perineal position at Valsalva (mm)	
Operative parameters: 92. Date of surgery 93. Pre-op Hemoglobin (g/dl) 94. Pre-op pain scale (0-10) 95. Anesthesia (1=general;2=spinal;3=combined) 96. Randomization (1=rectocele plication;2=site-specific repair) 97. Perineal body repair (1=yes; 2=no) 98. Enterocele repair (1=yes; 2=no) 99. Surgery time (min) 100. Blood loss (ml) 101. Number of sutures used posterior repair	

102. Intra-op complications (1=yes;2=no). 103. Dindo Grade (0-5) 104. Specify……..	
Post-operative parameters: 105. Day of discharge (days of admission in hospital;0-7) 106. Day 1 Hb (g/dl) 107. Pain score 6 hours (0-10) 108. Pain score 12 hours (0-10) 109. Pain score 24 hours (0-10) 110. Pain score 36 hours (0-10) 111. Parenteral analgesia used (doses) 112. Oral simple analgesia used (doses) 113. Oral compound analgesia used (doses) 114. First bowel motion (hours from surgery) 115. Post-op complication (1=yes;2=no). Specify ……	☐
8-Week follow up visit: 116. Date of visit: 117. PFDI-20 (score= 0-300) 118. POPDI-6 (score= 0-100) 119. CRADI-8 (score= 0-100) 120. UDI-6 (score= 0-100)	

121.	PFIQ-7 (score= 0-300)	
122.	UIQ-7 (score= 0-100)	
123.	CRAIQ-7 (score= 0-100)	
124.	POPIQ-7 (score= 0-100)	
125.	PISQ-12 (score 0-48)	
126.	PGI-I (1=improved, 2=worsened)	
127.	Pain score (0-10)	
Symptoms:		
128.	Bulge (1=yes; 2=no; 3= unknown)	
129.	Obstructed defecation (1=yes; 2=no; 3= unknown)	
130.	Obstructive voiding (1=yes; 2=no; 3= unknown)	
131.	Position-dependent voiding (1=yes; 2=no; 3= unknown)	
132.	Recurrent UTI (1=yes; 2=no; 3= unknown)	
133.	Nocturia (1=yes; 2=no; 3= unknown)	
134.	Detrusor overactivity (1=yes; 2=no; 3= unknown)	
135.	Lower back pain(1=yes; 2=no; 3= unknown)	
136.	Lower abdominal pain(1=yes; 2=no; 3= unknown)	
137.	Post-op complications (1=yes;2=no).	
138.	Dindo Grade (0-5)	
139.	Specify …….	
Clinical examination:		

140.	Aa (-3 to +3 cm)	
141.	Ba(-3 to +3 cm)	
142.	GH (cm)	
143.	PB (cm)	
144.	TVL (cm)	
145.	C (cm)	
146.	D (cm)	
147.	Ap(-3 to +3 cm)	
148.	Bp(-3 to +3 cm)	
149.	Pyramid (cm)	
150.	DRE (rest) (0-5)	
151.	DRE (squeeze) (0-5)	
152.	Demonstrable SUI (1=yes; 2=no; 3=empty bladder)	
153.	Trigger points puborectalis (1=yes; 2=no; 3=not known)	
154.	Trigger points obturator internus (1=yes; 2=no; 3=not known)	
155.	Trigger points coccygeus (1=yes; 2=no; 3=not known)	
156.	Hemorrhoids (0=none;1=grade1; 2=grade2; 3=grade3; 4=grade4)	
Uroflow:		
157.	Uroflow – average flow (ml/sec)	
158.	Uroflow – peak flow rate (ml/sec)	
159.	Uroflow – time to maximum flow rate (sec)	
160.	Uroflow – voiding time (sec)	

161.	Uroflow – flow time (sec)	
162.	Uroflow – volume voided (ml)	
163.	Uroflow – stream (1=continuous;2=intermittent)	
164.	Uroflow – postvoid residual (ml)	
Rectal balloon testing:		
165.	First sensation (ml)	
166.	First desire (ml)	
167.	Normal desire (ml)	
168.	Rectal urgency (ml)	
169.	Maximum capacity (ml)	
170.	Urinary voiding desire (ml)	
171.	No sensation at maximum volume (1=yes; 2=no; 3=not applicable)	
Transperineal ultrasound:		
172.	Levator hiatus – rest (mm)	
173.	Levator hiatus – contraction (mm)	
174.	Levator hiatus – Valsalva (mm)	
175.	UVJ – rest (mm)	
176.	UVJ – Valsalva (mm)	
177.	Anterior prolapse (mm)	
178.	Uterine prolapse (mm)	
179.	Vault prolapse (mm)	

180.	Enterocele prolapse (mm)	
181.	Rectocele depth (mm)	
182.	Rectocele length (mm)	
183.	Rectovaginal septum intact (1=yes; 2=no; 3=unsure)	
184.	Rectovaginal septum defect size (mm)	
185.	Rectal intussusception (1=yes; 2=no; 3=not known)	
186.	Rectal ampulla at rest (mm)	
187.	Rectal ampulla at Valsalva (mm)	
188.	Peak rectocele – UVJ (mm)	
189.	Peak rectocele – mid-urethra (mm)	
190.	Peak rectocele – distal urethra (mm)	
191.	Perineal position at rest (mm)	
192.	Perineal position at Valsalva (mm)	
193.	Success at 2 months (1=yes, 2=no)	
6-Month follow up visit		
194.	Date of visit:	
195.	PFDI-20 (score= 0-300)	
196.	POPDI-6 (score= 0-100)	
197.	CRADI-8 (score= 0-100)	
198.	UDI-6 (score= 0-100)	
199.	PFIQ-7 (score= 0-300)	
200.	UIQ-7 (score= 0-100)	

201.	CRAIQ-7 (score= 0-100)	
202.	POPIQ-7 (score= 0-100)	
203.	PISQ-12 (score 0-48)	
204.	PGI-I (1=improved, 2=worsened)	
205.	Pain score (0-10)	
Symptoms:		
206.	Bulge (1=yes; 2=no; 3= unknown)	
207.	Obstructed defecation (1=yes; 2=no; 3= unknown)	
208.	Obstructive voiding (1=yes; 2=no; 3= unknown)	
209.	Position-dependent voiding (1=yes; 2=no; 3= unknown)	
210.	Recurrent UTI (1=yes; 2=no; 3= unknown)	
211.	Nocturia (1=yes; 2=no; 3= unknown)	
212.	Detrusor overactivity (1=yes; 2=no; 3= unknown)	
213.	Lower back pain(1=yes; 2=no; 3= unknown)	
214.	Lower abdominal pain(1=yes; 2=no; 3= unknown)	
215.	Post-op complications (1=yes;2=no).	
216.	Dindo Grade (0-5)	
217.	Specify …….	
Clinical examination:		
218.	Aa (-3 to +3 cm)	
219.	Ba(-3 to +3 cm)	

220.	GH (cm)	
221.	PB (cm)	
222.	TVL (cm)	
223.	C (cm)	
224.	D (cm)	
225.	Ap(-3 to +3 cm)	
226.	Bp(-3 to +3 cm)	
227.	Pyramid (cm)	
228.	DRE (rest) (0-5)	
229.	DRE (squeeze) (0-5)	
230.	Demonstrable SUI (1=yes; 2=no; 3=empty bladder)	
231.	Trigger points puborectalis (1=yes; 2=no; 3=not known)	
232.	Trigger points obturator internus (1=yes; 2=no; 3=not known)	
233.	Trigger points coccygeus (1=yes; 2=no; 3=not known)	
234.	Hemorrhoids (0=none;1=grade1; 2=grade2; 3=grade3; 4=grade4)	
Uroflow:		
235.	Uroflow – average flow (ml/sec)	
236.	Uroflow – peak flow rate (ml/sec)	
237.	Uroflow – time to maximum flow rate (sec)	
238.	Uroflow – voiding time (sec)	
239.	Uroflow – flow time (sec)	
240.	Uroflow – volume voided (ml)	

241.	Uroflow – stream (1=continuous;2=intermittent)	
242.	Uroflow – postvoid residual (ml)	
Rectal balloon testing:		
243.	First sensation (ml)	
244.	First desire (ml)	
245.	Normal desire (ml)	
246.	Rectal urgency (ml)	
247.	Maximum capacity (ml)	
248.	Urinary voiding desire (ml)	
249.	No sensation at maximum volume (1=yes; 2=no; 3=not applicable)	
Transperineal ultrasound:		
250.	Levator hiatus – rest (mm)	
251.	Levator hiatus – contraction (mm)	
252.	Levator hiatus – Valsalva (mm)	
253.	UVJ – rest (mm)	
254.	UVJ – Valsalva (mm)	
255.	Anterior prolapse (mm)	
256.	Uterine prolapse (mm)	

257.	Vault prolapse (mm)	
258.	Enterocele prolapse (mm)	
259.	Rectocele depth (mm)	
260.	Rectocele length (mm)	
261.	Rectovaginal septum intact (1=yes; 2=no; 3=unsure)	
262.	Rectovaginal septum defect size (mm)	
263.	Rectal intussusception (1=yes; 2=no; 3=not known)	
264.	Rectal ampulla at rest (mm)	
265.	Rectal ampulla at Valsalva (mm)	
266.	Peak rectocele – UVJ (mm)	
267.	Peak rectocele – mid-urethra (mm)	
268.	Peak rectocele – distal urethra (mm)	
269.	Perineal position at rest (mm)	
270.	Perineal position at Valsalva (mm)	
271.	Success at 6 months (1=yes, 2=no)	
12-Month follow up visit		
272.	Date of visit:	
273.	PFDI-20 (score= 0-300)	
274.	POPDI-6 (score= 0-100)	
275.	CRADI-8 (score= 0-100)	
276.	UDI-6 (score= 0-100)	
277.	PFIQ-7 (score= 0-300)	

278. UIQ-7 (score= 0-100)

279. CRAIQ-7 (score= 0-100)

280. POPIQ-7 (score= 0-100)

281. PISQ-12 (score 0-48)

282. PGI-I (1=improved, 2=worsened)

283. Pain score (0-10)

Symptoms:

284. Bulge (1=yes; 2=no; 3= unknown)

285. Obstructed defecation (1=yes; 2=no; 3= unknown)

286. Obstructive voiding (1=yes; 2=no; 3= unknown)

287. Position-dependent voiding (1=yes; 2=no; 3= unknown)

288. Recurrent UTI (1=yes; 2=no; 3= unknown)

289. Nocturia (1=yes; 2=no; 3= unknown)

290. Detrusor overactivity (1=yes; 2=no; 3= unknown)

291. Lower back pain(1=yes; 2=no; 3= unknown)

292. Lower abdominal pain(1=yes; 2=no; 3= unknown)

293. Post-op complications (1=yes;2=no).

294. Dindo Grade (0-5)

295. Specify …….

Clinical examination:

296.	Aa (-3 to +3 cm)	
297.	Ba(-3 to +3 cm)	
298.	GH (cm)	
299.	PB (cm)	
300.	TVL (cm)	
301.	C (cm)	
302.	D (cm)	
303.	Ap(-3 to +3 cm)	
304.	Bp(-3 to +3 cm)	
305.	Pyramid (cm)	
306.	DRE (rest) (0-5)	
307.	DRE (squeeze) (0-5)	
308.	Demonstrable SUI (1=yes; 2=no; 3=empty bladder)	
309.	Trigger points puborectalis (1=yes; 2=no; 3=not known)	
310.	Trigger points obturator internus (1=yes; 2=no; 3=not known)	
311.	Trigger points coccygeus (1=yes; 2=no; 3=not known)	
312.	Hemorrhoids (0=none;1=grade1; 2=grade2; 3=grade3; 4=grade4)	
Uroflow:		
313.	Uroflow – average flow (ml/sec)	
314.	Uroflow – peak flow rate (ml/sec)	
315.	Uroflow – time to maximum flow rate (sec)	

316. Uroflow – voiding time (sec)

317. Uroflow – flow time (sec)

318. Uroflow – volume voided (ml)

319. Uroflow – stream (1=continuous;2=intermittent)

320. Uroflow – postvoid residual (ml)

Rectal balloon testing:

321. First sensation (ml)

322. First desire (ml)

323. Normal desire (ml)

324. Rectal urgency (ml)

325. Maximum capacity (ml)

326. Urinary voiding desire (ml)

327. No sensation at maximum volume (1=yes; 2=no; 3=not applicable)

Transperineal ultrasound:

328. Levator hiatus – rest (mm)

329. Levator hiatus – contraction (mm)

330. Levator hiatus – Valsalva (mm)

331. UVJ – rest (mm)

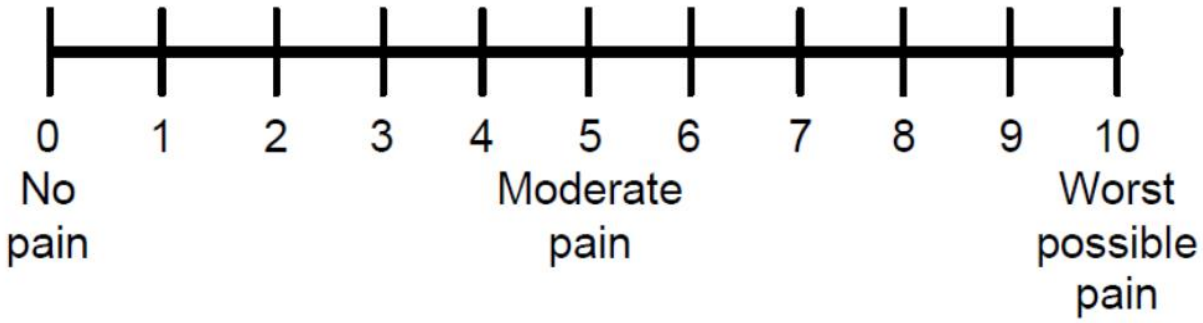
332. UVJ – Valsalva (mm)

333. Anterior prolapse (mm)

334. Uterine prolapse (mm)

335.	Vault prolapse (mm)	
336.	Enterocele prolapse (mm)	
337.	Rectocele depth (mm)	
338.	Rectocele length (mm)	
339.	Rectovaginal septum intact (1=yes; 2=no; 3=unsure)	
340.	Rectovaginal septum defect size (mm)	
341.	Rectal intussusception (1=yes; 2=no; 3=not known)	
342.	Rectal ampulla at rest (mm)	
343.	Rectal ampulla at Valsalva (mm)	
344.	Peak rectocele – UVJ (mm)	
345.	Peak rectocele – mid-urethra (mm)	
346.	Peak rectocele – distal urethra (mm)	
347.	Perineal position at rest (mm)	
348.	Perineal position at Valsalva (mm)	
349.	Success at 12 months (1=yes, 2=no)	
350.	Duration of last FU (months)	
351.	Success at last FU (1=yes, 2=no)	
352.	Repeat operation (1=yes, 2=no)	
353.	Time to repeat operation (months)	
354.	Different operation (1=yes, 2=no)	
355.	Time to different operation (months)	
356.	Operation for complication (1=yes, 2=no)	
357.	Operation for UI (1=yes, 2=no)	

ADDENDUM 11: NUMERIC PAIN SCALE



ADDENDUM 12: ARTICLE SUBMISSION – VALIDATION OF THE PFDI-20 AND PFIQ-7 QUESTIONNAIRES

Etienne Henn

From: em.iujo.0.50a4fe.26572ff9@editorialmanager.com on behalf of International Urogynecology Journal - Editorial Office <em@editorialmanager.com>
Sent: 18 January 2017 09:48 PM
To: Etienne Henn
Subject: IUJO-D-17-00035: Submission Confirmation for VALIDATION OF THE PFDI-20 AND PFIQ-7 QUALITY OF LIFE QUESTIONNAIRES IN TWO AFRICAN LANGUAGES

Dear Dr Henn,

Your submission entitled "VALIDATION OF THE PFDI-20 AND PFIQ-7 QUALITY OF LIFE QUESTIONNAIRES IN TWO AFRICAN LANGUAGES" has been received by the International Urogynecology Journal

The submission id is: IUJO-D-17-00035
Please refer to this number in any future correspondence.

You will be able to check on the progress of your manuscript by logging on to Editorial Manager as an author. The URL is http://iujo.edmgr.com/.

Thank you for submitting your work to our journal.

Kind regards,

Editorial Office
International Urogynecology Journal

Note: Should you require any further assistance please feel free to contact the Editorial Office by clicking on the "contact us" in the menu bar to send an email to us.

Alternatively, please call us at 001-630-468-7784 (outside the US)/(630)-468-7784 (within the US) anytime from Monday to Friday.

Now that your article will undergo the editorial and peer review process, it is the right time to think about publishing your article as open access. With open access your article will become freely available to anyone worldwide and you will easily comply with open access mandates. Springer's open access offering for this journal is called Open Choice (find more information on www.springer.com/openchoice). Once your article is accepted, you will be offered the option to publish through open access. So you might want to talk to your institution and funder now to see how payment could be organized; for an overview of available open access funding please go to www.springer.com/oafunding.
Although for now you don't have to do anything, we would like to let you know about your upcoming options.

1

ADDENDUM 13: ARTICLE SUBMISSION – VALIDATION OF THE PISQ-12 QUESTIONNAIRE

Etienne Henn

From: em.ijg.0.50ae71.cc8a6b91@editorialmanager.com on behalf of International Journal of Gynecology & Obstetrics <em@editorialmanager.com>
Sent: 20 January 2017 02:07 PM
To: Etienne Henn
Subject: Submission Confirmation

01-20-2017

ETIENNE W Henn, MMed

Obstetrics nd Gynaecology
University of the Free State Faculty of Health Sciences Obstetrics nd Gynaecology
G71
PO Box 339
University of the Free State
Bloemfontein 9301
SOUTH AFRICA

hennew@ufs.ac.za

Dear Dr Henn:

We are pleased to acknowledge receipt of the following manuscript:

Validation of a sexual function quality of life questionnaire in the African languages of Afrikaans and Sesotho Clinical Article

It has been forwarded for early review and consideration for publication in the International Journal of Gynecology and Obstetrics. When the editorial review is completed we shall inform you of our decision.

You will be able to check on the progress of your paper by logging in to Editorial Manager as an author. The URL is http://ijg.edmgr.com/.

Your manuscript will be given a reference number shortly.

We appreciate the opportunity to review this manuscript.

Please proceed to the following link to update your personal classifications and keywords, if necessary:
http://ijg.edmgr.com/l.asp?i=117926&l=CTDLBIW8

Sincerely,

IJGO Editorial Office
International Journal of Gynecology and Obstetrics Follow on Twitter: @IJGOLive

1

ADDENDUM 14: ARTICLE SUBMISSION – CLINICAL INFLUENCE OF TPUS

Ultrasound in Obstetrics and Gynecology

Home

Author

Review

Submission Confirmation

Print

Thank you for your submission

Submitted to
Ultrasound in Obstetrics and Gynecology

Manuscript ID
UOG-2017-0018

Title
THE INFLUENCE OF TRANSPERINEAL ULTRASOUND ON CLINICAL DECISION-MAKING IN WOMEN WITH PELVIC ORGAN PROLAPSE

Authors
Henn, Etienne
Burger, Divan
Richter, Barry

Date Submitted
16-Jan-2017

Author Dashboard

ADDENDUM 15: ABSTRACT SUBMISSION – IUGA CONGRESS 2017-

RECTOPEXY RCT

Print this Page for Your Records Close Window

Control/Tracking Number: 2017-A-218-IUGA
Activity: Abstract
Current Date/Time: 1/16/2017 5:17:26 AM

RECTOPEXY IN COMBINATION WITH A SACROCOLPOPEXY: RESULTS FROM A RANDOMIZED CONTROLLED TRIAL

Author Block: E. W. HENN[1], D. A. BURGER [2];
[1]Dept. Obstetrics & Gynaecology, Bloemfontein, South Africa, [2]Univ. of Pretoria, Pretoria, South Africa.

Abstract:

Introduction: Sacrocolpopexy is the gold standard procedure for women with advanced pelvic organ prolapse (POP) that invariably includes descent of the apical compartment[1]. The addition of a rectopexy can additionally eliminate a deep cul-de-sac and is associated with improved defecatory outcomes, especially in women with associated symptomatic rectoceles or rectal intussusception[2]. Uncertainty exists whether the combination of these procedures provide a superior clinical result.

Objective: The primary objective was to evaluate the effect of a ventral mesh rectopexy in combination with a sacrocolpopexy on the anatomic and symptomatic outcomes after surgery.

Methods: This was a randomized controlled trial performed in an urogynecology referral center in women with advanced multi-compartment POP scheduled for a sacrocolpopexy. Participants were randomly assigned to undergo either a sacrocolpopexy alone or combined with a ventral mesh rectopexy. Exclusion criteria included an intact uterus and previous mesh-based pelvic reconstructive surgery. An interim analysis was planned after approximately 50 participants. The primary objective was anatomic and functional outcome after 12 months. These were respectively evaluated by means of the pelvic organ prolapse quantification (POP-Q) system and validated condition-specific quality of life

ADDENDUM 16: ABSTRACT ACCEPTANCE RCOG WORLD CONGRESS 2017-

RECTOCELE PLICATION

Etienne Henn

From: sendmail@oxfordabstracts.com on behalf of RCOG 2017 <Lethishan@turnersconferences.co.za>
Sent: 12 December 2016 04:01 PM
To: Etienne Henn
Subject: RCOG 2017: Abstract Acceptance Notice

Dear Author,

It is with great pleasure that we advise you that your abstract titled – Rectocele plication: Description of a novel surgical technique and results of clinical outcome – reference no. – 0354 – has been accepted for ORAL PRESENTATION at the RCOG 2017 Congress.

Presentations will be 10 minutes, this includes 7 minutes presentation time and 3 minutes for questions, answers or discussion.

A separate email will be sent to the top 500 abstract authors regarding publication in BJOG. Please note that authors who are selected for publication in BJOG must be registered and their fees must be paid by no later than the 06th January 2017.

All accepted authors must be registered and their fees must be paid by no later than the 01st February 2017 in order to be included in the Congress Programme.

The Congress Programme is available on the website www.rcog2017.com and will be updated in due course with the abstracts that have been accepted. Please check the programme regularly for updates.

We also require a short biography from you. Please send your biography to Lethisha - Lethishan@turnersconferences.co.za by the 31st of January 2017. Further communication will be sent in due course with information on the speaker preparation centre times and helpful presentation information.

If you have any questions, please contact Lethisha – Lethishan@turnersconferences.co.za and include your abstract reference no. in all communications.

We look forward to welcoming you to the RCOG 2017 Congress in Cape Town.

With best wishes,
Meeting Administrator

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1

ADDENDUM 17: ABSTRACT ACCEPTANCE – BJOG PUBLICATION 2017-

RECTOCELE PLICATION

Etienne Henn

From: Lethisha Narayan <Lethishan@turnersconferences.co.za>
Sent: 13 December 2016 11:29 AM
To: Etienne Henn
Subject: RCOG 2017: Abstract Acceptance for BJOG Publication

TURNERS CONFERENCES
Complete Conference Solutions
turnersconferences.co.za

Dear Author,

RE: ABSTRACT ACCEPTANCE FOR BJOG PUBLICATION

It is with great pleasure that we advise you that your abstract:

Title: Rectocele plication: Description of a novel surgical technique and results of clinical outcome
Reference No.: 354

Has been selected for publication in the BJOG journal.

Authors who have been selected for publication need to be registered and their registration fees paid by the 06 January 2017. Due to publication deadline dates, Authors who have not registered and settled their fees by this date will unfortunately not be published.

Registration can be done online at http://www.rcog2017.com/Registration.asp

We look forward to receiving your registration form. If you have any questions, please don't hesitate to contact me, Lethishan@turnersconferences.co.za Please remember to quote your Reference Number in all communications.

Kind regards
Lethisha

Lethisha Narayan | Scientific Programme

Tel: +27 31 368 8000 | **Email:** Lethishan@turnersconferences.co.za
Turner House, 38 Jonsson Lane, Durban | PO Box 1935, Durban, 4000
Website: www.turnersconferences.co.za | **Secretariat:** www.turnerssecretariat.co.za
Twitter: @turnersconfer

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ADDENDUM 18: ABSTRACT SUBMISSION - IUGA CONGRESS 2017-PERINEAL REPAIR

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Control/Tracking Number: 2017-A-221-IUGA
Activity: Abstract
Current Date/Time: 1/16/2017 9:10:14 AM

THE EFFECT OF A CONCOMITANT PERINEAL BODY REPAIR AT THE TIME OF A POSTERIOR VAGINAL REPAIR: DOES IT PROVIDE A SUPERIOR CLINICAL OUTCOME?

Author Block: E. W. HENN;
Dept. Obstetrics & Gynaecology, Bloemfontein, South Africa.

Abstract:

Introduction: The female perineal body is a relatively small, but complex anatomical structure due to the sum of its components. It plays an often underrated role in pelvic floor function. The term perineorrhaphy is used to reflect the surgical repair of this structure. This term does however not define a specific procedure, but is a general description for an assortment of techniques. A perineorrhaphy is often combined with a posterior vaginal repair.

Objective: The aim of this retrospective study was to describe a specific surgical technique for the repair of the perineal body and explore the clinical contribution of this procedure to that of a posterior vaginal repair.

Methods: This is a retrospective case-control study. Records were retrieved for all cases who underwent a perineal body repair in combination with a posterior vaginal repair (PBPR) for the period January 2010 until December 2015 in a referral urogynecology unit. The control group, identified in the same time period, were made up of all women who received only a posterior vaginal repair (PR). Exclusion criteria were patients who underwent associated pelvic floor procedures, those where mesh were used in the posterior compartment and where the follow-up period was less than 12 months. Pre- and post-operative symptoms, clinical findings and quality of life (QOL) metrics were evaluated and reported on. A minimum follow-up period of 12 months was a prerequisite for inclusion. Successful primary surgery was anatomically defined as a posterior

ADDENDUM 19: ABSTRACT SUBMISSION – IUGA CONGRESS 2017-

RECTOCELE RCT

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Control/Tracking Number: 2017-A-203-IUGA
Activity: Abstract
Current Date/Time: 1/16/2017 5:18:48 AM

A DOUBLE-BLIND, NON-INFERIORITY RANDOMIZED CONTROLLED TRIAL OF TRANSVAGINAL PROCEDURES FOR THE REPAIR OF A RECTOCELE

Author Block: E. W. HENN[1], B. W. RICHTER [1], D. A. BURGER [2];
[1]Dept. Obstetrics & Gynaecology, Bloemfontein, South Africa, [2]Department Statistics, Dept. Obstetrics & Gynaecology, Bloemfontein, South Africa.

Abstract:

Introduction: Posterior compartment prolapse is a prevalent condition. It is mostly due to a rectocele and is often accompanied by defecatory disorders. A large number of surgical procedures have been described to correct a rectocele and these are in part a reflection of the philosophical approaches towards correcting a rectocele. The defect-specific posterior repair (DSR) has been used universally by gynecologists to correct the vaginal bulge with good reported outcomes. Colorectal surgeons on the other hand prefer to correct the rectal disorder by means of transanal or abdominal procedures. There are very few randomized trials to assess these procedures.

Objective: To randomly evaluate a DSR in comparison to a rectocele plication repair (RPR) in regards to objective and subjective outcomes after 1 year.

Methods: A non-inferiority randomized trial design was used and participants who required a surgical repair of a rectocele were enrolled to either a RPR or a DSR after consenting. Inclusion criteria were isolated posterior compartment disorders and no previous mesh-based pelvic procedures. A non-inferiority margin of 15% was identified, based on the reviewed literature which resulted in a sample size of at least 50 patients. A pragmatic approach was followed in regards to participant assessment and follow-up due to limited healthcare

ADDENDUM 20: ETHICS APPROVAL LETTERS

UNIVERSITY OF THE FREE STATE
UNIVERSITEIT VAN DIE VRYSTAAT
YUNIVESITHI YA FREISTATA
UFS·UV
HEALTH SCIENCES
GESONDHEIDSWETENSKAPPE

IRB nr 00006240
REC Reference nr 230408-011
IORG0005187
FWA00012784

16 March 2016

DR EW HENN
DEPT OF OBSTETRICS & GYNAECOLOGY
FACULTY OF HEALTH SCIENCES
UFS

Dear Dr EW Henn

HSREC NR 51/2016
DR EW HENN
DEPT OF OBSTETRICS & GYNAECOLOGY
PROJECT TITLE: VALIDATION OF THE PELVIC FLOOR DISTRESS INVENTORY (PFDI-20), PELVIC FLOOR IMPACT QUESTIONNAIRE (PFIQ-7) AND THE PELVIC ORGAN PROLAPSE/INCONTINENCE SEXUAL QUESTIONNAIRE (PISQ-12) IN A SOUTH AFRICAN POPULATION

1. You are hereby kindly informed that the Health Sciences Research Ethics Committee (HSREC) reviewed the above research project and it was presented at the meeting on 15 March 2016. Research may not be conducted before the following condition(s) has/have been met and the HSREC grants final approval for the project:

   - *The signed permission letter from the Free State Department of Health must be submitted before final approval will be granted.*

2. **PLEASE NOTE:** This ethics letter must accompany your application for approval to the Department of Health for their consideration, along with submitting the online application.

   *Upon receipt of the above document(s), the HSREC will issue a final approval letter. Only thereafter may the study be conducted.

3. The Committee must be informed of any serious adverse event and/or termination of the study.

4. Any amendment, extension or other modifications to the protocol must be submitted to the HSREC for approval.

5. Kindly use the **HSREC NR** as reference in correspondence to HSREC Administration.

6. Thus, this letter only serves as **conditional** approval.

7. The HSREC functions in compliance with, but not limited to, the following documents and guidelines: The SA National Health Act. No. 61 of 2003; Ethics in Health Research: Principles, Structures and Processes (2015); SA GCP(2006); Declaration of Helsinki; The Belmont Report; The US Office of Human Research Protections 45 CFR 461 (for non-exempt research with human participants conducted or supported by the US Department of Health and Human Services-(HHS), 21 CFR 50, 21 CFR 56; CIOMS; ICH-GCP-E6 Sections 1-4; The International Conference on Harmonization and Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH Tripartite), Guidelines of the SA Medicines Control Council as well as Laws and Regulations with regard to the Control of Medicines, Constitution of the Ethics Committee of the Faculty of Health Sciences.

Yours faithfully

.....
DR SM LE GRANGE
CHAIR: HEALTH SCIENCES RESEARCH ETHICS COMMITTEE

Health Sciences Research Ethics Committee
Office of the Dean: Health Sciences
T: +27 (0)51 401 7795/7794 | F: +27 (0)51 444 4359 | E: ethicsfhs@ufs.ac.za
Block D, Dean's Division, Room D104 | P.O. Box/Posbus 339 (Internal Post Box G40) | Bloemfontein 9300 | South Africa
www.ufs.ac.za

UNIVERSITY OF THE FREE STATE
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YUNIVESITHI YA FREISTATA

UFS·UV
HEALTH SCIENCES
GESONDHEIDSWETENSKAPPE

IRB nr 00006240
REC Reference nr 230408-011
IORG0005187
FWA00012784

01 August 2016

DR EW HENN
DEPT OF OBSTETRICS & GYNAECOLOGY
FACULTY OF HEALTH SCIENCES
UFS

Dear Dr EW Henn

HSREC NR 51/2016
DR EW HENN
DEPT OF OBSTETRICS & GYNAECOLOGY
PROJECT TITLE: VALIDATION OF THE PELVIC FLOOR DISTRESS INVENTORY (PFDI-20), PELVIC FLOOR IMPACT QUESTIONNAIRE (PFIQ-7) AND THE PELVIC ORGAN PROLAPSE/INCONTINENCE SEXUAL QUESTIONNAIRE (PISQ-12) IN A SOUTH AFRICAN POPULATION

1. You are hereby kindly informed that, at the meeting held on 26 July 2016, the Health Sciences Research Ethics Committee (HSREC) approved the above project after all conditions were met.
2. The Committee must be informed of any serious adverse event and/or termination of the study.
3. Any amendment, extension or other modifications to the protocol must be submitted to the HSREC for approval.
4. A progress report should be submitted within one year of approval and annually for long term studies.
5. A final report should be submitted at the completion of the study.
6. Kindly use the **HSREC NR** as reference in correspondence to the HSREC Secretariat.
7. The HSREC functions in compliance with, but not limited to, the following documents and guidelines: The SA National Health Act. No. 61 of 2003; Ethics in Health Research: Principles, Structures and Processes (2015); SA GCP(2006); Declaration of Helsinki; The Belmont Report; The US Office of Human Research Protections 45 CFR 461 (for non-exempt research with human participants conducted or supported by the US Department of Health and Human Services- (HHS), 21 CFR 50, 21 CFR 56; CIOMS; ICH-GCP-E6 Sections 1-4; The International Conference on Harmonization and Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH Tripartite), Guidelines of the SA Medicines Control Council as well as Laws and Regulations with regard to the Control of Medicines, Constitution of the HSREC of the Faculty of Health Sciences.

PROF WJ STEINBERG
VICE CHAIR: HEALTH SCIENCES RESEARCH ETHICS COMMITTEE

Health Sciences Research Ethics Committee
Office of the Dean: Health Sciences
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E-mail address: StraussHS@ufs.ac.za

Ms H Strauss/jdpls

2014-03-06

REC Reference nr 230408-011
IRB nr 00006240

DR EW HENN
DEPT OF OBSTETRICS AND GYNAECOLOGY
FACULTY OF HEALTH sciences
UFS

Dear Dr Henn

ECUFS NR 12/2014
PROJECT TITLE: THE IMPACT OF TRANSLABIAL ULTRASOUND ON CLINICAL DECISION MAKING IN WOMEN WITH PELVIC ORGAN PROLAPSE.

1. You are hereby kindly informed that at the meeting held on 4 March 2014 the Ethics Committee condoned the approval of the study after all the conditions have been met when the signed permission letter from DR NRJ van Zyl, Head: Clinical Services, Universitas Academic Hospital was submitted and the signature of Dr L Juul were obtained.

2. Committee guidance documents: Declaration of Helsinki, ICH, GCP and MRC Guidelines on Bio Medical Research. Clinical Trial Guidelines 2000 Department of Health RSA; Ethics in Health Research: Principles Structure and Processes Department of Health RSA 2004; Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa, Second Edition (2006); the Constitution of the Ethics Committee of the Faculty of Health Sciences and the Guidelines of the SA Medicines Control Council as well as Laws and Regulations with regard to the Control of Medicines.

3. Any amendment, extension or other modifications to the protocol must be submitted to the Ethics Committee for approval.

4. The Committee must be informed of any serious adverse event and/or termination of the study.

5. .All relevant documents e.g. signed permission letters from the authorities, institutions, changes to the protocol, questionnaires etc. have to be submitted to the Ethics Committee before the study may be conducted (if applicable).

6. A progress report should be submitted within one year of approval of long term studies and a final report at completion of both short term and long term studies.

7. Kindly refer to the ETOVS/ECUFS reference number in correspondence to the Ethics Committee secretariat.

Yours faithfully

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PROF WH KRUGER
CHAIR: ETHICS COMMITTEE

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Direkteur: Fakulteitsadministrasie / Director: Faculty Administration
Fakulteit Gesondheidswetenskappe / Faculty of Health Sciences

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Ms H Strauss

2011-07-27

DR E HENN
DEPT OBSTETRICS AND GYNAECOLOGY
FACULTY OF HEALTH SCIENCES
UFS

REC Reference number: REC-230408-011

Dear Dr Henn

ETOVS NR 09/2011
PROJECT TITLE: THE EFFECT OF RECTOPEXY DURING ABDOMINAL SACROCOLPOPEXY FOR PELVIC ORGAN PROLAPSE.

- You are hereby kindly informed that the Ethics Committee approved the above study at the meeting held on 25 January 2011 on condition that:
  - ***The report from the Evaluation Committee has to be submitted***
  - ***A third person has to be involved when Informed Consent is obtained from the patient***
  - ***The Patient Information Brochure has to be revised to be more simplistic***
  - ***Permission letters received from Dr N van Zyl, Universitas Hospital and Prof PH Wessels, Dept of Obstetrics and Gynaecology have to be submitted to the Ethics Committee***
- Committee guidance documents: Declaration of Helsinki, ICH, GCP and MRC Guidelines on Bio Medical Research. Clinical Trial Guidelines 2000 Department of Health RSA; Ethics in Health Research: Principles Structure and Processes Department of Health RSA 2004; Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa, Second Edition (2006); the Constitution of the Ethics Committee of the Faculty of Health Sciences and the Guidelines of the SA Medicines Control Council as well as Laws and Regulations with regard to the Control of Medicines.
- Any amendment, extension or other modifications to the protocol must be submitted to the Ethics Committee for approval.
- The Committee must be informed of any serious adverse event and/or termination of the study.
- A progress report should be submitted within one year of approval of long term studies and a final report at completion of both short term and long term studies.

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Republiek van Suid-Afrika / Republic of South Africa

- Kindly refer to the ETOVS reference number in correspondence to the Ethics Committee secretariat.

Yours faithfully

.....
CHAIR: ETHICS COMMITTEE

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Fakulteit Gesondheidswetenskappe
Department of Obstetrics and Gynaecology / Faculty of Health Sciences

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19 Julie 2004

Prof Beyers Hoek
Voorsitter : Etiekkomitee
Fakulteit Gesondheidswetenskappe
UV

Beste Beyers

NAVORSING OF DATA-BASIS Ethics 116/04

Ons Departement beskik oor 'n groot en volledige databasis in Onkologie en veral Uroginekologie. Dit loop al vir so 8 jaar. In die begin het ons etiese toestemming verkry om daaruit navorsing te doen, maar ons kan nie die dokumentasie opspoor nie. Gevolglik doen ons weer aansoek.

Sover het ons 4 publikasies daaruit verkry en werk tans aan nog 2. In November kom nog een wanneer 'n mediese student van Tukkies hier navorsing kom doen. Met die 4 wat gepubliseer is, het ons geen probleme ervaar om dit by die tydskrifte (almal oorsese geakkrediteerde tydskrifte) goedgekeur te kry nie.

Met vriendelike groete

Hennie

PROF HS CRONJÉ
HOOF: DEPT OBSTETRIE EN GINEKOLOGIE
iv/

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Ms M Marais/hv

2014-11-27

REC Reference nr 230408-011
IRB nr 00006240

DR EW HENN
HEAD OF UROGYNAECOLOGY
DEPT OF OBSTETRICS AND GYNAECOLOGY
FACULTY OF HEALTH SCIENCES
UFS

Dear Dr Henn

ECUFS NR 222/2014
DR EW HENN DEPARTMENT OF OBSTETRICS AND GYNAECOLOGY
PROJECT TITLE: TRANSVAGINAL REPAIR OF RECTOCELE: A NON-INFERIORITY RANDOMIZED CONTROLLED TRIAL.

1. You are hereby kindly informed that the Ethics Committee reviewed the above research project and it was presented at the meeting on 25 November 2014. Research may not be conducted before the following condition(s) has/have been met and the Ethics Committee grants final approval for the project:

   1.1 ***The approval from the PHRC is outstanding and has to be obtained and submitted to the Ethics Committee before the study may be conducted.***

   [Upon receipt of the above document(s), an approval letter will be issued by the Ethics Committee. Only thereafter may the study be conducted].

2. Committee guidance documents: Declaration of Helsinki, ICH, GCP and MRC Guidelines on Bio Medical Research. Clinical Trial Guidelines 2000 Department of Health RSA; Ethics in Health Research: Principles Structure and Processes Department of Health RSA 2004; Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa, Second Edition (2006); the Constitution of the Ethics Committee of the Faculty of Health Sciences and the Guidelines of the SA Medicines Control Council as well as Laws and Regulations with regard to the Control of Medicines.

3. Any amendment, extension or other modifications to the protocol must be submitted to the Ethics Committee for approval.

4. The Committee must be informed of any serious adverse event and/or termination of the study.

5. All relevant documents e.g. signed permission letters from the authorities, institutions, changes to the protocol, questionnaires etc. have to be submitted to the Ethics Committee before the study may be conducted (if applicable).

6. A progress report should be submitted within one year of approval of long term studies and a final report at completion of both short term and long term studies.

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Ms M Marais

2015-05-25

REC Reference nr 230408-011
IRB nr 00006240

DR E HENN
DEPARTMENT OF OBSTETRICS AND GYNAECOLOGY
UFS
BLOEMFONTEIN

Dear Dr E Henn

ECUFS NR 222/2014 **DEPARTMENT OF OBSTETRICS AND GYNAECOLOGY**
PROJECT TITLE: TRANSVAGINAL REPAIR OF RECTOCELE: A NON-INFERIORITY RANDOMIZED CONTROLLED TRIAL.

1. You are hereby kindly informed that, at the meeting held on 19 May 2015, the Ethics Committee approved the above project.

2. Committee guidance documents: Declaration of Helsinki, ICH, GCP and MRC Guidelines on Bio Medical Research. Clinical Trial Guidelines 2000 Department of Health RSA; Ethics in Health Research: Principles Structure and Processes Department of Health RSA 2004; Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa, Second Edition (2006); the Constitution of the Ethics Committee of the Faculty of Health Sciences and the Guidelines of the SA Medicines Control Council as well as Laws and Regulations with regard to the Control of Medicines.

3. Any amendment, extension or other modifications to the protocol must be submitted to the Ethics Committee for approval.

4. A progress report should be submitted within one year of approval of long term studies and a final report at completion of both short term and long term studies.

5. Kindly use the ECUFS NR as reference in correspondence to the Ethics Committee Secretariat.

Yours faithfully

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DR SM LE GRANGE
CHAIR: ETHICS COMMITTEE

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