PELVIC ORGAN PROLAPSE AND PELVIC FLOOR MUSCLE STRENGTH

Compiled by

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Declaration

I hereby declare that the work submitted here is the result of my own independent investigation. Where help was sought, it has been acknowledged. further declare that this work is submitted for the first time at this university towards a M.Sc. degree and that it has never been submitted to any other university for the purpose of obtaining a degree.		
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List of Acronyms

BMI Body mass index

EMG Electromyography

EMG-E Electromyography endurance

EMG-S Electromyography strength

HRT Hormone replacement therapy

PFM Pelvic floor muscle

PFMS Pelvic floor muscle strength

POP Pelvic organ prolapse

POP-Q Pelvic organ prolapse quantification system

s seconds

SD standard deviation

SUI stress urinary incontinence

 μV microvolt

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NOMENCLATURE

Pelvic floor muscle strength is defined in the terms of Abrams *et al.* (2002), by the strength of a voluntary contraction, that can be graded by a validated grading system as the modified Oxford scale where zero is no contraction and five is a strong contraction. Other means of assessment can also be used. In this study an electromyography measurement was also made, using a Chattanooga Intellect advanced machine (model number 2762CC) and a vaginal electrode.

Pelvic organ prolapse is "the descent of one or more of: the anterior vaginal wall, the posterior vaginal wall, and the apex of the vagina (cervix/ uterus) or vault (cuff) after hysterectomy. Absence of prolapse can be defined as stage 0 support; prolapse can be staged from stage I to IV", using the POP-Q system. This is how the International Continence Society defined POP in 2002 Abrams *et al.* (2002, 120).

Pelvic organ prolapse quantification exam (POP-Q) is the examination of a woman with POP in order to precisely and uniformly describe the condition in a patient. The POP-Q terminology was developed by the International Continence Society. (Bump *et al.*, 1996)

Chapter I

Introduction:

The context, objectives and justification

1.1 Introduction

Pelvic organ prolapse (POP) is an uncomfortable and embarrassing health problem. Women often do not know what POP is until they present with symptoms and signs related to it. Clinically, medical practitioners and physiotherapists have made the observation that the strength of the pelvic floor muscle (PFM) correlates inversely to the development of POP. If this will be confirmed by research, the implication would be that women could affect the evolvement of this health problem themselves, with guidance from medical practitioners and physiotherapists. Pelvic floor exercises, for example, will strengthen the pelvic floor. This may improve various aspects of POP and thereby surgery can be prevented.

1.2 Background to the problem

The editorial letter of the *International Urogynecology Journal*, Whiteside (2004, 367) says that pelvic floor dysfunction, including pelvic organ prolapse (POP) as well as urinary and fecal incontinence, is a complicated problem. He further remarks: "Women develop these problems and we fail completely to know the etiology, the best means of assessment and the best means of correction". (Whiteside, 2004, 367) Whiteside concluded that this should prompt us to more and better research.

POP is the downward displacement of the uterus (or vaginal apex if the uterus was removed), bladder or rectum from the normal anatomical position within the pelvis. In severe cases, it leads to protrusion of the vaginal wall (Hagen, Stark & Cattermole, 2004: 19). Disturbances and deficiencies in pelvic floor muscle (PFM) activity can be associated with conditions such as POP, though it is important to keep in mind that other factors such as fascial laxity and smooth muscle dysfunction are also involved (Sapsford, 2004: 6).

POP is a common condition affecting up to 30% of women attending gynecology clinics (Bump, Matthiassen, Bø, Brubaker, DeLancey, Shull & Smith, 1996: 10) and almost 50% of women over 50 years old (Samuelsson, Victor, Tibblin & Svärdsudd, 1999: 299). It has been estimated that approximately 50% of parous women have some degree of decreased support of the pelvic floor resulting in POP (Olsen, Smith, Bergstrom, Colling & Clark, 1997: 501), but only 20% of these are symptomatic (Digesu, Kullar, Fantl & Wyman, 2005: 178). In spite of the decreased quality of life when having to live with POP symptoms, only 10 - 20% of women seek medical care (Olsen *et al.*, 1997: 501).

In an epidemiological study of surgically managed POP and urinary incontinence, Olsen *et al.* (1997), found that pelvic floor dysfunction is a major health issue for older women. The study results showed that the lifetime risk of undergoing a single operation for POP or incontinence is 11.1%. Re-operation occurred in 29.2% of cases, and the time intervals between repeat procedures decreased with each successive repair. Swift, Pound and Dias (2001: 190-191) found that once a person has undergone surgery for POP, their risk of developing another POP is 500% greater than for the general population. More recent success rates for various types of surgery for POP ranged between 77 – 82% (Koduri & Sand, 2000: 403-404).

According to Weber, Abrahms, Brubaker, Cundiff, Davis, Dmochowski, Fischer, Hull, Nygaard and Weidner (2001), pelvic floor dysfunction afflicts women three

to seven times more than it does men. The gender disparity is markedly evident between the ages of 45 and 69. United States Census projections estimate that the number of women between the ages of 45 and 69 will increase from 27% of the women population in 2000 to 31% in 2020. Furthermore, the number of women 65 years and older in 2000 will more than double by 2050. It has been estimated that almost 500 000 procedures for POP and urinary incontinence are performed in the United States annually (Weber *et al.*, 2001). POP is the pelvic floor disorder most often requiring surgical repair (Summers, Winkel, Hussain & DeLancey, 2006: 1438). These figures underline the seriousness of the problem.

POP is a major cause of morbidity in women. The most frequently verbalized complaint of women with POP is the feeling of "something coming down". Women may report a bulge or a "feeling of pressure" in the vagina. From sometimes being totally asymptomatic in the morning, the discomfort increases as the day progresses, but lying down does give relief (Digesu et al., 2005: 176). Other symptoms associated with anterior vaginal prolapse include the need to reduce the bulge (urinary splinting) in order to void, hesitancy, poor stream, straining to void, incomplete emptying and recurrent urinary tract infections (Tan, Lukacz, Menefee, Powell & Nagar, 2005). Posterior vaginal prolapse may produce symptoms, including incomplete evacuation, constipation, straining, fecal urgency and digital assistance for evacuation (Tan et al., 2005). Obstructed defecation (impaired defecation with the need to use digital pressure in the vagina, perineum or rectum to aid in bowel evacuation) is a symptom endured by 30% of women with uterovaginal POP and between 30 and 100% of women with symptomatic rectoceles (Maher & Baessler, 2005). Sexual dysfunction are also reported (Mouritsen & Larson, 2003).

POP and related pelvic floor dysfunction has an influence on the quality of life of the affected women. Mouritsen and Larson (2003: 126) have found that 75% of women with POP thought that their symptoms have a moderate to severe impact on their life. These symptoms impact severely on the sufferer's daily activities and quality of life (Hagen, Stark & Cattermole, 2004: 19).

Pelvic support weakness may contribute to the development of POP and SUI (Zhu, Lang, Chen & Chen, 2005: 404). According to DeLancey's "hammock-hypothesis", the levator ani muscle (the most important PFM) is the main support of the normal position of the pelvic organs (DeLancey, 1994: 1713). Focusing on urinary incontinence, Morkved, Salveson, Bø and Erik-Nes (2004: 387) determined that continent women had a significant increment in muscle thickness compared to incontinent women. Amaro, Moreira, Gameiro and Padovani (2005:353) also focused on stress urinary incontinence and found that pelvic floor muscle strength was significantly higher in the continent group.

The correlation between muscle strength and urinary continence, however, does not apply to POP. In this regard <u>Weber et al.</u> (2001: 182) states that more research is needed to determine the value of PFM-testing during physical examination of the POP-patient.

1.3 The problem statement

In the past, women's health physiotherapists focused on the management of urinary incontinence. More recently, however, these physiotherapists manage women with POP as well (Hagen, Stark & Cattermole, 2004), with treatment mainly aimed at strengthening the PFM in order to prevent POP from being symptomatic. In view of many uncertainties in this field, an important basic step would be to evaluate the association between measured PFMS and the existence of POP.

1.4 Objectives of the study

The purpose of the study is to investigate the possible correlation between the strength of the PFM and POP, and to determine the threshold where POP will manifest itself.

Two hypotheses are set:

Hypothesis 1

A decrease in the strength of the PFM will correlate with an increase in POP.

A decrease in the strength of the PFM will not correlate with an increase in POP.

Hypothesis 2

A PFMS threshold can be determined to predict the onset of POP. The researcher predicts that symptomatic POP starts when the PFMS is less than 3 on the Oxford scale or less than 15 μ V when testing with the EMG.

A PFMS threshold will not be determined to predict the onset of POP.

1.5 Justification

Apart from building on a foundation of knowledge, the study can be a motivational determinant for physiotherapists to become involved in the rehabilitation of the PFM, theoretically being able to influence the outcome of pelvic organ descent and to prevent severe POP. In a very practical way, a PFM strength threshold will allow gynecologists during regular examination to see which patients have a risk for developing POP, and to refer these patients for physiotherapy in time for conservative treatment still to be effective.

1.6 Design of the study

Chapter I provide an introduction to the report. The background and motivation for the study is given. The objectives are set and the value of the study presented.

Chapter II is a review of the literature concerning POP and PFM strength.

Chapter III is a detailed description of the methodology.

The results follow in chapter IV.

Finally, in chapter V the results are analyzed and discussed, and recommendations made.

1.7 Conclusions

Against this background, the need for research has been made clear. The results can possibly be published in an urogynecology magazine. It can also be distributed to physiotherapists and medical practitioners, especially gynecologists as they see women on a regular basis. It can also be of value to present information on this subject, including the results of this study, in popular women's magazines and general public health magazines.

Chapter II

Literature study: Anatomy, pathophysiology, symptoms and epidemiology relating to POP and the PFM

2.1 Introduction

In this chapter, the anatomy of structures related to support of the pelvic organs will be discussed. It will be followed by the pathophysiology of POP and thereafter the symptoms of POP. Eventually the epidemiology of POP, including the incidence and risk factors, will be discussed.

2.2 Anatomy of the pelvic floor

2.2.1 PFM

Clinically it is seen that most women with POP, also have damage of the PFM (pelvic diaphragm) (Gill & Hurt, 1998: 757). DeLancey (1994: 1713) compared the levator ani muscles (main PFM) to a hammock that supports and maintains the position of the pelvic organs.

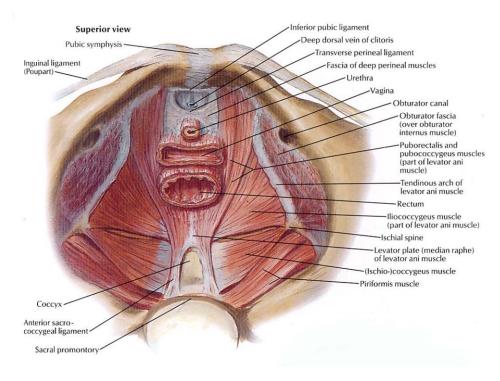


Figure 1: The PFM (superior view) (Netter, 1994).

2.2.1.1 Levator ani muscle (see figure 1)

The levator ani muscle is the most important muscle regarding pelvic organ support (Wei & DeLancey, 2004: 10). The levator ani and coccygeus muscles, together with the fascia covering the superior and inferior aspects of these muscles, form the pelvic diaphragm. The pelvic diaphragm has the appearance of a bowl or funnel as it stretches between the pubic symphysis anteriorly and the coccyx posteriorly and from one lateral wall to the other (Moore & Dalley, 2006: 369). The levator ani is a broad muscular sheet that consists of three parts:

 The Pubococcygeus muscle is a thick U-shaped muscle. It arises from the pubic bones on either side of the midline, and passes back almost horizontally. The most medial fibers relate to the sphincter of the urethra and further back some fibers insert into the vagina (pubovaginalis) and perineal body and rectum (puboanalis). Behind the rectum, most pubococcygeal fibers form a plate (levator plate), which attaches to the coccyx (Wendell-Smith & Salmons (ed.), 1995: 831; Moore & Dalley, 2006: 369-371).

- Iliococcygeus is the thin or aponeurotic posterior part of the levator ani muscle. It arises from the arcus tendinous levator ani (a fibrous band on the pelvic wall) and inserts into the coccyx (Wendell-Smith, & Salmons (ed.), 1995: 831; Moore & Dalley, 2006: 371). The iliococcygeus, together with coccygeus, forms a relatively horizontal sheet across the opening within the pelvis in order to provide a shelf on which the organs may rest (Wei & Delancey, 2004: 11).
- Puborectalis is the thickened, most medial part of levator ani. At its origin, it is inseparable from pubococcygeus, but subsequently passes below it and unites with its partner to form a U-shaped muscular sling that passes posterior to the anorectal junction (Wendell-Smith, & Salmons (ed.), 1995: 831; Fröhlich, Hötzinger and Fritsch, 1997: 227).

The levator ani muscles are innervated by fibers from the second and third sacral spinal segments. Normally, the antero-medial parts are supplied by the pudendal nerve and the postero-lateral parts by direct branches from the sacral plexus (Wendell-Smith, & Salmons (ed.), 1995).

The levator ani muscle is a striated muscle, consisting of approximately twothirds type I (slow twitch) muscle fibers responsible for the resting tone. The other third of the fibers are type II (fast twitch) muscle fibers, responsible for quick, powerful contractions when needed (Gilpin *et al.*, 1989: 20-21).

The other less important component of the pelvic diaphragm, the coccygeus, is postero-superior to levator ani. **Coccygeus** is a triangular muscular-tendinous sheet, with the apex originating from the ischial spine, the side fused to the

sacro-spinous ligament and the base of the triangle inserted into the coccyx and fifth sacral vertebrae (Wendell-Smith & Salmons (ed.), 1995: 832).

The pelvic diaphragm is normally in a state of tonic contraction, even when sleeping, and its tone increases in reaction to an increase in intra-abdominal pressure (Gill & Hurt, 1998: 758). The function of the levator ani muscle is to support the abdominal-pelvic viscera and keep the pelvic viscera in place (Moore & Dalley, 2006: 373). The levator plate acts almost like a trampoline, receiving and resisting sudden increases in intra-abdominal pressure (Gill & Hurt, 1998: 758). The pelvic floor muscles also contract with the abdominal muscles and the abdominal-thoracic diaphragm to increase the intra-abdominal pressure, when for example coughing, sneezing, laughing, lifting and blowing nose (Sapsford, 2004: 4). Furthermore, all medial fibers are contributing to continence, compressing the visceral canals when contracting, and must relax to allow expulsion (Moore & Dalley, 1999: 373). In this regard, the puborectalis is of critical importance to maintain rectal continence and to aid defecation (Moore & Dalley, 2006: 373; Fröhlich, Hötzinger & Fritsch, 1997: 227).

2.2.1.2 Perineal membrane

Also called the urogenital diaphragm, the perineal membrane is a thin layer underneath the pelvic diaphragm. The perineal membrane attaches the urethra, vagina and perineal body to the ischiopubic rami. It lies at the level of the hymenal ring (Wei & Delancey, 2004: 13).

2.2.1.3 Muscles of the urogenital triangle

The superficial muscles of the perineum lie distally to the pelvic diaphragm. The ischiocavernosus muscle and the bulbospongiosus mainly have sexual functions, but the bulbospongiosus also close the vaginal opening when contracting. The superficial and deep transverse perineal muscles stabilize the perineal body. The muscles of the urogenital triangle may not be directly involved in support of the pelvic organs, but they do insert centrally into the perineal body, which also

serves as a fixation point for the distal vagina and anus (Peschers & DeLancey, 1996: 12; Wendell-Smith & Salmons (ed.), 1995: 835).

2.2.2 The endopelvic fascia

The endopelvic fascia attaches the bladder, uterus, vagina and rectum to the pelvic sidewalls. It is composed of a fibrous, connective tissue layer extending diffusely throughout the pelvic floor to form a continuous sheet-like mesentery. The endopelvic fascia is subdivided into the parametrium and the paracolpium. The two components of the parametrium are the cardinal and uterosacral ligaments, which are part of the structural support of the uterus. The cardinal and uterosacral ligaments are called ligaments, but are in fact two different parts of a single mass of loose tissue. The paracolpium attaches the upper two thirds of the vagina to the pelvic wall. It is continuous with the parametrium when the uterus is present. The parametrium helps suspend the vaginal apex after hysterectomy (Glowacki & Wall, 1996; Wei & DeLancey, 2004: 5-6).

2.2.3 The vagina

The vagina is a fibromuscular tube. It is nine to ten centimeters long in a woman of reproductive age. From a lateral view, starting at the entroïtus, the vagina follows a gentle curve backwards to its apex within the hollow of the sacrum. The axis of the upper two thirds of the vagina shifts posteriorly in order to place the upper third of the vagina in a horizontal plane at the level of the third or fourth sacral vertebrae (Gill & Hurt, 1998: 758).

The distal third of the vagina is in close contact with the urethra anteriorly, the perineal body posteriorly and the levator ani muscles laterally. The wall of the upper third of the vagina is directly connected to the cervix, and suspended

postero-laterally over the cul-de-sac of Douglas by the uterosacral-cardinal complex. The vagina is thus shaped like a dome, with anterior, lateral and posterior fornices (Gill & Hurt, 1998: 758; Peschers & DeLancey, 1996: 9).

As the vagina of a woman is normally directed posteriorly, increased intraabdominal pressure causes the upper third of the vagina to close like a flapvalve, compressing the upper third of the vagina and the cul-de-sac against the rectum and levator plate (Peschers & DeLancey, 1996: 9).

One of the functions of the vagina is to support the other pelvic organs. Anteriorly, the lower vaginal wall supports the urethra, the middle part supports the bladder and the upper part supports the cervix. At the posterior vaginal wall, the lower part resists the anterior displacement of the rectum, and the upper part resists the descent of the small bowel. As the anterior vaginal wall lies upon the posterior vaginal wall, the posterior vaginal wall and perineal body also need to support the organs on top of the anterior wall (Gill & Hurt, 1998: 758).

2.3 Pathophysiology of POP

POP is the result of abnormality in pelvic floor architecture, at cellular or gross morphological levels (Hilton & Dolan, 2004: 5). The abnormality leads to failure of the pelvic floor support and causes weakening of the anterior, posterior or apical wall of the vagina. The end result is the downward displacement of the bladder, uterus (or vaginal vault after hysterectomy), rectum or small bowel into the vagina and in severe cases protrusion from the vaginal canal. Multiple pelvic floor support defects would cause multiple organs to protrude, while isolated, little or no damage to the PFM would cause fewer problems (Gill & Hurt, 1998: 757).

2.3.1 Normal pelvic organ support

When attempting to investigate pelvic floor function, knowledge of the fascial connection between the muscles and the organs is crucial. The ligaments and fascia of the pelvic floor are structured more like a mesentery when compared to a skeletal ligament, as it consists of loose connective tissue, smooth muscle, elastic fibers, blood vessels and nerves (Peschers & DeLancey, 1996: 13).

The ligaments cannot withstand constant forces. Because of the composition of connective tissue, it is unsuitable to withstand gravitational forces over a long period of time. If the stress of the great weight of abdominal pressure were only imposed on the ligaments and fascia within the pelvis, they would have stretched. This knowledge clarifies that the pelvic floor ligaments are not the primary factors that prevent the vagina and uterus from prolapsing (Peschers & DeLancey, 1996: 13).

The muscular tonus is responsible to keep the organs in place, as is the case in other parts of the body. The urogenital hiatus of the levator ani is the opening in the levator muscle through which the urethra, vagina and rectum pass. The urogenital hiatus is bound anteriorly by the pubic bones, laterally by the levator muscles and posteriorly by the perineal body and external anal sphincter. Therefore, the normal tonic activity of the levator ani muscle would keep the urogenital hiatus closed and prevent prolapse. When the levator muscle contracts, it compresses the vagina, urethra and rectum against the pubic bone and also lifts the pelvic floor and organs in a cephalic direction (Wei & DeLancey, 2004: 11).

As the levator ani muscles constantly contract and close the opening of the vagina, it eliminates any opening within the pelvic floor through which prolapse can occur. A dynamic horizontal shelf is formed, supporting the pelvic organs (Wei & DeLancey, 2004: 11).

Norton compared the uterus and vagina to a boat anchored in place by the mooring (endopelvic fascia and ligaments) and supported by the water (PFM). Without the moorings, the boat cannot stay in place. But if the water level drops, the moorings are strained beyond their capacity to support the boat. The ligaments and fascia stabilize the organs in place, but the constant adjustments in muscle activity of the PFM prevent overstretching of the ligaments. Injury to the PFM predisposes the women to POP (Wei & DeLancey, 2004: 12-13).

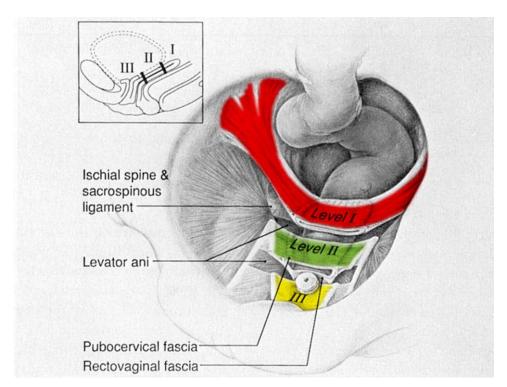


Figure 2: The three levels of pelvic floor support (Wei & DeLancey, 2004: 6).

Regarding the vagina, DeLancey described three levels of pelvic floor support (see figure 2). At level I the cervix and upper third of the vagina are <u>suspended</u> almost vertically from the pelvic wall by the cardinal and uterosacral ligaments. At level II, the middle third of the vagina is <u>attached</u> laterally to the arcus tendinous fascia of the pelvis and superior fascia of levator ani muscles. At level III, the

vagina is <u>fused</u> with the urethra anteriorly, the perineal body posteriorly and the levator ani muscles laterally (Wei & DeLancey, 2004: 6).

Loss of support only at level I would result in uterine and vault prolapse. It can be combined with an enterocele. Loss of support at level II would lead to cystocele or rectocele or both. If the failure of support is at level I and II, prolapse of the apex would be combined with a cystocele or rectocele or both, and it is called a complex vaginal eversion. At level III, the medial fibers of the levator ani muscle are fused to the distal vagina. Therefore, loss of stability at level III has to do more with the ability of the PFM to keep the vagina closed than with the ability of the vagina to stay attached to the surrounding structures (DeLancey, 1992: 1721 -1722; Hilton & Dolan, 2004: 6).

To summarize, normal POP is maintained by three mechanical principles, as suggested by Peschers and DeLancey (2002):

- The endopelvic fascia suspends the pelvic organs through its attachment to the pelvic sidewalls.
- The PFM keeps the vaginal entroïtus closed and acts as a dynamic support and a shelf for the organs to rest on.
- A flap-valve effect is created from the near horizontal position of the uterus on the vagina.

2.3.2 Pelvic support defects

The pelvic floor is a musculo-skeletal unit with passive, neural and active subsystems of control (Panjabi, 1992). Injury to the PFM causes damage to the active subsystem, responsible for support of the pelvic organs against gravity, at rest and with slow, rapid and unpredicted loading (Sapsford, 2004). The neural and active subsystems are closely linked and both influence the function of the PFM.

2.3.2.1 PFM injury

As the PFM volume influences the anatomical position of the pelvic organs (Morkved *et al.*, 2004), injury of the PFM will presumably have an influence on the etiology of POP. The following authors found evidence to substantiate this remark.

Gilpin, Gosling, Smith and Warrell (1989) compared the histological and histochemical analysis of biopsy samples of pubococcygeus in two groups. In the first group were woman with normal urinary control and no prolapse, and in the second group were woman with SUI or POP or both. Their results indicated marked local partial denervation accompanied by reinnervation and a significant increase in the number of fibers showing pathological damage in the symptomatic group.

Allen, Hosker, Smith and Warrell (1990) found EMG evidence of partial denervation in the PFM after the first vaginal delivery in 80% of the study population. The degree of degeneration ranged from slight to severe and symptomatic. However, the authors remarked, denervation progresses with ageing, and further denervation with subsequent deliveries is plausible and could lead to POP.

Investigating the morphology of the pubococcygeus muscle, Zhu *et al.* (2005) detected striated muscle in 26,3% of the SUI group and only in 15,8% of the POP group. The remaining specimens only had connective tissue, smooth muscle and fat tissue. An explanation of these statistics would be degeneration of the levator ani muscle, causing a decrease in density of the muscle and therefore less probability of finding striated muscle in a specimen. They also showed that the diameter of fibers in the POP and SUI group was significantly smaller than the control group. They further demonstrated splitting of the fibers, pointing to

necrosis and degeneration, a pathological alteration of the levator muscle and damage to the innervation.

Smith, Hosker and Warrell (1989) also found partial denervation and consequent weakening of the pelvic floor in women with POP. Building on this, Berglas and Rubin (1953) found that in women with POP, the levator plate sags, inclining the axis of the vagina to the vertical and widening the entroïtus. Eventually, the strain on the fascial supports of the pelvis would be increased.

Support for the finding of Berglas and Rubin comes from DeLancey and Hurd (1998). These authors measured the size of the genital hiatus and found an enlarged hiatus correlated with more advanced prolapse.

Most authors focus on the importance of the levator ani muscle in pelvic floor support. As the bulbocavernosus muscle surrounds the vaginal entroïtus, and reduces the size of the vaginal entroïtus on contraction, Shafik, Mostafa, Shafik and El-Sibai (2002) investigated its role in the pathogenesis of utero-vaginal prolapse. On straining a reflex bulbocavernosus contraction is evoked, which they hipothesize increases the intravaginal pressure in order to counteract the increase in intra-abdominal pressure. This, in turn, may cause narrowing of the vaginal canal and support of the organs.

In a further study, Shafik, El-Sibai, Shafik and Ahmed (2003) demonstrated weaker contractile activity of bulbocavernosus and puborectalis muscles in patients with rectocele, with resultant gaping of the entroïtus. These patients also had significantly low basal vaginal pressure. They propose that the basic reason for the development of a rectocele was that the rectal pressure was higher than the vaginal pressure, resulting in bulging of the septum into the vagina.

Thus, injury of the PFM can be myogenic or neurogenic. The pathogenesis of POP mainly involves the levator ani muscle, but can possibly also involve other PFM.

2.3.2.2 Connective tissue injury

The fascias of the passive subsystem have variable degrees of movement (Spence-Jones, Kamm, Henry & Hudson, 1994). The degree of movement would be increased if direct rupture of the fibers of the connective tissue occurred during childbirth (Barbiero, Sartori, Girão, Baracat & De Lima, 2003: 331), or if the tensile strength of the fibers was decreased by prolonged straining at stool (Spence-Jones *et al.*, 1994).

Clinically, it is seen that some women with risk factors (see page 25) do not develop POP, and vice versa. The reason seems to be that risk factors are only important if there is a predisposition to POP (Takano, Girão & Sartori, 2002).

Injury of the PFM can result in a chain reaction of decreased muscle tone, increased loading of the ligaments, the ligaments becoming progressively less elastic, and eventually the support systems are unable to keep the pelvic organs in position. If the ligaments are more fragile, the risk of developing POP is bigger. In the case of exceptionally weak connective tissue, displacement of the pelvic organs can happen, even with intact muscles. Dissimilarity is also seen in women with strong ligaments that do not have POP, although they have weak muscles (Peschers & DeLancey, 1996).

Collagen may play an important role in the pathogenesis of POP, as it is accountable for the strength of the pelvic connective tissue (Gill & Hurt, 1998: 763). 30% of total proteins in the human body are collagen (Barbiero *et al.*, 2003: 331). Norton (1993) found that women with POP had an increase in the weaker type III collagen. Takano *et al.* (2002) found that women with POP had a lower content of total collagen in the parametrium and in the vaginal apex. In contrast

to this, Barbiero *et al.* (2003) found no statistically significant difference in the quantity of type I collagen in the parametrium of women with and without POP. They did, however, find that the type I collagen was shorter, thinner and disorderly arranged, thus demonstrating a difference in the quality of the fiber.

As discussed in the anatomy section, the uterosacral and cardinal ligaments are an important part of the level I pelvic organ support to the cervix and the upper vagina. Therefore Gabriel, Denschlag, Göbel, Fittkow, Werner, Gitsch and Waterman (2005) assessed the morphological characteristics of the uterosacral ligament in postmenopausal women with and without POP, as well as compared the structural components. They found that women with POP had a significantly higher collagen III expression compared to women without POP. Whereas the function of collagen I is related to mechanical strength in connective tissue, the function of collagen III has to do with tissue elasticity and extensibility. The tissue laxity in women with POP could be explained by the higher collagen III amount. Ewies, Al-Azzawi and Thompson (2003) showed that the quantity of collagen III in biopsies obtained from cardinal ligaments is directly related to the presence of POP.

One needs to keep in mind that connective tissue is a living structure, which undergoes remodelling in response to several factors. But when ligaments are healed by collagen scarring they lose elasticity and strength and can be elongated. In the case of a lacerated muscle, dense connective tissue would fill the site of injury. Although the relative amount of collagen within the ligament may seem to be increased in samples from women with POP, the reason may be poorly oriented collagen that filled the site of injured smooth muscle. Thus, in response to muscle injury, there can be qualitative defects in collagen that again can result in weakening of the pelvic floor. Age is an important factor, as with ageing, decreased elasticity and worsened innervation and vascularization of the pelvic floor will be found. The result is a decrease in pelvic organ support and

eventually it may cause POP (Ozdegirmenci, Karslioglu, Dede, Karadeniz, Haberal, Gunhan & Celasun, 2005).

The possibility therefore exists that a decrease in either the quality or the quantity of the collagen content in connective tissue plays a role in the pathogenesis of POP.

2.4 Signs and symptoms of POP

Although it is not life threatening, POP is a condition that debilitates and distresses the sufferer. Not enough is known about the influence of the symptoms of POP and the related pelvic floor dysfunction on the sufferer. Adding to the problem is the fact that many women delay for years before they discuss their symptoms with a medical practitioner. They are either hesitant to talk about the subject, or they have low expectations of the health system (Mouritsen & Larson, 2003: 122).

The most frequently verbalized complaint of women with POP is the feeling of "something coming down". Women may report a bulge or a "feeling of pressure" in the vagina. From sometimes being totally asymptomatic in the morning, the discomfort increases as the day progresses, but lying down does give relief (Digesu *et al.*, 2005). Other symptoms associated with anterior vaginal prolapse include the need to reduce the bulge (urinary splinting) in order to void, hesitancy, poor stream, straining to void, incomplete emptying and recurrent urinary tract infections (Tan *et al.*, 2005). Posterior vaginal prolapse may produce symptoms, including incomplete evacuation, constipation, straining, fecal urgency and digital assistance for evacuation (Tan *et al.*, 2005). Obstructed defecation (impaired defecation with the need to use digital pressure in the vagina, perineum or rectum to aid in bowel evacuation) is a symptom endured by 30% of women with uterovaginal POP and between 30 and 100% of women with symptomatic

rectoceles (Maher & Baessler, 2005). Sexual complaints are also reported (Mouritsen & Larson, 2003: 126).

In this regard, Rogers, Villarreal, Kammerer-Doak and Qualls (2001) compared the sexual function of women with and without urinary incontinence and/or POP. The women with urinary incontinence and/or POP have poorer sexual functioning and less frequent sexual activity. They were also more likely to avoid sexual activity for fear of incontinence.

Jelovsek and Barber (2006) said that women who seek treatment for POP do it because they want to improve their quality of life and that body image may be a key determinant for quality of life. In a case-control study, the authors found that women with advanced POP were more likely to feel self-conscious, less likely to feel physically attractive, less likely to feel feminine and less likely to feel sexually attractive than normal controls, indicating a decrease in body image. Other tests demonstrated that women with severe POP also suffered significantly lower quality of life on the physical scale and had a decrease in condition-specific quality of life.

Mouritsen & Larsen (2003) investigated the symptoms, bother and POP-Q in women referred with POP. They found that mechanical symptoms were the most bothersome, as it was reported in 70% of cases. SUI was established in 27% and urge incontinence in 21%, totaling 45% of the women with POP. The complaints of urinary incontinence were not confined to patients with anterior vaginal prolapse, but seem to be a sign of global pelvic floor weakness. In contrast to this, problems to evacuate were significantly related to patients with posterior vaginal wall prolapse. In addition to this, more or less 50% of posterior vaginal wall patients complained of constipation. In the study population only half of the women were sexually active. Sexual complaints, such as mechanical or psychological problems caused by the POP, dyspareunia, vaginal dryness and diminished libido, were common. The authors concluded that although symptoms

were frequently reported, they were not related to a specific compartment (Mouritsen & Larson, 2003).

In direct opposition to this, Tan *et al.* (2005) found that urinary splinting is 97% specific for anterior POP. In order to test the predictive value of prolapse symptoms, Tan *et al.* did a large database study with 1912 women. Their most captivating finding was the fact that the report of a bulge is 81% predictive of POP. With advancing degrees of POP, symptoms magnified.

Patients often do not realize that a more severe POP may cause kinking or obstruction of the urethra, therefore masking the urinary incontinence (Bergman, Koonings & Ballard, 1988:1171).

Investigating the symptoms and quality of life of women with POP, Digesu *et al.* (2005) found that 45% of the asymptomatic women had stage I or II POP. Of critical importance was that in all these cases, the leading edge of the vagina was above the hymenal ring. Swift, Pound and Dias (2001: 280) have the same opinion, reporting that women only become symptomatic when the bulge protrudes out of the vaginal canal (some stage II and all of stage III and IV).

To conclude, POP can have an intense influence on the quality of life of the sufferer, causing physical, social, psychological, occupational, domestic and/or sexual limitations of their lifestyles.

2.5 Epidemiology

2.5.1 Introduction

POP is one of the most common indications for gynecology surgery and one would expect to find a wealth of information regarding the condition. On the

contrary, there is not enough epidemiological information regarding POP (Mayne & Assassa, 2004: 3). POP often only becomes symptomatic when the descending segment is through the entroïtus. Therefore POP is often not recognized until end-stage disease exists. The long time span after the inciting or promoting event, makes it difficult to conduct epidemiological studies (Bump & Norton, 1998: 732).

2.5.2 Incidence

Olsen *et al.* (1997: 503) investigated the epidemiology of surgically managed POP and urinary incontinence in a large managed care population in Oregon. The risk of undergoing a single operation for POP or incontinence by eighty years of age was more than 10%. Surgery had to be repeated in almost 30% of cases, and the time intervals between repeat procedures decreased with each successive repair. The author also remarked that the patients that were surgically managed represent only a small portion of all POP patients, as the others are conservatively managed or never seek medical care for their symptoms (Olsen *et al.*, 1997: 503-505).

Samuelsson *et al.* (1999: 301-304) tested 487 women in a primary health care district in Sweden. The prevalence of any degree of POP was 30,8%. However, only 2% of the women with POP had a prolapse where the leading edge of the bulge reached the entroïtus. Swift (2000) examined almost 500 women, using the POP-Q method. The spread of the POP-Q stages in the population revealed a bell-shaped curve. Most women had stage 1 or 2 support. Only a few had either stage 0 (excellent support) or stage 3 (moderate to severe pelvic support defects) results.

In a recent epidemiological study that used self-reports and that was done among a Swedish population, it was found that one out of twelve women complained of POP symptoms (Tegerstedt, Maehle-Schmidt, Nyrén & Hammerström, 2005).

2.5.3 Risk factors

There is a need for more epidemiological studies to resolve the risk factors for POP (Swift, 2000: 280-282).

2.5.3.1 A number of authors have found that advancing **age** has a strong association with greater degrees of POP. According to Olsen *et al.* (1997: 504), the age-specific incidence magnified with advancing age. Swift, Pound and Dias (2001: 190) reported a 12% increase in the incidence of severe POP with each year of advancing age. The incidence roughly doubled every ten years. Undeviating from the above, Samuelsson *et al.* (1999: 301) reported that the prevalence of any form of POP was 6,6% in women between twenty and thirty years old. This prevalence increased to 55% for women between fifty and sixty years old. The main reason for the influence of age on POP is that age weakens the supportive tissue (DeLancey, 1992: 1722).

2.5.3.2 The literature is in agreement that **parity** has an influence on the development of POP. Samuelsson *et al.* (1999: 301) demonstrated POP in 44% of parous women, compared to 5,8% of non-parous women. The Oxford Family Planning study found that parity was the risk factor most strongly related to POP. The risk escalated with each child, but then tapered once the woman had two children. Having had one child, a woman's risk increased to being four times more likely to develop POP. If a woman had four or more children, her risk crescendo to eleven times the risk of a woman with no children (Mant, Painter & Vessey, 1997: 585).

This is the reason why Wei and DeLancey (2004: 3) mentioned that the most vulnerable time for the structures supporting the pelvic organs is during childbirth. During labour, pelvic neuropathies can be caused either by direct pressure of the fetal head on small branches of the pudendal nerve or myoneural junction, or indirectly by stretching of the nerve (Allen *et al.*, 1990: 778). Apart from nerve damage, vaginal deliveries can also cause direct rupture of the fibers of the PFM or ligaments (Barbiero *et al.*, 2003: 331).

There is, however, a debate whether it is the pregnancy, the delivery process or the size of the vaginally delivered infant that is the culprit to be blamed for damage to the pelvic support that causes POP.

Swift, Pound and Dias (2001, 190) identified only the weight of the largest infant delivered vaginally as a risk factor – thus "the passenger and the route of passage" that is the etiological risk factor. Their data suggested a 24% increase in the incidence of severe POP with each 1 lb increase in the weight of the largest infant delivered vaginally. Timonen, Nuoranne, and Meyer (1968: 370) found that one third of the POP patients delivered a child weighing more than 4000g, compared with only 9,5% in the general population.

In contrast to the above, O'Boyle, O'Boyle, Ricks, Patience, Calhoun and Davis (2003: 47-48) demonstrated that POP-Q stage was significantly higher in the third trimester of pregnancy than in the first, demonstrating that changes in pelvic organ support happen also prior to delivery. The possibility that pregnancy is a risk factor was confirmed by a later observational study by O'Boyle, O'Boyle, Calhoun and Davis (2005: 72). Their findings, however, also indicated that POP-Q stage might be higher in women who delivered vaginally, compared to women who delivered by caesarean.

Furthermore, many variables influence the complex event of parity. Sultan, Kamm, Hudson, Thomas and Bartram (1993) showed that forceps delivery and

episiotomy cause pelvic floor dysfunction, but vacuum extraction and any caesarean were protective. In opposition to this, MacAthur, Bick and Keighley (1997) found that both forceps and vacuum extraction cause pelvic floor dysfunction, whereas only elective caesarean and not an emergency procedure is protective.

Klein, Gauthier, Robbins, Kaczorowski, Jorgensen, Franco, Johnson, Waghorn, Gelfand, Geralnick, Luskey and Joshi (1994) showed that episiotomy was associated with weakening of the PFM, and advised that routine episiotomy should be stopped. In contrast to this, Taskin, Wheeler and Yalcinoglu (1996) reported that routine episiotomy when combined with antepartum PFM exercises, was as effective as caesarean delivery in preventing advanced POP 2 months after delivery.

Finally, although parity is a strong determinant for POP, it is not a necessary condition. Tegerstedt *et al.* (2005) found that POP was present in 2,4% of nulliparous women.

2.5.3.3 Radical pelvic surgery and radiation are visibly inciting factors for pelvic floor dysfunction (Bump & Norton, 1998: 738). Swift (2000: 281) reported a reasonably strong association between higher POP-Q system stage and history of **hysterectomy**. Only 1,2% of women with an intact uterus had POP-Q stage 3 prolapse, compared to more than 5% of women with a history of hysterectomy. Swift, Pound and Dias (2001: 191) determined that history of hysterectomy doubled a woman's risk of developing severe POP.

The route of hysterectomy may also have an influence on the development of POP. Where one study did not find any relationship between route of hysterectomy and later vaginal vault prolapse, Swift (2000): 281 established a greater incidence of POP after vaginal hysterectomy than after abdominal hysterectomy. One of the explanations for the seemingly higher risk after vaginal

hysterectomy may be that normally women with POP and an intact uterus are managed with a vaginal hysterectomy as part of the prolapse treatment (Swift, 2000: 281). The reason for the hysterectomy might be more important than the route.

During cadaveric dissections, DeLancey (1992: 1722) demonstrated that normally the uterus and upper vagina are supported by the cardinal and uterosacral ligament complex and the paracolpium in level I. This layer of tissue is more or less 6 cm wide. During abdominal hysterectomy the cardinal and uterosacral ligaments are detached from the cervix, leaving only 2 -3 cm of the paracolpium attached to the vagina. This may well predetermine patients to vaginal eversion later in life as the general deterioration in connective tissue occurs with age.

Cronjé and De Beer (2004: 259) described that of more or less 600 patients with recorded POP, only 19% presented with an intact uterus. The authors explained that as important support structures, including the cardinal and uterosacral ligaments, attach to the uterine cervix, removal of the cervix would cause these structures to retract. When the vaginal vault is left with little support, it is predisposed to prolapse, especially posterior compartment prolapse.

In contrast, Thakar (2004: 23) found that pelvic organ dysfunction is not common after simple hysterectomy. The author reported that there are consistently high satisfaction rates and improvement in quality of life and psychological outcome. The author concluded that the explanation might be that the nerve content of the cardinal and utero-sacral ligament is richer in the middle to lateral thirds towards the pelvic sidewall. During simple hysterectomy only the ligaments with nerves innervating the cervix and uterus are interrupted, but during radical hysterectomy the ligaments are also divided more laterally.

Lastly, the Oxford Family Planning Association (Mant, Painter & Vessey, 1997) indicated that surgery incidence rates to correct POP were higher for women who had undergone hysterectomy for reasons other than POP (0.290% per year) compared to women in general (0.162%). It was, however, highest for women who had a hysterectomy because of POP (1.58% per year). When investigating the association between POP surgery and later POP, Swift, Pound and Dias (2000: 281) reported that not surprisingly, as many as 15% of women with a history of surgery for POP, will have at least a POP-Q stage 3 defect, compared to 2% of women without previous POP surgery. The odds of having severe POP increase by over 500% in women with a previous history of POP surgery (Swift, Pound & Dias, 2001: 191).

- 2.5.3.4 It is known that **estrogen** increases the total skin collagen content (Bump & Norton 1998: 739-740). Smith, Heimer, Norgren and Ulmsten (1993) was the first to demonstrate that the PFM and ligaments have estrogen receptors. Lang, Zhu, Sun and Chen (2003) studied patients with premenopausal POP and showed that estrogen deficiency might contribute to the incidence or progress of POP. In agreement with the previous studies, Bai, Chung, Yoon, Shin, Kim and Park (2005) found significantly lower expression in estrogen and progesterone in post-menopausal women with POP, demonstrating that such receptors could be associated with POP and that the role of HRT could be found. In contrast, Swift, Pound and Dias (2001) notes a greater incidence of post-menopausal status amongst the POP women, but they found that it was a mere reflection of the increased age of these women over the control group. Swift (2000) could not demonstrate any relationship between a lack of HRT and POP either.
- 2.5.3.5 **Smoking and chronic obstructive pulmonary disease or chronic coughing** is thought to possibly have a promoting effect on the development of POP, because of the increase in intra-abdominal pressure. Swift *et al.* (2001) did not find any association. In contrast, Olsen *et al.* (1997) showed

that almost half of the women who had POP surgery were current or former smokers and one-fifth had chronic lung disease.

- 2.5.3.6 Bowel dysfunction may be a major etiological or associated factor in almost all women with POP, and in many women it may be the most important etiological factor (Spence-Jones et al., 1994). Snooks, Swash, Mathers and Henry (1990) demonstrated changes in pelvic floor neurological function and pudendal nerve function in severely constipated women who have strained at stool over a prolonged period. Spence-Jones et al. (1994) found that straining at stool as a young adult prior to developing POP symptoms, as well as a bowel frequency of less than twice per week as a young adult, was significantly more common in the POP group compared to the control group. Also, at the time of consultation, 95% of the women with POP were constipated, compared to only 11% in the control group. The need to digitate in order to evacuate was common. The women with POP also had a prolonged pudendal nerve motor latency (Spence-Jones et al., 1994). In contrast to this, Jelovsek, Barber, Paraiso and Walters (2005) found that either constipation is not a significant contributor, or that constipation contributes equally to development of urinary incontinence and POP. The authors suggested that the lack of use of standardized definitions of functional bowel and anorectal disorders might have an influence on their results.
- 2.5.3.7 **Obesity** is another possible promoting factor, as it also increases the intra-abdominal pressure. Olsen *et al.* (1997) demonstrated that most of the women in their cohort of women that received surgery to correct POP were overweight. Adding to this, the Oxford Family Planning Association found a significant association. Also, Timonen, Nuoranne and Meyer (1968) found that the women in the POP group weighed on the average 5 kilograms more than the women in the control group, but not more than other gynecological patients. In contrast, other authors found no difference in body mass index between women with and without POP (Samuelsson *et al.*, 1999; Swift, Pound & Dias, 2001).

- 2.5.3.8 Investigating the effect of a **retroflected uterus** as an associated factor in the development of POP, Samuelsson *et al.* (1999) found that there was no correlation and explained that it is possible that the uterus becomes more retroflected the more the cervix and the uterus descend in more severe cases of POP.
- 2.5.3.9 Occupational and recreational stresses may also be a promoting factor. Jorgenson, Hein and Gyntelberg (1994) examined the effect of **repetitive heavy lifting** on the development of POP. The surgery rates of 28 000 assistant nurses was compared to more than 1,6 million age-matched controls. The odds ratio for the nurses to have had POP surgery compared with that for controls was 1,6. The results of a study done by Woodman, Swift, O'Boyle, Valley, Bland, Kahn and Schaffer (2006) is in agreement with this finding. The authors examined more than 1 000 patients and found that women who were laborers or factory workers had significantly more severe POP than the other job categories (p < 0.001). This implies that heavy lifting may indeed contribute to POP.
- 2.5.3.10 Race and ethnicity may also be a predisposing factor (Bump & Norton, 1998). Bump (1981) cited white race as a risk factor for developing POP. Hoyte, Thomas, Foster, Shott, Jakab and Weidner (2005) compared pelvic morphology between asymptomatic African-American and white nulliparous women. They found increased levator ani muscle bulk among the African-American women, as well as closer puborectalis attachment indicative of a longer denser attachment of the levator muscle to the arcus tendineus levator ani. The only significant difference in bony pelvic morphology was that the pubic arch was wider among African-American women compared to white women. The authors explained that while a smaller pelvic floor seems to be a disadvantage for vaginal birth, African-American neonates are consistently of smaller average birth weight than white neonates.

2.5.3.11 **Posture** may have an influence on the development of POP. Radiological studies of the bony pelvis have found women with stage II or more POP, have less lumbar lordosis, a decreased lumbo-sacral angle and a more horizontally orientated pelvic inlet compared to women with stage I or less POP. These changes would result in a higher proportion of the weight of the abdominal and pelvic organs to be supported by the pelvic floor and not by the pelvic bones and abdominal wall (Schimpf & Tulikangas, 2005: 317).

2.5.4 Conclusion

In most women with symptomatic POP, damage to the PFM can be detected during examination (Gill & Hurt, 1998). Approximately 50% of parous women lose pelvic support, resulting in prolapse. While surgically managed patients represent only a small fraction of those affected, the lifetime risk of undergoing a single operation for POP or urinary incontinence still is 11.1% (Olsen *et al.*, 1997). POP has a negative effect on the quality of life of women, as the morbidity impacts on social, psychological, occupational, domestic, physical and sexual well-being (Rogers *et al.*, 2001).

Chapter III

Methodology: The research design, instruments and methods

3.1 Introduction

According to Currier (1990: 5) research can be defined as a meticulous and orderly study that uses scientific methods to assemble or reveal facts, tests hypotheses, and show relations. The purpose of the current study agrees with this definition, trying to compile information in order to test hypothesis and to establish possible relationships. In this chapter follows a discussion of the research design, as well as a detailed description of the method of research. The research ethics will be included. Methods, definitions, and descriptions conform to the standards recommended by the International Continence Society except where specifically noted.

3.2 The research design

Considering that the aim of the study was to find a correlation between POP and PFM strength, the need was for a <u>descriptive quantitative clinical research</u>. In particular, a <u>cross-sectional analytic study</u> was indicated. Quantitative research answers questions among measured variables with the purpose of explaining, predicting and controlling phenomena (Leedy & Ormrod, 2002: 101). Furthermore, a cross-sectional analytic study allows comparisons between subgroups, and may show a relationship between exposure and outcome (Joubert & Katzenellenbogen, 1997: 67).

3.3 Sample

Women who came for regular gynecology visits at the Urogynecology unit of the Universitas hospital, a tertiary teaching hospital of the University of the Free State, between October 2005 and June 2006, were included in the study. Only the women seen by two of the gynecologists (both gynecologists have a special interest in urogynecology) were included in the study. A total of 117 women were included in the study. It was planned to include 400 women in the sample, but since the study could not be performed at Pelenomi Hospital, this number could not be achieved in the allocated time period. Even when the time period was extended from 3 to 9 months, the number planned could not be reached.

Inclusion criteria: female, age between 20 and 85 years.

Exclusion criteria: patients with previous prolapse surgery, pregnancy, collagen diseases, as well as patients that could not understand the instructions because of a language problem.

3.4 Measurements

Three measurements were employed for data collection in this research. They included the POP-Q measurement, PFM testing according to a modified Oxford scale and EMG testing of the PFM. A "participant information form" was also used in order to have more information about the participants, relevant to POP. The mere reason for these questions was to be able to explain certain findings better during the discussion.

3.4.1 "Participant information form" (see appendix A)

A structured questionnaire with close-ended questions was used. The questionnaire was designed according to the recommendations for minimum data collection for all pelvic floor disorders related to characteristics of the study

population (Weber *et al.*, 2001). The reason for this standard minimum amount of data is to ensure an adequate description of population characteristics and allow comparison between studies. The questions are based on the factors that pose a risk for the development of POP. These risk factors were discussed under the heading epidemiology in chapter II. Weber *et al.* (2001) continued that additional data should be obtained according to each study's primary and secondary objectives. Additional to the questions proposed by Weber *et al.*, question 11 (see addendum A) was included to detect the activity level of women included in the study. There seems to be a link between PFMS and activity level and in some women general activity can even maintain PFM function without any specific PFM exercises (Gordon & Logue, 1984).

The POP-Q stage and compartment, PFM strength according to the Oxford scale and EMG results were also recorded on the participant information form.

The researcher asked the questions on the "Participant information form" to the woman in the language of preference (translator used).

3.4.2 The POP-Q test

The lack of standardized terminology in pelvic floor disorders used to be a major hindrance to performing and interpreting research (Weber *et al.*, 2001). A standard system of terminology accepted by the International Continence Society, the American Urogynecologic Society, and the Society of Gynecologic Surgeons for the description of female POP and pelvic floor dysfunction minimized this obstacle (Bump *et al.*, 1996). Reproducibility studies done in six centers in the United States and Europe concluded that the interobserver and intraobserver reliability of the system, including the pelvic organ prolapse quantification exam (POP-Q), is good (Bump *et al.*, 1996). The validity of the system is good.

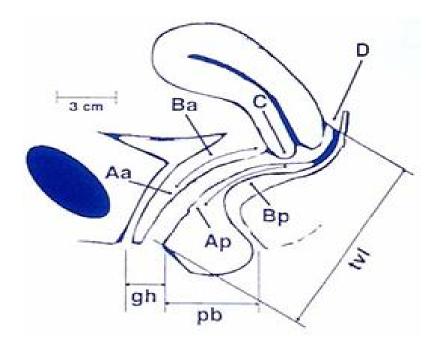


Figure 3: POP – Q Scoring system for prolapse

The POP-Q considers six defined points within the vagina (see figure 3): two anterior (Aa and Ba), two posterior (Ap and Bp) and two apical (C and D) (Fig 1). Each point is expressed as distance in centimeters (cm) from the hymen. The hymen can be considered as a fixed landmark for reference. Points are measured with the woman performing maximum Valsalva. Each point is defined as zero if it is seen at the level of the hymenal ring and as a negative or positive number if it is seen above or below the hymen, respectively (Bump *et al.*, 1996).

Point Aa is located in the midline 3 cm proximal to the external urethral meatus on the anterior vaginal wall. Point Ba represents the most distal position of the upper portion of the anterior vaginal wall from the vaginal cuff or anterior vaginal fornix to the point Aa.

On the posterior vaginal wall, Point Ap is located in the midline 3 cm proximal to the hymen. Point Bp represents the most distal position of the upper portion of the posterior vaginal wall from the vaginal cuff or the posterior vaginal fornix to point Ap.

Point C is the most distal part of the anterior lip of the cervix (or the vaginal cuff in a woman who has undergone total hysterectomy). Point D represents the location of the posterior fornix and it is omitted if the woman underwent total hysterectomy.

Lastly, POP-Q considers three more measurements: total vaginal length (TVL), genital hiatus (GH) and perineal body (PB), expressed in centimeters. The prolapse can be differentiated according to the position of the lowest portion of the prolapse. Stages of prolapse range from 0 to IV, and are defined as follows (Bump *et al.*, 1996):

- Stage 0: No prolapse is demonstrated. Points Aa, Ap, Ba and Bp are all at
 -3 cm and either point C or D is between -TVL cm and (TVL-2) cm.
- Stage I: The standards for grade 0 are not met, but the most distal portion of the prolapse is more than 1 cm above the level of the hymen.
- Stage II: The most distal portion of the prolapse is 1 cm or less than 1 cm proximal to or distal to the plane of the hymen.
- Stage III: The most distal portion of the prolapse is more than 1 cm below the plane of the hymen but protrudes no further than the total vaginal length (TVL) in centimeters.
- Stage IV: Complete eversion of the total length of the lower genital tract is basically demonstrated. The distal portion of the prolapse protrudes to at

least (TVL-2) cm. Most of the time, the leading edge of the prolapse will be the cervix or vaginal cuff scar.

The gynecologist determined the POP-Q stage.

3.4.3. The digital PFMS test according to a modified Oxford scale

An intravaginal palpation was performed by the researcher using a palpation protocol conforming to the validated PERFECT scheme of Laycock. Before testing the strength of the PFM, it is important to establish that the correct PFM contraction is being performed. During a maximum voluntary contraction the anus retracts, the perineum is drawn inwards and the posterior vaginal wall moves towards the anterior wall. A digital examination is performed with one finger on the bulk of the PFM on the inside of the vagina and the non-examining hand positioned on the abdomen. The maximum voluntary force (Pmax) was assessed on a six-point Oxford grading scale:

- Grade 0 indicates no distinguishable PFM contraction.
- Grade 1 indicates a very weak PFM contraction and feels like a flicker.
- Grade 2 represents a weak PFM contraction, as an increase in tension in the muscle can be detected, but no lift or squeeze can be identified.
- Grade 3 represents a moderate contraction. A degree of lifting of the posterior vaginal wall, squeezing on the finger and drawing-in of the perineum can be detected.
- Grade 4 indicates a good PFM contraction. On examination it is found that
 the posterior vaginal wall elevates against resistance, while the perineum
 draws in. When the index and middle finger are placed laterally in the
 vagina and separated, the contraction would squeeze them together
 against resistance.
- Grade 5 describes a strong PFM contraction. Elevation and approximation
 of the PFM still occur in spite of strong resistance (Laycock & Jerwood,
 2001).

Bump *et al.* (1996) mentioned digital vaginal examination as one of the types of PFM testing that are currently used in clinical practice and scientific literature. The authors stated that it is important that a maximum PFM contraction should not involve the abdominal wall muscles and other muscles, and should be without a Valsalva manoeuvre. In the "Report from the Standardization Sub-committee of the International Continence Society", defining the strength of a voluntary PFM contraction by a validated grading system as the Oxford 1-5, was included in the different assessment options (Abrahms *et al.*, 2002). Devreese *et al.* (2006) stated that visual inspection and digital test are easy and reliable methods for evaluating PFMS. Amaro *et al.* (2005) were able to demonstrate significant results using digital testing of the PFM. Validity of the digital method was demonstrated by the highly significant correlation between digital and perineometric techniques in a sample of 233 women (Laycock & Jerwood, 2001).

The PERFECT scheme of Laycock shows an intra-tester agreement of 71% and a test-retest agreement of 69% (Laycock, 1992).

3.4.4 The electromyography (EMG) test of the PFM strength

The second instrument used for testing the PFM strength, is EMG testing. The test was performed by the researcher. The machine used was a Chattanooga Intellect Advanced, model number 2762CC. A vaginal electrode is used with another electrode on the inferior aspect of the buttock muscle, just above the origin of the Hamstring muscles, to act as an earth. Firstly, the average of three maximal contractions was recorded. Secondly, the time that a medium contraction (target set at 50% of the three average contractions) could be held was recorded. The endurance of PFM contraction was assessed in seconds, with a maximum of 20 seconds. The data was saved on a computer card for accurate measurement.

According to Bump et al., EMG of the PFM can be recorded alone or in conjunction with other measurements. The authors also comment that it must be

taken into consideration that signals from wrongly contracted nearby muscles may interfere with signals from the muscles of interest. Observation for perineal movement can be considered as an additional validation procedure (Bump *et al.*, 1996). Additionally, in the "Report from the Standardization Sub-committee of the International Continence Society" it is noted that PFM strength can be assessed by, among others, electromyography (Abrahms *et al.*, 2002). It is a well-known fact that measuring the pressures in the pelvic cavity is difficult, since all increases in intra-abdominal pressure may interfere with the meaurements (Amaro *et al.*, 2005). The same problem applies to intra-vaginal EMG measurement. However Bø *et al.* (1990) have shown that problems regarding measurements of pressures in the pelvic cavity can be solved by clinical observation and proper teaching. In this study, an experienced physiotherapist and clinical observation were used to control these factors.

The reliability of the EMG measurement is good as discussed above. The validity is also good as was determined by test-retest trials.

3.5 Method of data collection

After signing informed consent (see appendix B and C), the researcher (physiotherapist) asked the patient the questions on the questionnaire. The participants were asked to empty their bladder before the examination. The participants were examined in the supine position with the hips and knees flexed at 90°. The gynecologist examined the prolapse. Each compartment was assessed separately while the other compartments were retracted with a speculum. Assessments were made during maximum Valsalva manoeuvre. Verbal encouragement was used to ensure the Valsalva manoeuvre is at a maximum. The patient was asked to confirm if the prolapse is as big as was experienced during daily activities. The nine POP-Q measurements were determined by a ruler. The stage of the prolapse was defined from 0 to IV, in the anterior, middle and posterior compartments of the vagina. As both gynecologists

are very experienced in this field, as well as teaching other gynecologists at congress workshops how to do POP-Q tests, the reliability of the inter-observer variability was very good.

In order to limit bias the **digital PFM test** was done before the EMG test, to prevent the **physiotherapist** being influenced by the results of the EMG test. It also serves as an assessment to see if the patient is doing the PFM contraction correctly and a time to teach the patient how to perform a PFM contraction. The patient was situated in the same position as during POP-Q assessment. The digital examination was done, using one finger. The contraction was then graded according to a modified Oxford scale, from zero to five. Only one physiotherapist (the researcher) tested the PFMS. The intra-observer reliability was good, as was determined with test-retest trials.

All subjects underwent an **intravaginal EMG measurement**, using a 2-canal vaginal sensor and the reference electrode under the left buttock. The participant was asked to perform three voluntary maximum PFM contractions and the value of the average (Pmax) was recorded. After a rest period of 20 seconds, the participant was asked to hold a medium contraction (50% of Pmax) for as long as she can. All the data was saved onto a computer card for accurate measurement. The **physiotherapist** observed the perineum to detect abnormal straining during an attempt to do a PFM contraction, and also observed and palpated for accessory muscle contraction of the abdominal wall, gluteus and adductor muscles.

The examiner documented all findings on the "participant information form".

3.6 Data processsing

The data was processed and reviewed by the Department of Biostatistics of the University of the Free State. The first research question was answered using

cross-tables and the correlations was determined through Fischer's exact test with 95% CI for relative risks. In order to answer the second research question, sensitivity and specificity of different thresholds were determined.

3.7 Ethical considerations

All participants were informed of the nature of the study, the procedures and their right to refuse or withdraw. There was nobody that refused to participate. An informed consent letter (see appendix B and C) was signed in each case. No harm was done during the examination. Care was taken not to cause embarrassment. The examinations were done under professional circumstances in a room separate from the consultation room and with a nurse in attendance. The respondents' information remained anonymous and confidential.

Approval was obtained from the Ethical Committee of the University of the Free State and the Head of the Universitas Hospital and Pelonomi Hospital, Bloemfontein, before conducting the study (see appendices D, E and F).

3.8 Pilot study

A pilot study was conducted for a period of 2 weeks in order to test the instruments. The data was not included in the study.

3.9 Limitations

Firstly, the population of 117 women is not large enough to allow generalization of results. Secondly, the population included more older and symptomatic women than young asymptomatic women, making it difficult to draw statistically significant comparisons. The researcher also experienced practical problems

where one hospital clinic (Pelonomi Hospital) was too busy to allow time for research. Another constraint is that the EMG machine registered a minimum value of 10 μ V, making a reading below 10 μ V impossible.

3.9 Conclusion

In order to establish the correlation between PFMS and POP, women coming for regular examination to an urogynecology clinic were tested. In order to be able to describe and compare the study population, information was collected regarding demographic and medical details, as well as information on their activity level. PFMS were tested using two methods: digital testing using a modified Oxford-scale and EMG testing with a vaginal electrode. POP was tested using the POP-Q staging system. In the following chapter, the results will be discussed.

Chapter IV

Results

4.1 Introduction

In order to establish what the correlation between POP and the strength of the PFM is, 117 women were tested. Firstly, data was gathered regarding factors that can influence POP in order to be able to give a good description of the population (see information form A). Secondly, the degree of POP was measured using the standardized POP-Q tool. Thirdly, the strength of the PFM was tested digitally, using the modified Oxford scale. And lastly, the strength and endurance of the PFM was tested with an EMG machine.

Results were summarized by frequency and percentages (categorical variables) and medians, quartiles, minima and maxima (numerical variables). Spearman rank correlations were calculated between measures of PFMS and POP. The sensitivity and specificity of predicting various cutpoints of digital measurement according to a modified Oxford scale and EMG measurement were calculated.

In order to answer the first research question, the data regarding POP and PFMS were compared. The answer to the second research question, namely what the threshold of PFMS is where symptomatic POP begins, was addressed by means of sensitivity and specificity tests. More data regarding POP and the PFMS in the study population was revealed. Eventually, the two different ways of testing the PFMS were compared.

4.2 Data of the study population

4.2.1 The characteristics of the study population

(see Table I and II)

Data related to characteristics of the study population was collected according to the recommendations by Weber *et al.* (2001). The objective for these recommendations by Weber *et al.* is the need for high-quality research on the subject of pelvic floor disorders. The standard minimum amount of data allows adequate description of the population characteristics and allows comparison between studies.

The **age** of the women ranged from twenty to eighty two (mean 50.4 and SD 16.6). The **parity** of the women ranged from zero to nine. Ten (8.5%) of the women had more than four children. Sixteen (13.7%) of the women were nulliparous.

Regarding **method of giving birth**, 14 babies were born by caesarean section, compared to 93 via vaginal birth. The **weight of the heaviest baby** that was given birth to by the women assessed, ranged from 1 364 gram to 6 900 gram (median 3 500). **Hormone replacement therapy** was used by 39% of the women.

Most of the women in the study population were white (74.4%). The median of the **body mass index** was 26.3. About a quarter of the women were **smokers** (26%). Of all the women assessed, 43% had undergone a **hysterectomy**.

Only a few of the women had a history of serious **medical problems**, only the 9% who had lung problems is worth mentioning.

TABLE 1: DEMOGRAPHIC AND MEDICAL DETAILS

AGE: (n = 117)

Age Group	Frequency	Percentage
<u><</u> 29	16	13.7
30 – 39	24	20.5
40 – 49	10	8.6
50 – 59	29	24.8
60 – 69	22	18.8
<u>></u> 70	16	13.7

PARITY: (n = 116)

0 Children 13.8 % 1-2 44.8 % 3-4 32.8 % 5 or more 8.6 % Max 9

GRAVITY: (n = 116)

0 12.9 % 1-2 35.3 % 3-4 36.2 % 5 or more 15.5 % Max 10

VAGINAL BIRTHS: (n = 116)

0 19.8 %

1-2 43.1%

3 or more 37.1%

CAESAREAN SECTIONS: (n = 116)

0 87.6 %

1-2 20.6%

3-4 1.8%

MAX BIRTH WEIGHT HEAVIEST INFANT: (n = 116)

Median 3 500 g

Min 1 364 g

Max 6 900 g

MENOPAUSAL STATUS: (n = 117)

Pre 39.3 %

Post 60.7 %

HRT: (n = 117)

Yes 39.3 %

No 60.7 %

If yes,

0 - 5 yr 30.4 %

6 – 10 yr 8.7 %

11 – 19 yr 26.1 %

20 + 34.8 %

RACE: (n = 117)

White 74.4 %

Black 18 %

Coloured 7.7 %

BMI: (n = 117)

Median 26.4

Minimum 17.2

Maximum 53.5

SMOKERS: (n = 117)

Yes 25.6 %

No 74.4 %

If yes, smoking for (in years):

0-5 20 %

6 – 10 16.7 %

11 – 20 20 %

21 – 30 30 %

31 – 40 10 %

40 + 3.3 %

PREVIOUS HYSTERECTOMY: (n = 117)

Yes 43 %

No 57 %

PAST MEDICAL HISTORY: (n = 117)

Neurological disease 2.6 %

Diabetes mellitus 1.7 %

Lung disease 9.4 %

In addition to other information of the study population, it was also important to know more about their activity level. Regarding the questions detecting the particular women's **activity level** (see Table II), 73.3% said that they do their housework themselves, but 69.2% also said that they have a cleaner who works four to five days a week. Only 36.8% of the women said that they walk to work and shops. Furthermore, only 26.5% of the women were taking care of small children, a responsibility that requires a certain amount of activity. 52.1% of the women said that they do regular exercises, but the intensity of the exercises ranged from walking for ten minutes with a small dog to training to run the Comrades marathon. Eventually, only 33.6% of the women answered affirmatively when they were asked if they had an active lifestyle.

TABLE II: ACTIVITY LEVEL OF POPULATION

Do Own Housework:

Yes 73 %

No 31 %

Cleaner:

Once a week 4 %

2 - 3 / week 27 %

4-5 / week 69 %

Walk to work / shops:

Yes 37 %

No 63 %

Take care of small children:

Yes 26.5 %

No 72.5 %

Exercise:

Yes 52 %

No 48 %

If yes, exercise:

3 x / week or more 80 %

< 3 x / week 13 %

1 x / week 7 %

Active lifestyle:

Yes 34 %

No 66 %

From the data in table I and II it is evident that the study population was more older, inactive women with a high body mass index.

4.2.2 Results of the POP-Q test in the study population

The <u>POP-Q test</u> (see figure 4) was done to determine the severity and site of POP. Stage 0 represents no POP and stage IV a full eversion of the vagina.

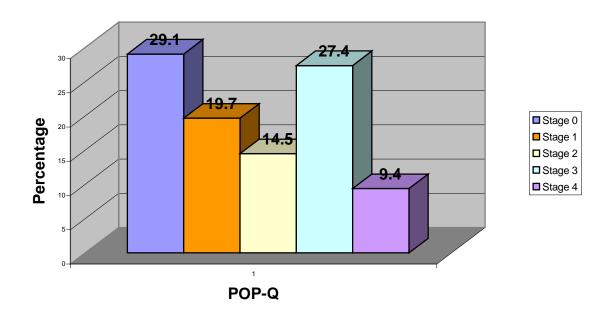


Figure 4: The spread of the stages of POP in the population.

The population represented different stages of POP. Unfortunately, the site of weakening of the vaginal wall was not documented from the start of the study, and there are 47 cases in which it was not done. Of the remaining women, 44.3% had an anterior POP, 30% had a posterior POP, 20% had an apical POP and 4.3% had a posterior POP with an enterocele.

4.2.3 Results of digital testing of the PFM using the modified Oxford scale

Digital testing of the <u>PFMS using the modified Oxford scale</u> was done and the PFMS was then graded from 0 to 5, where grade 0 represents no PFM contraction and grade 5 represents a strong PFM contraction (see figure 5).

PFMS (Oxford scale)

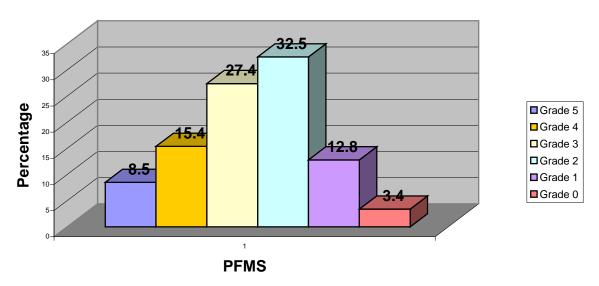


Figure 5: The results of digital testing of the PFM according to the modified Oxford scale in the population.

The results of digital testing of the PFM almost seems to resemble a bell-shaped curve, which would indicate a normal spread in the study population.

4.2.4 Results of EMG testing of PFMS

In order to get data that is as objective as possible on the PFMS, EMG testing was included in the methodology. The results of the **strength of the PFM (P max) when measuring with the EMG** machine, varied between minimum 0 μ V and maximum 85 μ V, with a median of 20 μ V. The endurance of a medium contraction (50% of P max) varied between 0 seconds and 20 seconds (the maximum cutoff time decided on by researcher), with a median of 5 seconds. The Spearman correlation coefficients also demonstrated a strong correlation (of 0.74) between PFMS and endurance as was measured with the EMG machine (p < 0.0001).

4.3 The relationship between POP and the strength of the PFM

A comparison was made of the POP-Q measurement compared to the PFMS according to the Oxford scale (see Table III and Table IV). In the women with grade 0 PFMS on the Oxford scale, 100% of the women had a POP (POP-Q stages I to IV). As the muscle strength improved from grade 2 upwards, the number and severity of POP decreased. In the case of grade 5 PFMS, only 30% of the women had a POP, and the prolapse was not severe (only POP-Q grade I) and no women had a symptomatic POP (POP-Q stages III and IV).

When tested with Spearman's correlation coefficient, the correlation (-0.57) of the PFMS measured according to a modified Oxford scale and the severity of POP as measured with POP-Q measurement, is significant (p < 0.0001).

TABLE III: Relationship between PFMS (Oxford scale) and POP (POP-Q staging)

	POP-Q	POP-Q	POP-Q	POP-Q	POP-Q	
	Stage 0	Stage I	Stage II	Stage III	Stage IV	TOTAL
PFMS	0	1	1	1	1	4
Grade 0	0%	25%	25%	25%	25%	
1	1	0	5	6	3	15
	6.7%	0%	33.3%	40%	20%	
2	5	5	5	19	4	38
	13.2%	13.2%	13.2%	50%	10.5%	
3	10	9	5	5	2	32
	31.3%	28.1%	15.6%	15.6%	6.3%	
4	11	5	1	0	1	18
	61.1%	27.8%	5.6%	0%	5.6%	
5	7	3	0	0	0	10
	70%	30%	0%	0%	0%	
TOTAL	34	23	17	32	11	117

TABLE IV: Association between PFMS (Oxford scale) and POP (POP-Q staging): differentiating any POP and symptomatic POP

PFMS	ANY PROLAPSE (> 0)	SYMPTOMATIC PROLAPSE (> Stage III)	
0	100 %	50%	
1	93.3%	60%	
2	86.8%	60.5%	
3	68.7%	21.9%	
4	38.9%	5.6%	
5	30%	0%	

From the data in table IV, it is evident that the severity of POP increased as the strength of the PFM decreased.

Table V compares the median of the **EMG measurement of the PFMS to the severity of POP (POP-Q measurement)**. It demonstrates that as the PFMS decreases, the severity of the POP increases. Among the women with no POP the median of their PFMS as was measured with the EMG, was 32.5μV and the median of the endurance was 12 seconds. As the severity of the POP increased, the EMG measurement of the PFM did not differ significantly, but the endurance of the contraction decreased remarkably. The EMG measurement of the strength of the PFM of the women with a stage II POP had a median of 15μV, which they could hold for only 2 seconds. The women in the study population with stage III POP had a median of PFM EMG measurement of 10μV with an endurance time of only 1 second.

When tested with Spearman Correlation, a moderately good correlation (-0.62) between PFMS as measured by EMG and POP was proven (p < 0.001).

TABLE V: Relationship between POP-Q and the strength (in μV) and endurance (in s) of the PFM (EMG)

POP-Q	N	Verieble	M	Medien	Lower	Upper
Stage	Obs	Variable	N	Median	Quartile	Quartile
0	34	EMG-S	34	32.5	25	40
		EMG-E	34	12	5	20
I	23	EMG-S	23	20	15	40
		EMG-E	23	12	5	20
II	17	EMG-S	17	15.1	10	20
		EMG-E	17	2	1	4
III	32	EMG-S	32	10	10	12.5
		EMG-E	32	1	1	4.5
IV	11	EMG-S	11	15	10	20
		EMG-E	11	3	1	4

The Spearman Correlation Coefficient (-0.55) between POP and the endurance of the PFM was strong (p < 0.0001).

4.4 Determining the threshold of PFMS where symptomatic POP begins

Table VI: Determining a threshold where symptomatic POP begins regarding PFMS using the modified Oxford scale.

	SENSITIVITY	SPECIFICITY
PFMS = Grade 0	2/43 = 4.7 %	72/74 = 97.3 %
PFMS ≤ Grade 1	11/43 = 25.6 %	66/74 = 89.2 %
PFMS < Grade 2	34/43 = 79.1 %	51/74 = 68.9 %
PFMS ≤ Grade 3	42/43 = 97.7 %	27/74 = 36.5 %
PFMS < Grade 4	43/43 = 100.0 %	10/74 = 13.5 %

The **threshold** for symptomatic POP therefore would be **grade 2** PFMS when using digital testing according to a modified Oxford scale. The positive predictive value is 60% and the negative predictive value is 85%. The accuracy is 73%.

Table VII: Determining a threshold where symptomatic POP begins regarding EMG testing of the PFMS.

	SENSITIVITY	SPECIFICITY
PFMS ≤ 0 μV	3/43 = 7.0 %	73/74 = 98.6 %
PFMS ≤ 10 μV	29/43 = 67.4 %	62/74 = 83.8 %
PFMS <u><</u> 15 μV	35/43 = 81.4 %	51/74 = 68.9 %
PFMS ≤ 20 μV	39/43 = 90.7 %	39/74 = 52.7 %
PFMS ≤ 25 μV	40/43 = 93.0 %	31/74 = 41.9 %
PFMS ≤ 30 µV	42/43 = 97.8 %	26/74 = 35.1 %
PFMS ≤ 35 µV	42/43 = 97.8 %	18/74 = 24.3 %
PFMS <u><</u> 41 μV	43/43 = 100.0 %	13/74 = 17.6 %

The **threshold** for developing symptomatic POP would be $\underline{15 \ \mu V}$ when considering EMG testing of the PFMS. The positive predictive value is 60% and the negative predictive value is 68%. The accuracy is 74%.

4.5 More information on POP in the study population

Table VIII compares the **degree of POP between different age groups.** The severity of POP increased with age. In women 29 years of age and younger only 5.3% had a POP more severe than stage I, compared to 87.6% of women in the age group 70 years and older.

TABLE VIII: DEGREE OF POP IN DIFFERENT AGE GROUPS

Freq							TOTAL
Col Pct	<u><</u> 29	30 – 39	40 – 49	50 – 59	60 – 69	<u>></u> 70	
	years	years	years	years	years	years	
Stage 0	14	13	3	2	0	2	34
	87.5%	54.1%	30%	5.9%	0%	12.5%	
Stage I	1	9	4	4	5	0	23
	6.3%	37.5%	40%	13.8%	22.7%	0%	
Stage II	0	1	2	3	9	2	17
	0%	4.2%	20%	10.3%	40.9%	12.5%	
Stage III	1	1	1	17	7	5	32
	5.3%	4.2%	10%	58.6%	31.8%	31.3%	
Stage IV	0	0	0	3	1	7	11
	0%	0%	0%	10.3%	4.6%	43.8%	
TOTAL	16	24	10	29	22	16	117

4.6 More information on PFMS in the study population

Table IX compared the **strength of the PFM between the different age groups** (as measured according to the modified Oxford scale). As expected, the strength of the PFM decreased with age. In the age group 29 years and younger, the PFMS measured 4 or 5 in 38% of the women. None of the women 70 years and older achieved this.

TABLE IX: PFMS (DETERMINED DIGITALY ACCORDING TO A MODIFIED OXFORD SCALE) BY AGE GROUP

PFMS							TOTAL
(Oxford)	<u><</u> 29	30 – 39	40 – 49	50 – 59	60 – 69	<u>≥</u> 70	
	years	years	years	years	years	years	
Grade 0	0	0	0	2	1	1	4
	0%	0%	0%	6.9%	4.6%	5.3%	
Grade 1	2	0	1	5	3	4	15
	12.5%	0%	10%	17%	13.6%	25%	
Grade 2	3	4	2	12	10	7	38
	18.8%	16.7%	20%	41.4%	45.5%	43.8%	
Grade 3	5	7	3	8	5	4	32
	31.3%	29.1%	30%	27.6%	22.7%	25%	
Grade 4	4	7	3	2	2	0	18
	25%	29%	30%	6.9%	9%	0%	
Grade 5	2	6	1	0	1	0	10
	12.5%	25%	10%	0%	4.5%	0%	
					_		
TOTAL	16	24	10	29	22	16	117

4.7 Comparison of the different measurement methods of the PFMS

Table X demonstrates the relationship between the PFMS as it was measured in the two different ways, namely manually according to a modified Oxford scale and with the EMG machine. A measurement of 0 on the Oxford scale was also $0\mu V$ when measured with the EMG machine. The correspondence can clearly be seen as a 2 on the modified Oxford scale compared to an EMG measurement of $10\mu V$, grade 3 on the Oxford scale compared with an EMG measurement of

 $20\mu V,$ a grade 4 compared with $35\mu V$ and lastly a grade 5 compared with a median of $57.5\mu V.$

TABLE X: THE RELATIONSHIP BETWEEN PFMS AS MEASURED ACCORDING TO A MODIFIED OXFORD SCALE AND WITH THE EMG MACHINE

PFMS	N	N	Median (EMG	Lower	Unner Quertile	
Oxford	Obs	IN	in μV) Quartile		Upper Quartile	
Grade	4	4	0	0	5	
0						
Grade	15	15	10	10	10	
1						
Grade	38	38	10	10	15	
2						
Grade	32	32	20	20	25	
3						
Grade	18	18	35	30	40	
4						
Grade	10	10	57.5	50	50	
5						

It is evident that the digital testing using the modified Oxford scale and the EMG testing of the PFMS compared well (r = 0.92; p < 0.0001).

4.8 Conclusion

In this chapter, results of all the data were given. There was a moderately significant correlation between POP and the two assessment techniques for the PFM used in the study, namely digital assessment according to a modified Oxford scale (r = - 0.57; p < 0.0001) and EMG testing (r = -0.62; p < 0.001). A threshold of PFMS where symptomatic POP manifest, was determined as grade 2 according to digital testing and 15 μ V according to EMG testing. In the following chapter the results will be discussed.

Chapter V

The final chapter: discussion, conclusion, limitations and recommendations

5.1 Introduction

The results of the study were shown in the previous chapter. These results will now be discussed. Thereafter the limitations, recommendations and conclusion will follow.

5.2.1 Discussion of the characteristics of the study population

The current study is not an epidemiological study and the questions on the questionaire were only included to be able to describe the study population when making comparisons to other studies. Therefore, the influence of these factors on POP and on PFMS will not be discussed in great detail.

However, one can see that the results of the current study are in alignment with previous studies. The severity of POP increased with <u>age</u>. In women 29 years of age and younger only 5.3% had a POP more severe than stage I, compared to 87.6% of women in the age group 70 years and older. Samuelsson *et al.* (1999: 301) reported that the prevalence of any form of POP was 6,6% in women between twenty and thirty years old. This prevalence increased to 55% for women between fifty and sixty years old. Other studies (Olsen et al., 1997: 504; Swift, Pound & Dias 2001: 190) also found that the age-specific incidence increased with advancing age. In the current study, the strength of the PFM was also tested and a decrease in PFMS with age was found accordingly. In the age

group 29 years and younger, the PFMS measured either 4 or 5 in 38% of the women. None of the women 70 years and older achieved this.

Only 29.1% of the women in the current study had stage 0 POP. This is in harmony with previous research and to be expected when all the risk factors present in the population are investigated. Only 16% of the women were nulliparous. Samuelsson *et al.* (1999:301) demonstrated POP in 44% of parous women compared to 5.8% of non-parous women. Of the 101 women who had children, 93 gave birth vaginally. Apart from nerve damage, vaginal deliveries can also cause direct rupture of the fibers of the PFM or ligaments (Barbiero *et al.*, 2003: 331). The size of the vaginally delivered infant was identified by Swift, Pound and Dias (2001, 190) as the culprit to be blamed for damage to the pelvic support that causes POP. In the current study, the median weigth of heaviest infant delivered vaginally was 3 500g and the maximum 6 900g.

Although 60.7% of the women in the study population was post-menopausal and 39% was using HRT, it can be a mere reflection of the higher age of the study population, as was found in the study by Swift, Pound and Dias (2001). From the study population in the current study, 74.4% of the women were white. Bump (1981) cited white race as a risk factor for developing POP. The median of the BMI in the current study population, was 26.4. Olsen et al. (1997) also demonstrated that most of the women with POP in their study were overweight. In the current study, 25.6% of the women were smokers and 9.4% had a history of lung diseases. Olsen et al. (1997) showed that almost half of the women who had POP surgery were current or former smokers and one-fifth had chronic lung disease. In the current study, 43% had undergone a hysterectomy. Swift (2000: 281) demonstrated a reasonably strong association between highter POP-Q stage and history of hysterectomy.

In addition to other information of the study population, it was also important to know more about their <u>activity level</u>. There seems to be a link between PFMS

and activity level and in some women general activity can even maintain PFM function without any specific PFM exercises (Gordon & Logue, 1984). Although 73% of the women in the study population said that they do some of their housework, only 37% walk to work or the shops and 26.5% take care of small children. While 52% said that they exercise regularly, these exercises ranged from walking with a small dog to running marathons. Eventually, only 34% considered their lifestyle to be active.

5.2.2 Discussion of the aims of the study

The first objective of the study was to determine if there is a possible correlation between PFMS and POP. The results of the study demonstrate a moderately significant negative correlation of 0.57 between POP and PFMS as was measured digitally according to a modified Oxford scale (p < 0.0001). The data clearly suggests this correlation when comparing the percentage of women with POP to the grade of PFMS (see table IV and V). 100% of the women with grade 0 PFMS had POP stages I – IV. Only 30 % of the women with grade 5 PFMS had a mild prolapse (POP-Q stage 1), or rather a mere descent.

The median of the PFMS (Oxford scale) of women with a stage 0 POP was grade 4, in the case of stage III POP the median was grade 3, and in women with stages III, IV and V the median was grade 2.

With regard to the EMG measurement of the PFM, the severity of POP also increased as the PFMS decreased (see Table V). There is a moderately significant correlation (r = -0.62) between the EMG measurement of the PFM and POP (p < 0.001). In women with no POP, the median of the PFMS was 32.6 μ V; in women with a stage I the median of the PFMS was 20 μ V; in women with a stage II the median of the PFMS was 15 μ V; and in women with a stage III, the median of the PFMS was 10 μ V; while in women with a stage IV POP the median of the PFMS measured 15 μ V. The reason why women with a stage IV POP

seem to have stronger PFM compared to women with stage III POP is that one woman with very strong PFM had stage IV apical POP. The difference between the pathology of prolapse of the apical compartment compared to other compartments will be discussed further on in this chapter. This however influenced the statistics as the number of women with stage IV POP was small (only 11 women).

The second objective of this study was to find a PFMS threshold where POP begins. The data of this study demonstrated that the threshold of PFMS where symptomatic POP manifests itself is grade 2 regarding digital testing using a modified Oxford scale (positive predictive value 60%; negative predictive value 85%; accuracy 73%). Regarding EMG testing of the PFM, the threshold of PFMS where symptomatic POP manifests, is 15μV (positive predictive value 60%; negative predictive value 68%; accuracy 74%).

5.3 General discussion

One of the most interesting findings of the study is the dramatic decrease in endurance of the PFM as the severity of POP increased. Women with either a stage 0 or I POP could hold a PFM contraction at a target set at 50% of the average of their three maximum contractions for a median of 12 seconds, while women with a more severe POP (stage II, III and IV) could hold the contraction for only 1 to 3 seconds. A significant negative correlation of 0.62 was demonstrated between endurance of the PFM (EMG measurement) and POP. There are no other studies known to the author to compare these results with. It does, however, make sense when considering that the levator ani muscle consists of approximately two-thirds type I (slow twitch) muscle fibers responsible for the resting tone (Gilpin *et al.*, 1989). The normal tonic activity of the levator ani muscle is responsible for keeping the urogenital hiatus closed and prevents prolapse. In healthy subjects, the pelvic diaphragm is normally in a state of tonic

contraction, even when sleeping, and its tone increases in reaction to an increase in intra-abdominal pressure (Gill & Hurt, 1998). From the data of this study, this decrease in endurance that affects the ability of the PFM to keep the pelvic viscera in place over an extended period of time may be important in the pathogenesis of POP. The fact that the endurance of the PFM is decreased also confirms to the symptoms of POP that could sometimes be totally asymptomatic in the morning, but the discomfort increases as the day progresses, and lying down does give relief (Digesu *et al.* 2005). From the data of this study it is evident that in women with POP, the PFM tire easily. Other characteristics of the PFM, for example the timing of contraction and awareness, were not measured in this study and would be more difficult to do, but would give valuable information.

Obviously, there will be women with intact muscles and a normal PFM that have POP because of pure connective tissue failure (Hsu *et al.*, 2006). This was also demonstrated in the current study. It is also possible that a woman may have strong PFM, but that other risk factors for POP compromised the outcome. Especially a woman with a habit of pushing downwards when sitting on the toilet, can cause stretching and descent of the pelvic floor as the PFM needs to relax in order for expulsion to be possible and cannot protect the tissue.

The results of this study are in agreement with a recent study by Hsu *et al.* (2006) that used dynamic MR imaging to compare the levator plate angle (in the posterior segment where the levator muscles unite with the similar muscle of the other side – therefore part of iliococcygeus muscle) in women with POP to women with normal support. They found that women with POP have a more vertically orientated levator plate angle, larger levator hiatus lengths and more caudal perineal body displacements, both of which correlated with the displacement of the levator plate. The authors are of opinion that the levator plate angle is an indication of damage to the levator ani muscle. This correlates with the clinical observation of an excessively deep pouch of Douglas in the majority of patients with severe POP (enteroceles).

As discussed under pathology of POP, Zhu *et al.* (2005) studied the morphological changes of the levator ani muscle (the pubococcygeus portion) of patients with POP and SUI. They found striated muscle fibers in biopsy specimens in 26% of the women in the SUI group, 16% of the women in the POP group and in 100% of the women in the control group whereas the remaining specimens only had connective tissue, smooth muscle and fat tissue. The absence of striated muscle fibers can certainly explain the fact that the current study found that the strength of the PFM is decreased in women with POP.

Another explanation for the findings of this study can be found in the results of research done by Dietz and Steensma (2006). These authors used 3D translabial ultrasound to assess the puborectalis/pubococcygeus complex of women referred for urodynamic tests. Their data allows insight into the clinical relevance of major levator trauma. The most common abnormality demonstrated was a detachment of the PFM from the pelvic sidewall, which they termed an 'avulsion injury'. Such an abnormality was seen in 14% of the women assessed. They also found that this avulsion of the PFM was associated with increased mobility of the anterior vaginal wall and uterus.

Furthermore, Thompson and O'Sullivan (2003) studied levator plate movement during voluntary PFM contraction in subjects with incontinence and POP. They found that in the POP group there was a higher than suspected number of women that depressed, instead of elevated, the levator plate. As is known, depressing the levator plate may weaken the pelvic ligaments and contribute to the pathology of POP. Previously it has been questioned if women know how to contract the PFM. Bump *et al.* (1991) found that when instructed to do a PFM contraction, 25% of women did a Valsalva manoeuvre instead. When doing a Valsalva manoeuvre the levator plate would depress instead of elevate.

Ghetti *et al.* (2004) also tested the PFM using the Oxford grading scale, but found only a weak correlation with severity of POP (r = -0.16; p < 0.0001). The authors, however, demonstrated that severity of POP correlated moderately with genital hiatus and with levator hiatus. A possible clarification for the nuance in the results between this study and the current study may be the fact that younger women with no POP were also included in our study that demonstrated a significant negative relationship between the PFMS in women with severe POP and women with no POP. A further reason may be that in the study by Ghetti *et al.* 1100 women were examined compared to 117 women in the current study.

The results of the current study are in agreement with the results of an epidemiological study by Samuelsson *et al.* (1999). The authors used a 2 finger vaginal palpation and graded the PFMS from 1 to 4. In a set of multivariate analysis, their results demonstrated that age, parity, PFMS (r = -0.32; p < 0.0001) and maximum birth weight are the 4 factors that were significantly related and independently associated with presence of POP. Modification in results can be explained by the difference in the study population. Samuelsson *et al.* examined women 20 to 59 years old, while the age of the women in the current study ranged from 20 to 84 years. Both studies agreed that PFMS decreased with age.

5.4 Strengths and limitations

Regarding methodology, the strength of the current study is the use of a standard reliable research tool for describing the various stages of pelvic organ support. Some of the advantages of the instruments used to test the strength of the PFM in the current study are that it reports a complete picture of the strength of all the parts (pubococcygeus, iliococcygeus and puborectalis) of levator ani as it contracts as a unit. Also, it gives a measurement of an active contraction of levator ani, which allows the researcher to test strength and endurance and not only the tonus of the muscle or the damage to the muscle. Peschers and Gingelmaier (2001) is of opinion that intravaginal EMG does not selectively depict

PFM activity, as non-pelvic muscle readings were possible during contraction of the adductors. While the authors of the current study are in agreement with the above, we also think that an experienced examiner can exclude these problems with careful observation. Further, several studies found that digital palpation is a good technique to assess the lift and strength of the PFM (Devreese *et al.*, 2004; Laycock, 1992), but Bø and Finkhagen (2003) reported that, although the technique is useful to assess for the correct muscle action, it is not sensitive enough to use to obtain scientific results. The authors of the current study chose to include digital assessment of the PFM as it is an inexpensive technique that, with proper training, can be done by medical professionals even in rural areas. One of the objectives of this research is to allow medical professionals to be able to identify women at risk for symptomatic POP.

Analogy of the two techniques of measuring the PFM demonstrates the similarity (see table X). Grade 0 on the Oxford scale compared to 0 μ V (EMG); grade 1 and 2 compared to 10 μ V (but the upper quartile of grade 2 is higher); grade 3 compared to 20 μ V; grade 4 compared to 35 μ V and grade 5 to 57.5 μ V.

Limitations of this study include the fact that the EMG machine could not take measurements between 0 and 10 μ V and any reading between 0 and 10 would be given as 10 μ V. This explains the fact that both a grade 1 and a grade 2 on the Oxford scale compares to 10 μ V when measured with the EMG. Another limitation was that the number of women tested was not enough to allow for generalizations to be made. Also, bias is introduced as the population is women that came to an urogynecology clinic for gynecology examination, which is different from women in a general population. On the questionnaire, the questions to detect the activity level of the population, was not specific enough.

Unfortunately, the type of POP was not documented from the start as different criteria for apical POP is possible (Samuelsson *et al.*, 1999). Also, it was not documented if a patient with POP is symptomatic or not.

From an anatomical point of view, strong PFM would not be able to prevent POP if there is a failure of support at level I. Therefore strong PFM would not be able to prevent simple eversion of the upper vagina (apical compartment POP) and/or downward displacement of the peritoneum that is attached to the posterior vaginal wall. Also, as the levator ani is part of the level III support of the vagina, it can supposedly not prevent a stage I POP. Rather, the function of the levator muscles is to act as a dynamic support and a shelf for the pelvic organs to rest on, as well as to keep the vagina closed and to prevent prolapse from progressing out of the vagina, under which circumstances prolapse is most likely to be symptomatic.

This study only concentrated on the PFM, which is only one aspect of a complex pelvic floor. Other factors are also important, for example the connective tissue and smooth muscle component. The importance of the strength of the PFM, however, lies in the fact that it can be influenced conservatively and preventatively.

5.5 Recommendations for further study

It is beyond the scope of the study to indicate that PFM exercises would be effective in the treatment of POP. Randomized controlled trials are needed to show whether PFM training can counteract the development of symptomatic POP.

5.6 Clinical implications

The major strength of the study is the moderately significant correlation between weak PFM and severe POP that is demonstrated using both digital testing and measurement using an EMG machine. During routine gynecology examination PFM testing using the modified Oxford scale can be included. In this way, women with weak PFM can be identified and sent for conservative physiotherapy treatment before the POP progresses to a symptomatic phase.

5.6 Final conclusion

There is a significant correlation between POP and PFMS when measured digitally according to a modified Oxford scale (r = -0.57; p < 0.0001) and when measured with EMG (r = -0.62; p < 0.001). The threshold of PFMS where symptomatic POP will manifest itself is grade 2 on the modified Oxford scale for digital testing (positive predictive value 60%; negative predictive value 85%; accuracy 73%) and 15 μ V for EMG testing (positive predictive value 60%; negative predictive value 68%; accuracy 74%).

Summary

PELVIC ORGAN PROLAPSE AND PELVIC FLOOR MUSCLE STRENGTH

Keywords: Pelvic Organ Prolapse (POP), Pelvic Floor Muscle Strength (PFMS), relationship, threshold.

The **objective** of the study was to research the relationship between pelvic floor muscle strength (PFMS) and pelvic organ prolapse (POP), and to find a threshold of PFMS where POP will manifest itself.

A clinical cross-sectional analytic study was indicated. PFMS was tested with digital assessment using the modified Oxford scale and EMG testing with a vaginal electrode. Prolapse was assessed with the Pelvic Organ Prolapse Quantification (POP-Q) terminology. The analysis included 117 women.

The correlation (-0.57) of the digital assessment of PFMS with POP is **significant** (p < 0.0001). 100% of women with grade 0 PFMS had a POP (POP-Q stage I-IV), while only 30% of women with a grade 5 PFMS had a POP of lesser severity (only stage I). Regarding EMG measurement of PFMS, there was a moderately significant correlation (r = -0.62; p < 0.001). However, one of the most interesting findings of the study was a significant correlation (-0.55) between the endurance of the PFM as was measured with EMG and POP (p < 0.0001). Women with either a stage 0 or I POP could hold a PFM contraction at a target set at 50% of the average of their three maximum contractions for a median of 12 seconds, while women with a more severe POP (stage II, III and IV) could hold the contraction for only 1 to 3 seconds.

The results confirm clinical observations of the **correlation** between a weak PFM and a more severe POP. The study demonstrated that the **threshold** of PFMS

where symptomatic POP manifests itself is grade 2 regarding digital testing using a modified Oxford scale (positive predictive value 60%; negative predictive value 85%; accuracy 73%) and 15µV when using EMG-testing (positive predictive value 60%; negative predictive value 68%; accuracy 74%).

These results have clinical implications: women with a risk for developing symptomatic POP can be identified earlier and treated conservatively.

Opsomming

BEKKENORGAANPROLAPS EN PELVIESE VLOER SPIERSTERKTE

Sleutelwoorde: Bekkenorgaanprolaps, Pelviese vloer spiersterkte, verhouding, drempelwaarde.

Die **doelstellings** van die studie was eerstens om die verhouding tussen die spiersterkte van die pelviese vloer en bekkenorgaanprolaps na te vors en tweedens om 'n drempelwaarde te vind in terme van spiersterkte van die pelviese vloer waar simptomatiese bekkenorgaanprolaps begin.

Daarom was 'n **kliniese analitiese dwarssnitstudie** aangedui. Die spiersterkte van die pelviese vloer is getoets met digitale vaginale ondersoek volgens 'n gemodifiseerde Oxford-skaal en deur middel van EMG-toetsing met 'n vaginale elektrode. Bekkenorgaanprolalaps is gemeet volgens die "Pelvic Organ Prolapse Quantification (POP-Q)" terminologie. Die analise het 117 vroue ingesluit.

Daar was 'n **betekenisvolle** assosiasie tussen spiersterkte van die pelviese vloer en bekkenorgaanprolaps (r = -0.57; p < 0.0001). 100% van die vroue met graad 0 pelviese vloer spiersterkte het 'n bekkenorgaanprolaps (POP-Q stadium I –IV) teenoor 30% van die vroue met 'n graad V spiersterkte van die pelviese vloer wat slegs 'n mindere mate van bekkenorgaanprolaps het (slegs stadium I). Wat die EMG-meting van die spiersterkte van die pelviese vloer betref, is daar ook 'n matige betekenisvolle korrelasie (r = -0.62; p < 0.001). Een van die mees interessantste bevindinge van die studie was egter 'n betekenisvolle korrelasie (r = -0.55; p < 0.0001) tussen die uithouvermoë van die pelviese vloerspier en bekkenorgaanprolaps. Vroue met 'n stadium 0 of I bekkenorgaanprolaps kon 'n pelviese vloer spierkontraksie vir 'n mediaan van 12 sekondes hou by 'n doel

wat gestel is op 50% van die gemiddeld van hul drie maksimum kontraksies. Vroue met 'n ernstiger graad van bekkenorgaanprolaps (stadia II, III en IV) kon die sametrekking vir slegs 1 tot 3 sekondes hou.

Die resultate bevestig die kliniese waarneming van die **korrelasie** tussen 'n swak pelviese vloerspier en 'n ernstiger graad van bekkenorgaanprolaps. Die studie demonstreer ook dat die **drempelwaarde** van die spiersterkte van die pelviese vloer waar simptomatiese prolaps begin, graad 2 is volgens digitale toetsing (gemodifiseerde Oxford-skaal) en 15 μ V volgens EMG-toetsing. Dit het kliniese implikasies: vroue met 'n risiko vir simptomatiese bekkenorgaanprolaps kan vroeër geïdentifiseer word en konserwatief behandel word.

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