OPTIMAL TIME FOR POST-OPERATIVE REFRACTION AFTER UNEVENTFUL CATARACT SURGERY

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Declaration

I, Cara Biddulph, declare that the Master's Degree research dissertation that I herewith submit for the Master's Degree qualification M.Optometry at the University of the Free State is my independent work, and that I have not previously submitted it for a qualification at another institution of higher education.

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Abstract

Background: There is a great discrepancy in current literature as to when the correct time is to do a refraction for spectacles after cataract surgery. Although the current trend is to leave the patient as independent as possible without spectacles, most patients will still need spectacles for optimal vision, mostly for near activities like reading.

Purpose: The main aim of this study was to determine when in the first six weeks after uneventful cataract surgery, the operated eye stabilises for the refraction of the new spectacles needed.

Methodology: 25 participants from the same practice were included in this study. Four variables were measured at six visits (these visits took place before cataract surgery and then at one day, one week, two weeks, four weeks and lastly six weeks after cataract surgery) to acquire the data after uneventful (no complications occurred) cataract surgery. The four variables that were investigated, included the best corrected visual acuity (BCVA), central corneal thickness (CCT), central macula thickness (CMT) and the refraction. Stabilisation of these measured variables may indicate the optimal time for refraction. The data was analysed to determine the change of these variables consecutively over the six weeks that the study took place and to investigate the period for each variable to reach stabilisation.

Results: Most participants (56%) had stable BCVA two weeks after uneventful cataract surgery. Most participants' CMT (96%) returned to baseline values at one day after cataract surgery. Most participants CCT (68%) returned to baseline values one week after cataract surgery, respectively. The refraction stabilised two weeks after uneventful cataract surgery.

Conclusion: The CMT had no effect on the refraction throughout the six weeks of the study. The CCT was found to stabilise one week after cataract surgery. The BCVA and refraction stabilised two weeks after uneventful cataract surgery, indicating that spectacles can be prescribed as early as two weeks after uneventful cataract surgery.

Main findings of the study

- The main aim of this study was to determine when in the first six weeks after uneventful cataract surgery the operated eye stabilises for the refraction of the new spectacles needed. The results of this study suggest that all variables stabilised as early as two weeks post-operatively.
- The first objective was to measure the difference in BCVA before uneventful cataract surgery and consecutively over a period of six weeks thereafter. The BCVA was found to stabilise two weeks after uneventful cataract surgery for the participants in this research study.
- The second objective was to measure the difference in central corneal thickness (CCT). It was found that the CCT returned to baseline value one week after uneventful cataract surgery.
- The third objective was the measurement of the central macula thickness (CMT). Although the CMT showed stabilisation at one day after cataract surgery for most participants, a clinically significant difference was observed at Week 4 and Week 6, rendering the data inconclusive as to when stabilisation occurs.
- The fourth objective was the measurement of the refraction. The refraction was measured from one day after uneventful cataract surgery until six weeks thereafter. During this time, it was noted that the refraction stabilises at two weeks after uneventful cataract surgery.
- Lastly, the possible associations between the stabilisation of the four measured variables were investigated. It was found that the best corrected visual acuity (BCVA) might be an indication as to when the optimal time for spectacle refraction after surgery is, as the results in this research study showed stabilisation of both the BCVA and the refraction two weeks after the cataract surgery.

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BCVA	-	Best Corrected Visual Acuity
CCT	-	Central Corneal Thickness
CMT	-	Central Macula Thickness
CMO	-	Cystoid Macula Oedema
D	-	Dioptre
IOL	-	Intraocular Lens
OCT	-	Optical Coherence Tomography
VA	-	Visual Acuity
µm	-	Micrometre
WHO	-	World Health Organization

Chapter 1.

INTRODUCTION

Cataract surgery is currently the most common ocular surgery performed (Micieli and Arshinoff, 2011). This surgery mostly has a good visual outcome, however the focus is often only on correction for either near or distance vision, resulting in the need for spectacles after surgery (Cuq *et al.*, 2008). Cataract surgery includes the removal of the opaque natural lens and substitution with an artificial intraocular lens. After surgery, spectacles are prescribed by an optometrist after a refraction is done to determine the residual refractive error of the eye.

Many factors contribute to the time after cataract surgery that the refractive state of the eye stabilises. Pre-existing pathology or chronic conditions may seriously affect the healing of the eye after surgery (González *et al.*, 2014) and may influence the time that the eye takes to stabilise so that spectacles could be prescribed.

Currently, literature is diverse regarding when refractions should be done after cataract surgery, ranging from one week to twelve weeks (Vliet *et al.*, 2010; Porter *et al.*, 2012; Juan *et al.*, 2013; Schuster *et al.*, 2013; Zyl *et al.*, 2014; Karpecki and Cunningham, 2015; Kessel *et al.*, 2015; Thanigasalam *et al.*, 2015; Caglar *et al.*, 2016). No research on the topic of ocular stabilisation after cataract surgery has been done in South Africa at the time that this research study was conducted. This causes discrepancy as to the ideal time for a spectacle refraction after uneventful cataract surgery. Incorrect spectacle refraction would be highly problematic in terms of cost and convenience to all involved. Consensus should be reached to enable accurate waiting time for the patient after the eye has stabilised. A full literature review discussing cataract surgery and its stabilisation in more detail will follow in Chapter 2.

The main aim of this study was to investigate when the optimal time for refraction is after uneventful cataract surgery. To best acquire the relevant information needed to conclude as to when the ideal time is to prescribe spectacles after uneventful cataract surgery, the data collected for this research study was obtained through an observational analytical cohort study design that is quantitative in nature. The objectives of this research study included the measurement of four variables, namely best corrected visual acuity, central corneal thickness, central macula thickness and refraction. The measurement techniques are discussed in Chapter 3 of this dissertation. The aim of measuring these variables was to conclude when stabilisation occurs after uneventful cataract surgery to ensure accurate spectacle prescription. For this current study, only patients undergoing uneventful (that is no intraoperative complications occurred) cataract surgery were included in this study.

The demanding culture of today's society expects prompt treatment with an effective outcome. Patients undergoing surgery must be provided with minimal discomfort and disruption as well as accurate information on the procedure, including the expected time frame from surgery to healing. A guideline on when the optimal time for a refraction after uneventful cataract surgery is, should be established.

Using the results and data analysis thoroughly described in Chapter 4, the researcher concluded in Chapter 5 as to when the optimal time to do a refraction for spectacles after uneventful cataract surgery is by discussing each of the variables measured. The researcher's recommendation summarised in Chapter 6, definitely has a very practical implication for the field of optometry.

Chapter 2.

LITERATURE REVIEW

2.1 Introduction

In this chapter, a literature review will be presented to provide the current opinion of authors on when ocular structures stabilise after uneventful cataract surgery and thus, when the optimal time for refraction and spectacle prescription is. The literature review will start with the visual system and how a cataract is formed and will end with the effect that complications have on the visual stabilisation.

2.2 The lens and its contribution to vision

Vision is created when light enters the optical system through the refractive media and signals neurons on the retina to send information to the brain. The first mechanism in the physiology of vision is called phototransduction, a process where the cone and rod receptor cells in the retina are activated by light to cause a visual impulse (Ross and Pawlina, 2006; Khurana, 2007; Merriam-Webster, 2019).

The processing and transmission of this visual stimulus is then done by retinal cells to the brain via the optic nerve. The foremost factor for clear visual perception is the transparency of the refractive media of the eye. One of the most significant refractive media in the eye is the lens as it is responsible for altering the focusing ability of the eye to incoming rays of light. Other refractive media of the eye include the cornea, aqueous humor and the vitreous body (Ross and Pawlina, 2006; Grosvenor, 2007; Khurana, 2007; Nolte, 2007; Levin *et al.*, 2011).

The lens is a biconvex structure that is located behind the iris and in front of the vitreous body. The lens is composed of the lens nucleus and the lens cortex. The nucleus is

formed until three months after birth, while the lens cortex is formed continuously thereafter through life. (Snell and Lemp, 1998; Ross and Pawlina, 2006; Kanski, 2007; Augusteyn, 2010; Stein *et al.*, 2018).

The lens capsule surrounds the crystalline lens. The lens capsule is essentially an elastic basement membrane that envelops the entire lens to maintain the shape of the lens, especially during accommodation (Snell and Lemp, 1998; Khurana, 2007). Recent studies by Pisciotta *et al.* (2018) and Ţălu *et al.* (2018), reported that although the lens capsule has a highly structured composition, ageing causes the geometric characteristics to change in size and form, resulting in the structure of the lens components becoming more irregular.

The subcapsular epithelium is a layer of cells, found only in the anterior surface of the lens. As the lens is an avascular structure, the epithelium is responsible for the metabolism of the lens. These epithelium cells become columnar in the equatorial region and divide and elongate to form new lens fibres. These new lens fibres are the causative factor for the continued growth of the lens cortex throughout the human life that leads to increased hardness of the lens (Snell and Lemp, 1998; Bhat, 2001; Ross and Pawlina, 2006; Khurana, 2007; Augusteyn, 2018).

The main functions of the lens are accommodation and refraction. The total refractive ability of the eye is close to 58 Dioptres (D), with the lens contributing to a third (approximately 19 D) of the refraction in the optical system of the eye. The avascularity of the lens ensures optimal movement of light to reach the retinal cells without diffraction and scatter of light rays (Snell and Lemp, 1998; Grosvenor, 2007; Khurana, 2007). The thickness of the unaccommodated lens varies from 3.5 mm to 5 mm and this lens thickness continues to increase with age. This increasing thickness causes the lens to gradually lose its elasticity and ability to accommodate, resulting in an unavoidable condition called presbyopia (Ross and Pawlina, 2006; Grosvenor, 2007; Levin and Albert, 2010; Yanoff and Sassani, 2015).

As previously mentioned, presbyopia is inevitable in the ageing human eye due to the increase in growth and thickness of the lens nucleus. Another common acquired

condition associated with the lens, where the lens loses transparency, is called a cataract. This condition will be discussed in detail in the following section (Ross and Pawlina, 2006; Fernández *et al.*, 2018).

2.3 Definition and prevalence of cataracts

The World Health Organization (WHO) defines a cataract as the "clouding of the lens of the eye which prevents clear vision". The word cataract comes from the Greek word 'katarráktēs' which translates to 'waterfall' or 'rapidly running water that turns white' and represents the appearance of the lens when a cataract is present (Brink and Lochner, 2011; Gault and Vander, 2016; World Health Organization, 2019).

Cataracts are one of the leading causes of avoidable blindness as well as vision impairment in the world. Other causes of blindness and vision impairment include glaucoma and uncorrected refractive error. It has been estimated that up to 80% of blindness worldwide is due to an avoidable cause. Vision impairment, even though not as serious as blindness, was established as a serious health issue almost a decade ago (World Health Organization, 2010, 2018; Pascolini and Mariotti, 2012; Bourne *et al.*, 2013; Chua and Cheng, 2016).

In Africa, cataracts remain the leading cause of visual impairment and blindness, followed by uncorrected refractive error, glaucoma and trachoma. The situation is the same in South Africa with cataracts being the leading cause of blindness in adults 50 years and older and a prominent cause of vision impairment as in the rest of the world (Bourne *et al.*, 2013; Aboobaker and Courtright, 2016; Lee and Afshari, 2016; Flaxman *et al.*, 2017). Interestingly, it has been noted in the literature that there are more female than male cataract patients in South Africa (Lewallen and Courtright, 2002).

Programs like *Vision2020*, an initiative of WHO and the International Agency for Prevention of Blindness, are assisting greatly in reducing the number of people suffering from reversible blindness caused by cataracts, as cataracts can be removed with an operation and the lens can be replaced with an artificial intraocular lens (World Health

Organization and International Agency for the Prevention of Blindness, 1999; Resnikoff and Foster, 2005).

Although a noteworthy average of 20 million cataract operations is performed each year worldwide, compared to an estimated 10 million cataract operations twenty years ago, the cataract surgery rate is regrettably the lowest in Africa compared to the other continents. Cataract surgery rate is defined as the number of cataract surgeries performed per year per million population. The cataract surgery rate in Africa in less than 500, although the target in Africa was set at 2000 in the year 2010 (Lecuona and Cook, 2011; Lindstrom, 2015).

Ageing is the most common cause of cataract formation in adults. With the ever-increasing age of the human race and expanding population size, the number of diagnosed and undiagnosed cataracts will undoubtedly rise and this age-related vision loss will have an even greater effect in the future. It is estimated that the world population has reached 7.7 billion in 2019. That is a population of 3.5 billion more than thirty years ago. The number of people older than 60 years is also estimated to double within 20 years from 400 million people in 2000, to 800 million people in 2020 (Foster, 2000; Rao *et al.*, 2011; United Nations Population Division, 2017; Alshamrani, 2018).

In 1990, 36.67% of blindness worldwide was caused by cataracts. This was also the case in Africa and Southern Africa where cataracts were responsible for 38.56% and 36.12% of blindness respectively. In 2015, this number changed only slightly with 35.15% of blindness worldwide caused by cataracts and in Africa and Southern Africa, the number of people blind from cataracts were 38.95% and 35.15% respectively (Foster, 2000; Lecuona and Cook, 2011; Khairallah *et al.*, 2015; Lindstrom, 2015; Flaxman *et al.*, 2017).

A cataract truly has a great effect on vision on an international scale and it is important to understand and know what exactly a cataract entails. Cataracts will be discussed in more detail in the following section.

2.4 Classification of cataracts

Cataracts can be classified as congenital cataracts or acquired cataracts. It is important to determine the cause of a cataract to prepare the surgical method with the least risk for complications or negative outcomes, and that will give the most desired visual outcome (Kanski, 2007; Steinert, 2010).

2.4.1 Congenital cataracts

A congenital cataract is present at birth or shortly thereafter and is often associated with other medical problems such as neuromyopathies or syndromes like Klinefelter (Steinert, 2010; Nur *et al.*, 2014; Nagamoto *et al.*, 2015; Castiglioni *et al.*, 2018).

Congenital cataracts have different appearances and can be located in the lens as a fleck cataract, anterior polar cataract or posterior polar cataract. Congenital cataracts are further classified according to morphology as idiopathic, hereditary, syndrome-related, caused by intrauterine infection or other causes (Haargaard *et al.*, 2004; Yanoff and Sassani, 2015).

Although hereditary congenital cataracts are caused by genetic defects present in the DNA, the majority of congenital cataracts has, however, been found to be of unknown cause (Graw, 2004; Haargaard *et al.*, 2004; Nadeem *et al.*, 2013; Yang *et al.*, 2015; Kuo *et al.*, 2017; Yazar *et al.*, 2017). A review of literature by Mets *et al.* (2008) identified Toxoplasma, Rubella, Herpes Simplex virus, Lymphocytic chorioretinitis virus, Treponema pallidum, Varicella-Zoster virus and Epstein-Barr virus as intrauterine infections that commonly cause eye problems like cataracts. Congenital cataracts are often also associated with certain syndromes like Klinefelter, Gregg and Goldenhar (Nur *et al.*, 2014; Shrestha and Adhikari, 2015; Makadia *et al.*, 2016).

The only treatment for congenital cataracts is surgery. In cases of unilateral congenital cataracts, it has recently been found that most surgeons choose to leave the patient aphakic (without any lens in the eye). Contact lenses are then used to promote visual

rehabilitation in the operated eye as the eye socket is still growing and changing shape. The prognosis after bilateral congenital cataract surgery, even if done when the infant is only a few months old, is not always positive. Most of these cases may still result in permanent vision problems, for example amblyopia or reduced depth perception, after surgery (Martin *et al.*, 2008; Steinert, 2010; Nadeem *et al.*, 2013; McAnena *et al.*, 2018).

2.4.2 Acquired cataract

The cause of an acquired cataract is quite different from that of a congenital cataract. The lens is made of small crystalline proteins. These crystalline proteins coalesce as the lens ages and form a large bundle that causes light to scatter when entering the eye. In nuclear cataracts, these crystalline protein aggregations exist in the cytoplasm and in cortical and posterior subcapsular cataracts, the aggregations are found to be present on the cell membranes (Augusteyn, 2010; Steinert, 2010; Fernández *et al.*, 2018).

Cataract formation is a multifactorial condition, but oxidative stress, a state of imbalance between oxidants and antioxidants, has been identified as an important factor in the onset and progression of age-related cataracts (Li *et al.*, 2009; Babizhayev and Yegorov, 2016). Oxidative damage to the lens proteins and lipids is thought to be significantly involved in the development of cataracts (Vinson, 2006; Kaur *et al.*, 2012). Certain risk factors and systemic diseases may influence this oxidative stress and consequently, the development of a cataract.

2.4.2.1 Risk factors for the development of an acquired cataract

In this section, the risk factors for the development of an acquired cataract are listed and discussed.

2.4.2.1.1 Age

Age is still regarded as the most significant risk factor for developing cataracts (Steinert, 2010; Atif *et al.*, 2018; Singh *et al.*, 2019; Taseer *et al.*, 2019). A South African study conducted by Phaswana-Mafuya *et al.* (2017), agreed that age is the most prevalent risk

factor for self-reported cataracts in this country, but the authors also add that systemic co-morbidities like diabetes, depression, stroke and hypertension are contributing to a higher risk for cataract development (Craig, 2015; Phaswana-Mafuya *et al.*, 2017).

Age-related cataracts are divided into three categories namely subcapsular, cortical and nuclear cataracts (Kanski, 2007; Bowling, 2016; Zhang and Li, 2017). Cortical cataracts have been found by some studies to be the most common type of age-related cataract but often more than one type of cataract is present in the same eye (Vrensen, 2009; Michael and Bron, 2011; Richter *et al.*, 2012; Alshamrani, 2018).

Subcapsular cataracts can be classified as either anterior or posterior according to the location of the opacity (Kanski, 2007). Anterior subcapsular cataracts are caused by fibrous metaplasia of the lens epithelium and are positioned directly under the anterior lens capsule (Kanski, 2007; Nathu *et al.*, 2009; Xiao *et al.*, 2015). Posterior subcapsular cataracts have vacuolated, granular or plaque-like appearances and are located just in front of the posterior capsule. A subcapsular cataract often causes loss of contrast sensitivity and a reduced visual acuity, especially when reading as the opacity is centrally located in the pupil on the visual axis (Vasavada *et al.*, 2004; Allen and Vasavada, 2006; Thompson and Lakhani, 2015).

Peripheral lens changes in the form of spokes or segmental opacities are referred to as cortical cataracts (Vrensen, 2009). Patients with cortical cataracts usually experience glare when driving at night due to the pupil being dilated in low light conditions. When the pupil is dilated, the peripheral cortical spokes are exposed, causing increased glare or scattering of light (Allen and Vasavada, 2006; Thompson and Lakhani, 2015).

Nuclear cataracts appear as a visible discolouration of the lens due to the steady accumulation of chromophores and insoluble crystalline. The lens nucleus in a nuclear cataract is thicker and harder than other age-related cataracts. In addition to the loss of vision, contrast sensitivity is significantly reduced with this type of cataract due to the marked discolouration of the natural lens (Heys and Truscott, 2008; Michael and Bron, 2011; Paz Filgueira *et al.*, 2016).

2.4.2.1.2 Systemic diseases

Steinert (2010) and Atif *et al.* (2018) identified metabolic disease, especially Diabetes Mellitus, as a major risk factor for cataract development. Diabetes is a disorder that affects a range of organs and systems in the human body due to a chronically high level of glucose within the blood (McGuire and Marx, 2015). Diabetic patients, even more so if it is a case of uncontrolled Diabetes, have a high level of glucose in the aqueous humour that diffuse into the lens and cause cortical fluid vacuoles to form that later evolve into mature cataracts that cause decreased vision (Bowling, 2016). Combined with smoking, the risk for presenile cataracts increase significantly in diabetic patients. Other systemic conditions like Hypertension is also associated with a higher incidence of cataract formation (Mamatha *et al.*, 2015; Nam *et al.*, 2018; Taseer *et al.*, 2019). Other systemic diseases such as myotonic dystrophy, atopic dermatitis and neurofibromatosis are listed in the literature to cause specific types of cataracts respectively (Bouzas *et al.*, 1993; Bowling, 2016; Pagoulatos *et al.*, 2018).

Myotonic dystrophy is a disease that presents as progressive facial and limb muscle weakness and can also involve other organs. A christmas tree cataract is a specific type of cataract commonly found in patients with Myotonic dystrophy that distorts the vision of the patient involved (Preston and Shapiro, 2013; Pagoulatos *et al.*, 2018; Papadopoulos *et al.*, 2018).

Atopic dermatitis is a chronic inflammatory skin disease characterised by an intense itching sensation. One out of ten of these patients suffer from vision loss due to the development of a shield-like cataract in the anterior capsule, developing between the ages of forty and sixty (Nagaki *et al.*, 1999; Namazi *et al.*, 2006; Bowling, 2016; Habif, 2016; Lambert and Teng, 2018).

Neurofibromatosis is a genetic disorder affecting many organs in the body causing a predisposition to tumour growth. Cataracts are present in more than half of these patients and cause reduced vision (Bouzas *et al.*, 1993; Feucht *et al.*, 2008). Often, a cataract may be induced not only by the systemic disease but also by the chronic medication used to treat the systemic disease (James, 2007; Craig, 2015).

2.4.2.1.3 Trauma

Trauma is another risk factor for developing a cataract. A traumatic cataract is caused by external injury or blunt trauma (for example getting hit on the eye) to the lens that causes the lens to become opaque (Kanski, 2007; Bowling, 2016). Common causes of such traumatic injuries include thorns, wooden sticks and stones that may get stuck into the eye. Blunt ocular trauma is by far the most common cause of a traumatic cataract (Nadeem and Naeem, 2016). Cataract surgery for traumatic cataracts is often more complicated than routine cataract surgery and the prognosis varies according to each case. Not only is the lens damaged during trauma resulting in a traumatic cataract, but additionally, other conditions, for example, glaucoma and endophthalmitis, may also occur (Steinert, 2010; Guclu *et al.*, 2017).

2.4.3 Cataract maturity

Cataracts are often also classified according to maturity as immature, mature, hypermature or Morgagnian cataracts.

An immature or incipient cataract is when the lens starts to become opaque. This causes a shift in refractive error, loss of contrast sensitivity and increased glare. When the lens is completely opaque, it is called a mature cataract. Leakage of fluid from the lens causes folds in the anterior capsule and is then referred to as a hypermature cataract. The final stage of cataract maturity is called a Morgagnian cataract, where the lens nucleus is misplaced inferiorly due to the liquification of the lens cortex (Stanfield *et al.*, 2004; Kanski, 2007; Schroeder Swartz, 2014).

In conclusion, cataracts can be classified according to type as discussed and also maturity. However, regardless of the type of cataract or the degree of maturity, all patients complain of the same symptoms, namely reduced vision often described as “looking through a misty/foggy window” (Hataye, 2018; Bedinghaus, 2019), and the same management is indicated in all cataracts, namely cataract surgery.

2.5 The clinical presentation of a patient with cataracts

In this section, the signs and symptoms of different cataracts will be discussed as well as how the cataract is usually detected by the optometrist or other qualified health care practitioners.

2.5.1 Signs and symptoms of a cataract

A cataract is formed by the lens of the eye and any opacity in this lens will undoubtedly affect vision. Per definition, a cataract is any opacity in the lens (Grosvenor, 2007; Kanski, 2007). As mentioned, patients might describe their vision as 'looking through mist' or 'fog' in the case of an advanced cataract. In early cataract formation, increased glare at night and subtle dullness in vision may be noticed, including changes in the intensity of colours. Later, a mature cataract may lead to severe loss of vision. As discussed in the previous section, the type of cataract often dictates the specific symptoms experienced by the patient (Michael and Bron, 2011; Hataye, 2018; Bedinghaus, 2019).

Many studies have been conducted to investigate the impact of visual impairment and blindness caused by cataracts (Briesen *et al.*, 2014; Dev *et al.*, 2014). Vision impairment can affect anyone as they get older, but vision loss and blindness are more marked in more impoverished communities, with one of the main reasons being cataracts. This is possible due to the lack of health care in rural areas, leading to late diagnosis of cataracts (World Health Organization, 2013; Panday *et al.*, 2016).

It is important to remember that cataracts do not only influence the visual acuity and contrast sensitivity of a patient but also subsequently reduce visual functions like walking and visual recognition. Patients with a cataract also commonly complain about glare and haloes during night driving (Craig, 2015; Swartz, 2016). Keeping this in mind, patients are not only referred to an ophthalmologist for cataract removal if the cataract causes loss of VA, but also when it reduces contrast, depth perception and colour, all of which have significant effects on visual functioning. (Ao *et al.*, 2014; To *et al.*, 2014).

A significant decrease in vision may greatly influence every aspect of life, from managing basic daily tasks to socialising with friends and family (Fraser *et al.*, 2013; Chua *et al.*,

2017). A cohort study by Hajek *et al.* (2016) emphasizes how visual impairment affects not only the physical function but also the mental well-being of patients, especially in the elderly. This mental effect was previously also researched by Hong *et al.* (2015), who found a positive correlation between visual impairment and depressive symptoms. Due to this significant effect, informed patients suffering from cataracts very often seek medical advice and treatment to improve their vision and overall quality of life (Alshamrani, 2018; Turner, 2019).

To assist patients with the possible removal of cataracts to improve their vision, certain tests are done during an ocular examination to identify a cataract. The tests to evaluate and diagnose cataracts will be discussed in the following section.

2.5.2 Clinical examination of a patient with a cataract

Specific tests can be done to evaluate and diagnose the presence of a cataract in a patient. A cataract can not only be diagnosed with reduced vision or patient experience alone. These tests will be described with the focus on the findings of the tests when cataracts are present.

The first step in the diagnosis of a cataract is realising that there is visual impairment present by assessing the patient's vision. There are several ways to assess vision, but a quick vision screening can be done with the pinhole technique (Craig, 2015). The pinhole visual measurement technique involves using an occluder with a small hole that converges light on the retina without the eye having to focus, thus eliminating any possible refractive error (Sun *et al.*, 2011; Elliot, 2014). If vision does not improve with this technique, there is a high possibility of pathology, like a cataract, being present or possibly amblyopia. When a cataract is present, the pinhole technique has been found to have a higher accuracy of detecting decreased vision due to posterior subcapsular cataracts and dense (not immature) cortical cataracts. This is because the middle of the lens has been affected by the spokes stretching from the periphery of the lens or central vacuoles in the lens. It is important to note that the pinhole technique is only a basic screening method and is not the most reliable method to screen for all types of cataracts

(Cook *et al.*, 2009; Marsden *et al.*, 2014). Therefor other pathology that may cause a reduction in vision should be investigated and the pinhole technique alone should not be used to confirm the cataract diagnosis.

The lens can be viewed by using a slitlamp biomicroscope. When a cataract is present, the usually clear and transparent crystalline lens appears opaque. A nuclear cataract is seen when using a slit beam and the lens typically has a brownish darker colour (Khurana, 2007; Srivastava *et al.*, 2014). Cortical and subcapsular cataracts are easily seen with a technique called retro-illumination. Retro-illumination is done by placing the slitlamp beam straight on the pupil to obtain a red reflex from the fundus. Any media opacity in the lens will appear as a silhouette and will be clearly visible against the bright red background of the light reflex (Elliot, 2014; Gilman, 2019). A cortical cataract may present with grey-white spokes in the lens periphery while a subcapsular cataract is seen as a dark spot in the centre of the lens (Khurana, 2007; Zhang and Li, 2017).

The lens can also be examined for the presence of a cataract by using an ophthalmoscope (Payne, 2005; Thompson and Lakhani, 2015; Taseer *et al.*, 2019). An ophthalmoscope will provide a retro-illumination view of the lens and an experienced practitioner may successfully diagnose a cataract in this manner. With modern imaging technology, cataracts can be further viewed and investigated on a three-dimensional level with an optical coherence tomography (OCT) system that can accurately document the state of the lens as well as physical parameters like thickness and density of the cataract (Castro *et al.*, 2018).

Optometrists are trained to do all these procedures, but the practising scope of optometrists differs world-wide. It ranges from being only allowed to dispense spectacles, to diagnosing and treating eye diseases (Naroo and Grit, 2009). In the following section, the role of optometrists in the cataract patient's diagnosis and treatment will be discussed.

2.5.3 Optometrist's role in cataract referral

The scope of Optometry in South Africa includes the detection of eye diseases, followed by the referral to the appropriate health care professional, mostly ophthalmologists for cataract removal surgery (Department of Health, 2006; Dobbelsteyn *et al.*, 2015). As primary health care practitioners, optometrists are often identified as the first professionals to diagnose a patient with a possible cataract (Gaskell *et al.*, 2001; Pierscionek *et al.*, 2009; Bowes *et al.*, 2018). In addition to the vital role optometrists have in initial cataract diagnoses, patient education of cataracts, as well as cataract surgery and intraocular lens options, are also essential responsibilities carried out by optometrists (Tan *et al.*, 2005; Pohl, 2013; Fuller, 2019).

In many first world countries, optometrists are holistically involved in ophthalmic procedures, including the whole cataract surgery process (Voyatzis *et al.*, 2014; Harper *et al.*, 2016). The scope of optometry in many countries has escalated to the point that the optometrist, especially in hospital setups, are also taking responsibility for important post-operative consultations (Vliet *et al.*, 2010; Voyatzis *et al.*, 2014; Harper *et al.*, 2016).

No matter what the scope for optometrists in a particular country is, optometrists will be involved in the cataract patient's case and proper knowledge about cataract surgery is essential. Cataract surgery will be explained in the next section.

2.6 Cataract Surgery

The most effective way to treat cataracts is with surgical intervention. Non-surgical forms of treatment, such as tinted spectacle lenses and optimised spectacle lens power, reduce symptoms of cataracts, but cannot make the opaque lens transparent again. Surgery will eventually be needed as the patient ages and the cataract becomes more densely opacified and seriously obstructs the patient's vision (Naidu *et al.*, 2002; Steinert, 2010; Thompson and Lakhani, 2015).

Phacoemulsification is currently the most common surgical technique being used worldwide (Thompson and Lakhani, 2015; Ahmad and Iqbal, 2016). Other surgical techniques for cataracts include intracapsular cataract extraction (ICCE), extracapsular cataract extraction (ECCE) and manual small incision cataract surgery (MSICS). All these surgical techniques have risks and the best type of surgery for the patient is evaluated and chosen according to the patient's specific circumstances. The nomenclature of these procedures is based on the effect of the surgery on the capsule. With the ICCE procedure, the entire lens together with the capsule is removed, whereas in ECCE, the nucleus and cortex are removed but the capsule and ligaments are left behind and into which the IOL is placed. Then finally phacoemulsification is an advancement of the ECCE where only small incisions are needed. (Riaz *et al.*, 2006; Bowling, 2016; Matta *et al.*, 2016).

Cataract surgery was originally performed by a method called 'couching', where the surgeon pushes the cataract into the vitreous and out of the way of the visual axis. This primitive technique is unfortunately still used today in poorer countries to treat patients with visually significant cataracts due to limited resources and the low cost of the 'couching' procedure (Signes-Soler *et al.*, 2012; Kretz *et al.*, 2014; Haripriya *et al.*, 2017).

Samuel Sharp performed the first successful intracapsular cataract extraction 1953 by applying pressure through a limbal incision using his thumb to dislocate the lens out of the eye. The patient is then left aphakic and needs unsightly spectacles (approximately +10 Dioptres) with notable prismatic effects after the surgery. Intracapsular cataract extraction is hardly ever done in modern times. This is due to the high incidence of intra-operative and post-operative complications (Hubbell, 1904; Murp, 1999; Gupta *et al.*, 2003; Thompson and Lakhani, 2015; Haripriya *et al.*, 2017).

The French doctor, Jacques Daviel, performed the first extracapsular cataract extraction in 1747. Although the extracapsular method is a considerable improvement from intracapsular cataract extraction, it makes use of a relatively big surgical incision that needs sutures afterwards. These sutures induce astigmatism and have to be removed after three months, delaying the healing time after surgery and also the refractive stabilisation (Hollick *et al.*, 1996; Kanski, 2007; Costea *et al.*, 2016).

Since the invention of the intraocular lens by Dr. Harold Ridley in 1949, surgical techniques also improved. Dr. Charles Kelman revolutionised cataract surgery in 1967 after a visit to the dentist where he developed the idea that a similar method than what was being used to clean teeth with ultrasound, could be used during cataract surgery to break up the opacified lens into smaller manageable pieces. This lead to the development of the phacoemulsification technique during which ultrasound is used to break the lens into smaller pieces. These lens pieces, called lens debris, are then removed with a vacuum apparatus. The whole surgery takes place through a 1.8 mm – 3 mm sutureless manual incision, while the lens capsule stays in place to hold the new synthetic intraocular lens (IOL) in position. This minimal surgical intrusion with relatively low risk, makes phacoemulsification cataract surgery a popular and safe treatment with much faster visual stabilisation after surgery (Geffen *et al.*, 2010; Thanigasalam *et al.*, 2015; Thompson and Lakhani, 2015; Ahmad and Iqbal, 2016).

Manual small incision cataract surgery is often used as an alternative to phacoemulsification in developing countries due to the reduced cost and relatively good visual outcome. Manual small incision cataract surgery essentially is done by making a sclerocorneal tunnel through a 6-7 mm incision through which the lens nucleus is prolapsed into the anterior chamber where it is then removed from the eye. Phacoemulsification, however, remains the preferred method where the necessary resources and medical skills are available to ensure the best possible outcome (Riaz *et al.*, 2006; Thompson and Lakhani, 2015; Ahmad and Iqbal, 2016; Singh *et al.*, 2017).

The best surgical technique for the specific patient and ocular health state is used, to ensure that after surgery, the visual prognosis will be an improvement in the patient's vision.

2.6.1 Indications for cataract surgery

The universal indication to undergo cataract surgery is symptomatic vision loss that cannot sufficiently be corrected with spectacles by the optometrist for the patient to continue with daily tasks and quality living (Thompson and Lakhani, 2015; Alshamrani,

2018). Health care systems worldwide have their unique systems of managing cataract patients to ensure the patients operated, are the patients that will benefit from surgery and have a positive outcome (Day *et al.*, 2015). For example, some institutions in South Africa have a minimum visual requirement of less than 6/12 visual acuity in the better eye to identify which patients are good candidates for cataract surgery (Cook *et al.*, 2012; Mabaso and Oduntan, 2014).

The importance of thorough planning and effective implementation, well-trained staff and proper infrastructure are critical to the outcome of the surgery. South Africa, especially in the rural public sector, is currently facing several challenges that are risking the positive outcome of cataract surgery. This includes lack of theatre equipment and consumables, shortage of time and as previously mentioned, an insufficient number of properly trained staff (Lecuona and Cook, 2011; Rao, 2015).

Cataracts may cause a change in the index of the lens and subsequently lead to a myopic (in the case of a nuclear cataract) or hyperopic (in the case of a cortical cataract) shift in refraction (Samarawickrama *et al.*, 2007; Iribarren and Iribarren, 2013). These patients might have to change spectacles every few months and it might be better to refer the patient for cataract surgery to reduce the cost of continuously having new spectacle lenses made (Swartz, 2016).

Although Shao et al. (2015) do not agree, a noticeable decrease in intraocular pressure has been found in narrow-angle glaucoma patients undergoing cataract surgery and cataract surgery has also been researched as a supplementary method to treat narrow-angle glaucoma patients (Husain *et al.*, 2012; Brown *et al.*, 2014). Since the volume that an IOL takes up is only a third of the volume of a natural lens, the replacement of the natural lens with the IOL seems to increase the anterior chamber volume, causing a decrease in the intraocular pressure.

Cataract surgery, therefore, has great benefits, but the most important benefit remains the excellent visual outcome that can be achieved with the intraocular lens technology available today.

2.6.2 Intraocular lens calculation

Harold Ridley, the inventor of the intraocular lens (IOL), felt that cataract extraction was only half of the remedy and that, to cure a cataract, another lens needs to be inserted in the place of the previous opaque natural lens. His courage to pursue this idea was prompted by a question asked by one of his medical students, Stephen Perry, during ward rounds. He simply asked if Ridley intended to replace the absent part of the eye that was removed during surgery. This initiated the design of the IOL (Ridley, 1952; Apple, 2007).

His idea was set into motion after observing World War II fighter pilot Gordon Cleaver that got a piece of plexiglass material in his eye. Harold Ridley noticed that the plexiglas acrylic canopy fragments that embedded in the pilot's eyes during the enemy fire, stayed in the eyes for years afterwards and had no adverse effect on the eye. His work opened the possibility of not only the standard IOL but paved the way for even more specialized intraocular lenses to be discovered in the future (Apple, 2003; Moore *et al.*, 2010).

The first IOL was made by a British Company, Rayner and Keeler Ltd. The IOL was a simple biconvex disc design fabricated from a plastic material called Acrylic or polymethylmethacrylate (PMMA) that is still used today. PMMA is a light, durable material, but because of its rigidity, the incision size needed to be at least as big as the diameter of the IOL. As this incision needs to be closed with a suture after the surgery, it may induce post-operative astigmatism. This aspect of the IOL led to the development of the foldable hydrogel and foldable silicone IOLs (Apple, 2007; Steinert, 2010; Kretz *et al.*, 2014).

The first IOL implant was done by Ridley in 1949 and resulted in a myopic overcorrection of more than 14 Dioptres. The following successful IOL implants done by Ridley ended with a refraction approximately two dioptres in the region of the pre-operative refraction, calculated from the opposite eye, with about one dioptre of astigmatism. Although this was a vast improvement from leaving a patient aphakic, patients today have high expectations and take the opportunity to be free of spectacles or less

dependent on spectacles seriously. The high demand for perfect vision forces the surgeon to aim for a plano (zero) refractive error after cataract surgery (Ridley, 1952; Father of the Intraocular Lens, 1997; Horváth *et al.*, 2014).

Different devices and equipment are used to measure the parameters required to calculate the power of the IOL needed for each cataract patient. The measurements is done according to the ideal post-operative refraction for the patient. New technology uses partial optical coherence interferometry (OCT) to acquire the values needed to calculate the power of the IOL needed for implantation. There are also many different formulas used in the calculation processes once the values have been obtained and in some instances, a specific formula may be more suitable for a specific patient or surgical technique to be used (Olsen, 2007; Wang and Chang, 2013; Doshi *et al.*, 2017).

Before cataract surgery, calculation of the IOL is done by the measurement of the biometry values of the eye. Many ways to determine the most accurate IOL power have been explored, but third- and fourth-generation formulas are most preferred in modern times. These formulas are used to calculate the power of the IOL to be implanted with the aim to leave the patient at a plano distance refraction after cataract surgery (Mansour, 2018), thus not needing a distance spectacle prescription.

Anterior chamber depth is the biometric value that can significantly influence errors in third-generation formula results. Third-generation formulas often used are SRK/T, Holladay I and Hoffer Q. The SRK/T formula is a combination of a linear regression method with a theoretical eye model that relies on an A-constant value to calculate the anterior chamber depth, using retinal thickness and corneal refractive index (Jeong *et al.*, 2017; Karabela *et al.*, 2017). The Hoffer Q formula uses a personalized anterior chamber depth, corneal curvature and axial length (Hoffer, 1993). It has been found that in certain cases, one formula might be superior to another. Some instances, in eyes with axial length of less than 22 mm, the Hoffer Q, Holladay I and SRK/T formulas provide better refractive outcomes than other formulas (Doshi *et al.*, 2017; Jeong *et al.*, 2017; Karabela *et al.*, 2017).

Popular new generation formulas are Holladay II, Barret Universal II and Haigis. The Holladay I and Holladay II formulas use four and seven parameters respectively to determine a 'surgeon factor' that is used in the formulas to calculate the IOL power needed. Haigis' formula uses a three-variable system that can be used for a wide range of axial lengths and anterior chamber depths using double regression analysis. The Barrett Universal II formula is superior to other formulas in that it uses both anterior and posterior corneal curvatures to calculate toric IOL power (Holladay *et al.*, 1988; Reitblat *et al.*, 2015; Schröder *et al.*, 2016; Park *et al.*, 2017).

The ophthalmologist will choose the correct formula or formulas to calculate the IOL for the patient, while keeping the patient's refractive state in mind. With the correct formula and accurate biometry, even speciality IOLs can be accurately predicted according to the patient's needs.

2.6.3 Types of intraocular lenses

Monofocal IOLs correct either distance or near vision. These type of lenses have been found to provide excellent visual quality with low aberrations. The explicit restriction with this type of IOL correction is that spectacles will be needed for either distance or mostly for near vision (Chang and Huggins, 2018; Farhoudi *et al.*, 2018; Pedrotti *et al.*, 2018).

Astigmatism is a refractive state that is present when unequal refractive powers are present in the different meridians of the eye. This is mostly due to the corneal or lens curvatures being unequal, resulting in different refractive powers over these meridians. Núñez et al. (2019) found that up to four out of ten cataract patients have astigmatism of more than one dioptre and that two out of ten cataract patients have astigmatism of more than one and a half dioptres. Patients with astigmatism often need a toric IOL to give a satisfactory visual outcome after surgery. If the vertical meridian is the steepest and the astigmatism is one dioptre or less, the astigmatism can be corrected with a surgical incision on the steepest axis where the incision will have the greatest effect on the refractive cylindrical power. This is because the surgical incisions cause scar tissue

that pulls the cornea flatter and thereby decreases the astigmatism of the cornea. Otherwise, it has been found that a toric IOL is the best option to correct the astigmatism to get the focus as close to plano as possible (Read *et al.*, 2007; Mencucci *et al.*, 2013; Barišić *et al.*, 2017).

In an attempt to have a broader range of functional vision, monovision through neuroadaptation may be considered as a focusing option. With monovision focus, the conventional monofocal IOL is used to correct the distance vision in the dominant eye and the near vision in the non-dominant eye. Patients who are motivated to be less dependent on spectacles often do well with this type of vision correction after cataract surgery. Although the patient might be able to perform basic daily tasks without correction, spectacles will still be required for some activities like driving and reading smaller print (Greenbaum, 2002; Bethke and Editor, 2014; Greenstein and Pineda, 2017; Goldberg *et al.*, 2018).

Modern surgery can, however, give great visual outcome at more than one or two distances with the use of multifocal IOLs. Educated presbyopic patients often see cataract surgery as a way to improve their visual situation and aim to be spectacle independent. Although most patients feel that they are free of vision correction after multifocal lens implants, visual symptoms like glare and halos at night may be problematic. Spectacles with polarization or anti-reflection coatings can significantly improve day and night-time vision respectively (Brooks and Borish, 2007; Baig *et al.*, 2016; Alio *et al.*, 2017).

Extended-depth-of-focus IOL is the latest IOL design that aims to meet the expectations of the modern presbyopic patient. These IOLs do not have the visual disturbances of multifocal IOLs, but might reduce near vision compared to multifocal IOLs. For this reason, the patient's visual activities will have to be considered when choosing between an extended-depth-of-focus or multifocal IOL (Barišić *et al.*, 2018).

The IOL options are wide and various options are available for each patient. Other factors to be discussed with the patient before cataract surgery include the type of

anaesthetic to be used during surgery. These options will be discussed in more detail in the next section.

2.6.4 Anaesthesia during cataract surgery

As with most medical procedures and surgeries, anaesthesia is used during cataract surgery to make it a more comfortable experience for the patient and the surgeon. The method of anaesthesia used during cataract surgery is dependent on the type of cataract surgery as well as the patient's general health and preference (Stanfield *et al.*, 2004; Oliver *et al.*, 2010).

Patients may choose to have general anaesthesia or local anaesthesia. Local anaesthesia is usually administered topically or with an anaesthetic block. General anaesthesia is not often used in modern times due to the increased risk for anaesthetic related complications, especially in the elderly. General anaesthesia may, however, be used in children and healthy young patients or in patients with mental incapacity or severe claustrophobia that prevents the patient from cooperating during the surgery (Day *et al.*, 2015; Thanigasalam *et al.*, 2015; Thompson and Lakhani, 2015; Tekin *et al.*, 2018).

As the patient is awake during topical anaesthesia, good communication between the surgeon and the patient is of utmost importance to ensure that the patient is aware of the different visual phenomenon he/she might experience during surgery like light flashes and black spots. Topical anaesthesia with eye drops blocks the trigeminal nerve endings only and patient cooperation is crucial for successful and comfortable surgery. It is the safest anaesthetic method for cataract surgery as the risk of serious complications associated with invasive anaesthetic methods are absent. Topical drop anaesthesia often causes ocular surface disease like dry eye and meibomian gland dysfunction. It remains the most time and cost-effective method and it intrudes minimally on the visual potential, allowing patients to be able to see and use their eye almost directly after surgery (Newman, 2000; Aslam *et al.*, 2015; Cunningham and Whitley, 2015; Thanigasalam *et al.*, 2015; Thompson and Lakhani, 2015; Mohammad *et al.*, 2017).

People with conditions like dementia can also be operated under local anaesthetic. To make the surgery more comfortable for patients with these types of conditions, extra time has to be spent with them to explain the surgery. The surgery itself can also be improved by clear communication during surgery as well as other simple comforts like an extra nurse and hand holding by a familiar person. The final decision on the type of anaesthetic should still be made by the surgeon. Patients should, therefore, be screened appropriately so that their ability to cooperate can be evaluated, and that the patient could be well prepared as to what to expect during the surgery (Joshi, 2013; Jefferis *et al.*, 2014; Mohammad *et al.*, 2017).

When topical anaesthesia is not desirable, the surgery is usually done with an anaesthetic block. This can be done by administering a peribulbar block, sub-tenon block or topical intracameral anaesthesia. The anaesthetic block mostly used for cataract surgery involves an injection of local anaesthetic behind the globe, but outside the muscle cone, called an extraconal or peribulbar block. The injection involves piercing a needle through the skin or conjunctiva to inject the anaesthetic agent at an approximate depth of about 20 mm from the inferior orbital rim, outside the posterior muscle cone (Kanski, 2007; Kumar and Williamson, 2013; Yanoff and Duker, 2014).

A study by Rezeq (2010) showed that topical methods are more time effective, making it a good choice for most surgeons. Anaesthetic block should be avoided in patients on certain medications like anticoagulants, to avoid unnecessary complications. Anaesthetic block can, in rare cases, also cause orbital cellulitis (Sharma *et al.*, 2005; Thompson and Lakhani, 2015). The most common short term side effect of a peribulbar block is akinesia, which is the loss of voluntary movement of the eye. Although this is desirable during surgery, the type of anaesthetic used can cause this effect to last much longer than the surgery time (Stanfield *et al.*, 2004; Messeha and Elhesy, 2015; Fayed *et al.*, 2018).

The most important consideration when choosing the type of anaesthetic for cataract surgery is that it is done with the least pain and discomfort and the lowest risk of complications for the patient.

2.6.5 Cataract surgery complications

Cataract surgery is a relatively safe surgery, but as with any surgical intervention, complications may still occur. Complications from cataract surgery have declined significantly over the last two decades due to improved technology and surgical methods (Behndig *et al.*, 2011; Cunningham and Whitley, 2015). Krader and Pohl (2011) found that 98% of cataract surgeries are uneventful, but that a wide variety of complications may arise in the remaining 2%. These complications will be discussed further in the sections to follow.

Complications that cause permanent damage or loss of vision after cataract surgery are very rare in current times. Complications should be treated accordingly as any intra-operative or post-operative complication may discourage a patient from having the second eye operated to remove a cataract (Allen and Vasavada, 2006; Bani *et al.*, 2012).

When it comes to the post-operative refraction, it is important to know when certain structures in the eye have returned to its original state after surgery, i.e. when no complications are present that could influence the stability of the refraction for spectacles (Juan *et al.*, 2013).

2.6.5.1 Intra-operative complications

Complications that can take place during surgery include vitreous haemorrhage, zonular rupture, corneal endothelial trauma and lens segments that fall into the vitreous. Other intra-operative complications include choroidal or subchoroidal haemorrhages, iris damage or posterior capsule rupture. Posterior capsular rupture is a significant complication and occurs most frequently of all the possible intra-operative complications mentioned (Addisu and Solomon, 2011; Newsom *et al.*, 2013; González *et al.*, 2014).

2.6.5.2 Post-operative complications

Post-operative complications may be sight-threatening and may cause permanent harm to the eye. These serious complications mostly occur shortly after the surgery (Porter *et al.*, 2012). It has been found by Jin et al. (2013) that even the size of the surgical incision

made during phacoemulsification cataract surgery may influence the risk of complications, for example, posterior capsule rupture and endophthalmitis.

Endophthalmitis is very uncommon, but has the most significant effect on vision and ocular health. This condition should be treated promptly (Payne, 2005; Krader and Pohl, 2011). Vitreous prolapse to the wound, retinal detachment, anterior uveitis and even orbital cellulitis have also been reported as serious post-operative complications after cataract surgery (Sharma *et al.*, 2005; Allen and Vasavada, 2006; Porter *et al.*, 2012).

Problems with too high, as well as too low intraocular pressure (IOP) have been reported after cataract surgery. In cases where there is an increase in IOP, it is mostly treated with a topical eye drop and found to return to normal one week after surgery. When the eye is found in a hypotonic state, which is when the IOP is too low, the cause should always be investigated so that the eye can be restored to a normal IOP before serious damage to the eye or vision occurs (Krader and Pohl, 2011; Chatziralli *et al.*, 2012; Porter *et al.*, 2012; Bhogal-Bhamra and Bilkhu, 2015).

There are often complications that occur from the IOL itself, for example, IOL luxation, IOL tilting as well as IOL rotation (González *et al.*, 2014; Bariah and Sy, 2018; Gundersen, 2018). A frequent complication occurring after cataract surgery is posterior capsular opacification (PCO). Posterior capsular opacification causes a decrease in vision and glare when occurring after cataract surgery. This complication occurs due to proliferation of lens epithelial cells across the posterior capsule. PCO is successfully and efficiently treated by an in-room YAG laser capsulotomy procedure that removes this part of the capsule and restores the vision in the operated eye (Payne, 2005; Karambelkar *et al.*, 2014; Cunningham and Whitley, 2015).

Ocular surface disease found after cataract surgery present with symptoms of fluctuating vision, dryness or irritation and include meibomian gland dysfunction as well as corneal disease which is a result of the mechanical trauma from surgery and the increased dryness of the ocular surface during, and after surgery (Bains and Hamill, 2014; Cunningham and Whitley, 2015). The most common corneal condition found after

cataract surgery is corneal oedema (Addisu and Solomon, 2011; González *et al.*, 2014; Kahawita and Goggin, 2015).

Kahawita and Goggin (2015) reported cystoid macula oedema (CMO) as the most common post-operative complication on data of almost 4000 patients. Bains and Hamill (2014) found this complication to occur from four weeks onward after the cataract surgery and although it can affect vision quite negatively, has been found to be self-limiting in most cases (Krader and Pohl, 2011; Cunningham and Whitley, 2015).

Corneal oedema and cystoid macula oedema might be the two complications that have the most significant effect on post-operative refraction (Krader and Pohl, 2011; Costagliola *et al.*, 2013) and will be discussed in more detail in the following sections.

2.6.6 Central corneal thickness

The cornea is a delicate structure made up of five layers: the epithelium, Bowman's layer, corneal stroma, Descemet membrane and the endothelium. Recently a new sixth corneal landmark has been described, called Dua's Layer. This pre-Descemet's layer is situated between the stroma and Descemet's membrane (Dua *et al.*, 2013; Bowling, 2016).

The cornea protects the eye from pathogens and other environmental factors. The principal role of the cornea is the transmission and refraction of light that enters the eye to stimulate vision, making transparency and refractive power two very fundamental characteristics of the cornea (Costagliola *et al.*, 2013; Dua *et al.*, 2013; Krachmer and Palay, 2014; Bowling, 2016; Mannis and Holland, 2017).

2.6.6.1 Corneal parameters

The average central thickness of the cornea is 540 µm. The exact increase in corneal thickness that is regarded as significant corneal oedema is not accurately described in the literature at the time of this research study. An increase in thickness within one or

multiple layers of the cornea is generally accepted and referred to as corneal oedema (Kanski, 2007; American Academy of Ophthalmology, 2013; Bowling, 2016).

Do *et al.*, (2015) found that corneal oedema after cataract surgery was usually subclinical, causing a vision loss of only one or two lines on the Snellen chart. Even though it has been found during the post-operative period that the worst vision correlates with the highest amount of corneal oedema present, the severity of corneal oedema cannot be quantified directly from the visual acuity measurement (Tsaousis *et al.*, 2016; Zheng *et al.*, 2016).

The corneal thickness should, however, be measured after cataract surgery to ensure that no permanent visual damage due to corneal oedema occurs. The CCT can be measured in several ways and will be further discussed.

2.6.6.2 Measurement of the cornea

Corneal oedema is best detected by measuring the central corneal thickness (CCT), preferably with the same device, before and after surgery (Tao *et al.*, 2013; Zheng *et al.*, 2016). The gold standard for measuring CCT has always been a digital ultrasonic pachymeter. This device uses the transit time for reflections of ultrasonic waves from the anterior to the posterior corneal surface in a simple formula to calculate the CCT (Metheetrairut *et al.*, 2018; Binnawi *et al.*, 2019).

In modern times, more options for measuring CCT has become available with optical coherence tomography (OCT) devices (Tao *et al.*, 2013; Zheng *et al.*, 2016). All devices have their unique features and functions, but studies have found that the Cirrus OCT and ultrasonic pachymeter produce the most reliable results, especially when the corneal thickness is found to be more than 650 µm (Calvo-Sanz *et al.*, 2018; Metheetrairut *et al.*, 2018). The researcher agrees that OCT is the most convenient and accurate method to determine the CCT.

When an increase in corneal thickness is measured, it is important to monitor this oedema to avoid permanent visual damage. The mechanism behind this post-operative complication will be discussed in the following section.

2.6.6.3 Mechanism of corneal oedema

Corneal oedema usually occurs due to mechanical injury, inflammation, infection, chemical injury or concurrent eye disease. No significant change in corneal thickness due to ageing has been proven, indicating that the corneal oedema is not an age-related occurrence. Certain systemic conditions like Diabetes Mellitus have been associated with a higher incidence of transient corneal oedema after cataract surgery. Reduced action of the corneal pump function is prevalent after cataract surgery. When corneal functioning is disrupted, there is an accumulation of extracellular fluid inside the cornea with consequent loss of transparency (Kamiya *et al.*, 2009; Costagliola *et al.*, 2013; Caceres, 2015; Do *et al.*, 2015).

Cataract surgery can damage the corneal endothelial cells leading to the dullness of vision, general discomfort and even pain of the eye. The most noticable effect of corneal oedema is reduced vision as the corneal cloudiness causes less light to enter the optical system and also causes more scattering of the light that enters the eye (González *et al.*, 2014; Feinbaum, 2015). An increased CCT is a noteworthy observation often found after cataract surgery.

2.6.6.4 The relevance of corneal oedema after cataract surgery

As previously mentioned, one of the most common complications after cataract surgery is corneal swelling. Although corneal oedema is still relatively common, the incidence of corneal oedema has declined in the past 20 years. This is due to improved surgical techniques and better surgical instrumentation (Rozegnał-Madej and Żarnowski, 2015).

Do *et al*. (2015) reported a prevalence of corneal oedema in 11.3% of subjects in their study. González *et al*. (2014) had a higher aged sample group and reported an even greater prevalence of corneal oedema in 15.42% of the subjects in their study after uneventful cataract surgery. This indicates the possibility that as many as one out of ten patients may suffer from corneal oedema after uneventful cataract surgery. An even higher incidence was found by Ahmad et al. (2013) in their study in which different

surgical techniques were used, with almost half of the patients having corneal oedema the following day after cataract surgery.

There are, however, many factors that contribute to the risk of developing corneal oedema, for example, the age of the patient. A study conducted in a sample with the majority having mature cataracts, reported a very high incidence of corneal oedema in 71.5% of participants, possibly due to the increased ultrasound power required to break up the cataract during surgery (Addisu and Solomon, 2011).

When an increased CCT is measured, it is important to know when to expect stabilisation of the CCT to accurately manage the patient by prescribing spectacles at the right time.

2.6.6.5 Corneal stabilisation after cataract surgery

The greatest increase in corneal oedema occurs one day post-operatively (Zheng *et al.*, 2016). Tao et al. (2013) found a significant increase of 32.1 ± 26.6 µm on the first post-operative day. Zheng et al. (2016) found a central corneal thickness of 639 ± 170 µm compared to the baseline measurement of 526 ± 31 µm. Ishikawa et al. (2018) found a slightly less aggressive difference of 549.9 ± 32.7 µm and 582.7 ± 46.3 µm for baseline and day one post-operative measurement respectively. The studies mentioned agree that the corneal oedema is insignificant after one week post-operatively. If the results of these studies are considered, it may be expected that the cornea has stabilised after one week post-operatively (Ward and Ajamian, 2009; Tao *et al.*, 2013).

Caceres (2015) and Caglar et al. (2017) agree that the CCT stabilised two weeks after surgery. Ahmad et al. (2013) and Kanski (2007) reported the recovery of CCT three weeks after cataract surgery. The recovery also depends on the surgical method used, the cataract maturity and patient characteristics.

In eyes with no predisposing factors, corneal oedema generally resolves spontaneously and there is usually no need to prescribe the patient with extra eye drops or clinical interventions (Juan *et al.*, 2013; Do *et al.*, 2015; Feinbaum, 2015). Corneal swelling causes refractive changes that limit fast visual rehabilitation. When the cornea becomes oedematous, the axial length of the eye increases and an accurate refraction for

spectacles cannot be obtained. Therefore, before prescribing new spectacles post-operatively, optometrists should ensure that the CCT is stable and that all corneal swelling has been resolved (Snell and Lemp, 1998; Grosvenor, 2007; Caglar *et al.*, 2016).

2.6.6.6 The importance of central corneal thickness for this research study

As discussed in the previous sections, the cornea is one of the most important refractive medias in the eye. It is necessary to know when to expect stabilisation of the cornea as it will certainly have a major effect on the accuracy of the post-operative refraction for spectacles.

2.6.7 Central macula thickness

Another significant complication involves the central area of the retina with the highest density of cone photoreceptors, called the macula. This yellowish xanthophyll rich area has a central point called the fovea. This macula area is the most important structure in the posterior segment of the eye and is used for good vision. Damage to the macula will cause a significant loss in central vision (Ross and Pawlina, 2006; Agarwal, 2012; Stein *et al.*, 2018).

2.6.7.1 Macula parameters

The macula area is visible as ‘n slightly more pigmented area approximately 5.5 mm wide. The centre of the macula, measures about 252 µm in thickness and any thickness greater than this can be regarded as macula thickening resulting from oedema (Chan *et al.*, 2006; Ross and Pawlina, 2006; Agarwal, 2012).

Small increases in the macula and overall retinal thickness are usually seen after cataract surgery, but this phenomenon does not always require treatment (Cagini *et al.*, 2009). Atalay *et al.* (2016) found an increase in CMT of more than 30 µm to be clinically significant. Mathys and Cohen (2009) and Jagow et al. (2007) agree that a small increase

in macula thickness has been noted after cataract surgery with no clinical significance or effect on vision.

A cross-sectional study by Kiliç *et al.* (2010), investigated macula properties in normal eyes and concluded that macula thickness is negatively correlated with age. Therefore, when no intervention is present, CMT should decrease with age, not increase as seen after surgery. An inverse relationship also exists between the axial length of an eye and the thickness of the intraretinal layers (Szigeti *et al.*, 2015). Jagow *et al.* (2007) proved with a control group of contralateral eyes that there is no significant change in CMT in the non-operated eyes compared to the gradual thickening of the macula in the operated eyes.

2.6.7.2 Measurement of central macula thickness

Cystoid macula oedema is detected relatively early after cataract surgery by measuring the central macula thickness (CMT) with an OCT imaging device. It is important to take an OCT image of the macula before, and not only after cataract surgery. The risk of CMO may then be determined and properly managed to avoid visual damage (Cagini *et al.*, 2009; Atalay *et al.*, 2016; Charles, 2018).

Optical coherence tomography has been proven to be a reliable method to measure macula thickness with good repeatability. The experienced clinician can also detect CMO during normal fundus biomicroscopy. Optical coherence tomography is a non-invasive and quick device that allows the clinician to get an excellent idea of the macula health, but further inspection of the macula area can also be done with a Fundus Fluorescein Angiogram if desired (Krader and Pohl, 2011; Lobo, 2012; Yeom *et al.*, 2019).

Regular follow up consultations after cataract surgery is important to measure the CMT so that this complication is not overlooked. The next section will discuss the mechanism of CMO after cataract surgery and what clinical signs to look out for during evaluation and diagnosis.

2.6.7.3 Mechanism of cystoid macula oedema

Irvine-Gass Syndrome, or CMO, is an often unrecorded complication after uneventful cataract surgery that causes a reduction in vision without any other detectable signs of post-operative problems being present. Any change in vision that is worse than the previous post-operative consultation may indicate the presence of CMO (Krader and Pohl, 2011; Cunningham and Whitley, 2015; Guo *et al.*, 2015).

Cystoid macula oedema is mostly the result of retinal thickening in the inner nuclear and outer plexiform layers of the retina, caused by the presence of fluid-filled cysts within these layers. These cysts appear as radially orientated spaces filled with clear macula fluid. Intracellular oedema of the Müller cells occur before extracellular oedema and might not be detected if an OCT is not used and correctly interpreted (Kanski, 2007; Rotsos and Moschos, 2008; Scholl *et al.*, 2011; Guo *et al.*, 2015).

Cystoid macula oedema likely occurs due to alteration in the inflammation and prostaglandin pathway that causes the release of inflammatory mediators into the eye. Krader and Pohl (2011) agree that prostaglandin, possibly released from the uveal vasculature, initiates an inflammatory process that leads to perifoveal vascular leakage. The exact mechanism is uncertain, but it has been speculated that the surgical manipulation of the iris can cause secondary inflammatory mediators to be released, leading to CMO. A related theory is that the alterations of proteins in the vitreous may also lead to CMO formation after cataract surgery (Scholl *et al.*, 2011; Zur *et al.*, 2011; Guo *et al.*, 2015).

A study by Cagini *et al.*, (2009) found a definite increase in macula thickness after uneventful cataract surgery and noted that this oedema might be due to a breakdown of the blood-retinal-barrier. The blood-retinal barrier is located posteriorly at the retinal pigment epithelium (RPE) and regulates the flow of substance from the choroid to the subretinal space. Damage to another barrier, called the blood-aqueous-barrier, has also been linked to CMO. The blood-aqueous-barrier is the anterior barrier composed of the non-pigmented cell layer of the ciliary epithelium and the endothelial cells of the blood

vessels in the iris and prevents the flow of substances, for example drugs, to the vitreous. (Scholl *et al.*, 2011).

In summary, the inflammatory disruption of retinal architecture increases fluid retention and leads to the formation of macula cysts that can negatively influence the patient's vision (Kanski, 2007; Rotsos and Moschos, 2008; Makri *et al.*, 2017).

2.6.7.4 The relevance of central macula oedema after cataract surgery

The available data on the prevalence of CMO in patients after cataract surgery is inconsistent and ranges from 1.23% to 5.85% (Murthy *et al.*, 2009; Zur *et al.*, 2011). Patient factors and type of cataract surgery again influences the incidence of this complication. The study by Do et al. (2015) reported a post-operative prevalence as high as 10.7%, five weeks after surgery.

Macula oedema can be treated with periocular or intraocular corticosteroids. Non-Steroidal Anti-inflammatory (NSAID's) topical eye drops may also be administered for quicker resolution of the macula oedema. Most cases of increased macula thickness will, however, resolve without treatment (Krader and Pohl, 2011; Guo *et al.*, 2015). Jagow et al. (2007) agree that subclinical CMO may be observed only and treatment might not be immediately necessary.

2.6.7.5 Stabilisation of central macula thickness after cataract surgery

Clinical CMO appears on average from four to six weeks post-operatively and stabilises about six months after surgery (Scholl *et al.*, 2011; Vukicevic *et al.*, 2012; Carricondo *et al.*, 2015).

CMO can be seen as early as three weeks post-operatively (Rotsos and Moschos, 2008; Krader and Pohl, 2011). An asymptomatic increase in CMT has been found at 12 weeks after cataract surgery (Cagini *et al.*, 2009). Gharbiya *et al.*, (2013) found that retinal thickness decreases after surgery and then increases from one week post-operatively.

This is possibly due to the influence of lens opacities on the pre-operative OCT measurements.

2.6.7.6 The importance of central macula oedema for this research study

The delicate macula is extremely important for optimal vision. Any damage to this area will undoubtedly have a great impact on a patient's vision and refractive error and it is important to know when this complication occurs after cataract surgery so that the optimal time for spectacle refraction can be concluded.

2.6.8 Expected visual outcome after cataract surgery

Hajek *et al*. (2016) and Ni *et al*. (2015) found that cataract surgery is a highly satisfying experience for the patient that produces excellent results in the vast majority of cases. Even in the most elderly patients, cataract surgery has been found to have an excellent visual outcome (Toyama *et al.*, 2018).

2.6.8.1 Improved visual acuity

Vision-related quality of life enhances significantly after successful cataract surgery. Vision improvement is traditionally measured by recording the best corrected visual acuity with the same visual acuity chart used previously. Besides best corrected visual acuity, other visual functions like contrast sensitivity and depth perception also improve remarkably after cataract surgery. Functional visual acuity has been found to improve in most patients. The dynamic vision, which refers to the potential to fixate on a target when there is relative movement between the target and the observer, also improves after cataract surgery (Fraser *et al.*, 2013; Ao *et al.*, 2014; Javed *et al.*, 2015; Chaudhary *et al.*, 2016).

Cataract surgery significantly improves the quality of life and can sequentially even improve general health. Better vision also enables better physical mobility. This is especially important for the elderly to reduce hip fractures and other injuries from falling due to impaired vision (Tseng *et al.*, 2012; Groessl *et al.*, 2013; Helbostad *et al.*, 2013).

2.6.8.2 Refraction waiting time after cataract surgery

One of the most important roles of an optometrist after cataract surgery, being primarily responsible for refractions, remains the post-operative refractive management. The patient might not need spectacles as regularly as before cataract surgery, but the best possible vision for distance and near tasks will be achieved when the patient is wearing correction. Consequently, post-operative consultations usually also include an accurate refraction and the prescription of spectacles when the eye has reached stability after the cataract surgery (Porter *et al.*, 2012; Caglar *et al.*, 2016; Harper *et al.*, 2016).

Optometrists and ophthalmologists traditionally wait six weeks before doing a refraction to determine the post-operative spectacle prescription. However, post-operative complications are the main factors to consider when determining a consultation date for this refraction as complications may cause the eye to reach stability only after a prolonged time following cataract surgery (Riaz *et al.*, 2006; Karambelkar *et al.*, 2014; Lu *et al.*, 2015).

The removal of the natural lens and the insertion of the new IOL with associated surgical incisions means that the focus of the eye will undoubtedly change after cataract surgery (Yorsten, 2013). In most cases, the patient will still need spectacles in the form of reading glasses or distance glasses, depending on the resulting refraction after surgery (Bani *et al.*, 2012; Caglar *et al.*, 2016). Patients with previous refractive surgery and those with high astigmatism in their pre-operative refraction, often have a higher risk of unpredictable refractive outcomes and often need full-time correction post-operatively (Helaly *et al.*, 2016).

There is a great discrepancy in current studies concerning the ideal waiting time to do a refraction after cataract surgery. Juan *et al.*, (2013), Kessel *et al.*, (2015) and Caglar *et al.*, (2016) showed that, although the corneal thickness may still fluctuate until two weeks after surgery, the refraction for spectacles may already stabilise after only one week in most cases and change minimally within the next two to four weeks after uneventful cataract surgery. Most optometrists appear to be doing a refraction four weeks after cataract surgery (Vliet *et al.*, 2010; Porter *et al.*, 2012; Schuster *et al.*, 2013;

Karpecki and Cunningham, 2015). Some optometrists have chosen to do a refraction only after twelve weeks as they feel the eye should be completely stabilised for refraction after this time period (Zyl *et al.*, 2014; Thanigasalam *et al.*, 2015).

Ahmad and Iqbal (2016), Carricondo et al. (2015), Bani et al. (2012) and Garcia-Gutierrez et al. (2014) have shown that there is constant improvement in surgical technique and medical technology, making it safe to do a refraction earlier compared to the traditional guideline of six weeks post-operatively.

2.6.8.3 Subjective and objective refraction

The main goal of performing an optical refraction after cataract surgery is to determine the correct spectacle prescription for the patient. This refraction can be done in a number of ways and often include objective as well as subjective tests. Although the traditional subjective method of testing is still the gold standard, objective manners in which to obtain spectacle prescriptions are being investigated and compared regularly to achieve the best results (Linden *et al.*, 2014; Bennett *et al.*, 2015; Carracedo *et al.*, 2018)

Subjective refraction refers to the method in which the patient actively takes part in the refractive process. The optometrist selects the final spectacle prescription based on the feedback and choices made by the patient during the refractive examination. This creates room for error, especially if the patient is unable to understand the tests. Patients with certain refractive states, for example, early-onset myopes, might take longer to respond during subjective refraction as they are more sensitive to the perception of blur (Cufflin *et al.*, 2007; Grosvenor, 2007).

During the objective refractive method, the optometrist relies on the optical principles of refraction without any input from the patient. In children, this is often achieved with a cycloplegic refraction (Grosvenor, 2007; Guha *et al.*, 2017; Altaf *et al.*, 2018). The cycloplegic refraction method includes using an eye drop to paralyse the ability of the lens to accommodate, dilates the pupil and is then followed by retinoscopy. There are many different ways to do retinoscopy. Retinoscopy uses the reflection of light from the retinoscope in the pupil to determine the spherical and cylindrical refractive error by

neutralising the light reflex observed during retinoscopy (Patel, 2014; Sobrinho *et al.*, 2017).

In modern practice, autorefractors are used on almost every patient. Some researchers found autorefraction to be a good starting point for a refraction but insist that a subjective refraction will always be needed after the autorefraction, when possible, for prescribing spectacles (Bennett *et al.*, 2015; Asiedu *et al.*, 2016). Cleary et al. (2009) and Juan et al. (2012) found that autorefraction is a good indication of the spectacle prescription in phakic as well as pseudophakic patients. Ultimately the accuracy of the spectacle prescription will depend on the quality of the autorefractor that is being used.

2.7 Conclusion

Assessing the information presented in the previous paragraphs on the literature reviewed, it is clear that there is no definite guideline available as to when spectacles may be prescribed after uneventful phacoemulsification cataract surgery. As mentioned earlier, most patients will still require spectacle correction after cataract surgery, even if it is only for reading. The obvious question remains, when is the ideal time to prescribe spectacles after cataract surgery? The researcher believes that the answer to this question will certainly have a very practical influence in the field of optometry.

Chapter 3.

METHODOLOGY

3.1 Introduction

This chapter will discuss the main aim of this research study and the methods used to collect the information for the final conclusions. The chapter starts with the identification of the problem and continues with the study design. The end describes the data analysis and ethical considerations.

3.2 Problem statement and aim

The role of an optometrist is crucial after cataract surgery. Since the visual status of the patient changes after cataract surgery in terms of the refraction, the patient may need new spectacles for either distance or near vision. It is evident from the current literature available and discussed in Chapter 2, that there is a discrepancy between different studies as to when the optimal time is to perform a refraction after uneventful cataract surgery (Vliet et al., 2010; Porter et al., 2012; Juan et al., 2013; Schuster et al., 2013; Zyl et al., 2014; Karpecki and Cunningham, 2015; Kessel et al., 2015; Thanigasalam et al., 2015; Caglar et al., 2016).

No studies could be found that have been conducted in South Africa during which the stabilisation of VA, corneal thickness, macula thickness and refraction after uneventful cataract surgery has been investigated. With this in mind, this study concludes with a recommendation as to when the recommended time is after uneventful cataract surgery when an optimal spectacle refraction may be obtained. The main aim of this study is to determine when, in the first six weeks after uneventful cataract surgery, the operated eye stabilises for refraction of the new spectacle prescription.

To address the problem stated, the following research questions will be asked:

i. What is the change in best corrected visual acuity (BCVA) within the first six weeks after surgery?
ii. What is the change in central corneal thickness (CCT) within the first six weeks after surgery?
iii. What is the change in central macula thickness (CMT) within the first six weeks after surgery?
iv. What is the change in refractive error within the first six weeks following surgery?
v. Is there any association between the stabilisation of VA, CCT, CMT and refraction?

As mentioned above, current literature has shown that there are discrepancies as to what the ideal waiting time is for an optimal refraction after uneventful cataract surgery. Many complications may influence the time that the eye takes to stabilise. However, for this study, the researcher will only investigate two possible complications, namely central corneal oedema and central macula oedema after uneventful cataract surgery. The researcher chose these two named complications as central corneal oedema is one of the most common anterior post-operative complications and macula oedema is considered one of the most common posterior post-operative complications. Both these complications are clinically relevant and literature has shown that the presence of these complications may cause a difference in vision and refraction (Lobo, 2012; Ahmad *et al.*, 2013; Juan *et al.*, 2013; Guo *et al.*, 2015).

3.3 Main aim

The main aim of this study was to determine when in the first six weeks after uneventful cataract surgery the operated eye stabilises for refraction of the new spectacles needed.

3.4 Research objectives

To achieve the aim, the following objectives were pursued:

- Measurement in the change of BCVA before and consecutively over a period of six weeks thereafter.
- Measurement in the change of CCT before and consecutively over a period of six weeks thereafter.
- Measurement in the change of CMT before and consecutively over a period of six weeks thereafter.
- Measurement in the change of refraction before and consecutively over a period of six weeks thereafter.
- Determining possible associations between the stabilisation of the four measured variables.

3.5 Study design

This current study has an observational analytical cohort study design that is quantitative in nature.

A quantitative research method is organized with the focus on a specific research question (Farghaly, 2018). Bailey (1997) described a quantitative research approach as structured research with predetermined goals and a specific question or problem statement that is addressed. The one distinguishing aspect of quantitative research is that it collects and analyses numerical data. Wellman *et al*. (2005) agree with Bailey (1997) that quantitative research is an objective, scientific method with definite results. A quantitative research approach was used in similar studies (Jagow *et al.*, 2007; Neumaier-Ammerer *et al.*, 2008; Rotsos and Moschos, 2008; Akçay *et al.*, 2012). The researcher is therefore confident that a quantitative approach will provide the most appropriate and conclusive results.

A cohort, analytical study design is done by observing a single group's outcomes over a period of time as is the case in this study. A cohort refers to a group of individuals who

share a common experience. The analytical design compares the experiences of the individuals to calculate the risk factors and outcome relationships (Bailey, 1997; Farghaly, 2018).

Outcomes were measured using instruments designed for obtaining the desired values. The resulting numerical data was thereafter objectively analysed (Creswell, 2014). The variables measured in this study are CMT, CCT, BCVA and refraction. The incidence of change of each variable was measured at specific points in time to determine when stabilisation of these complications resulted, after which a safe refraction for spectacles is possible.

3.6 Sample selection

3.6.1 Target population

The population of a study represents the full set of units or individuals that the sample is taken from to measure the variables being investigated (Wellman *et al.*, 2005). In this study, the units or participants refer to the cataract patients and the variables are BCVA, CMT, CCT and refractive error.

For the purpose of this study, the target population consisted of participants that had uneventful (no complications occurred during cataract surgery) phacoemulsification cataract surgery with a monofocal IOL implanted, done by the same surgeon (with topical anaesthesia or an anaesthetic block) and that is followed up at a specific practice.

This specific practice where the study was done, is the ophthalmologist's practice where the researcher was permanently employed at the time off the study. There was one ophthalmologist and one optometrist (the researcher) working at this practice, five days a week from 8am to 5pm. There are also two ophthalmic assistants and a receptionist. This is a well-established practice based in Erasmuskloof in Pretoria, Gauteng. The practice is located in a day hospital building, making the surgery and the consultations

easily accessible for the patients. Although this ophthalmologist specializes in retinal surgeries, almost 200 cataract surgeries are done at this practice per year (including combined surgeries and all IOL types). The patients at this practice are mostly from the middle class to higher income population.

3.6.2 Sampling method and sample size

Sampling can be done in a randomised or non-randomised manner. Randomised sampling relies on selecting participants from a significant population where each individual or unit has an equal chance of being selected, using one of a variety of sampling methods. The population reachable in this study is a small group and randomised sampling would not be a feasible sampling method (Wellman *et al.*, 2005). Therefore, in this study, a convenience sampling method was implemented.

Convenience sampling is a non-randomised sampling method (Suri, 2011; Palinkas *et al.*, 2015). For this research study, possible participants were identified using specific criteria (inclusion criteria) and selected accordingly. In the clinical setting where this research study took place, participants meeting the selection criteria were consecutively selected to participate.

Sampling bias can often cause a research study to sway in favour of a particular result which the researcher hopes to achieve. It is essential to be objective to reach results that are repeatable and that can be generalised (Hulley *et al.*, 2007; Creswell, 2014). To avoid sampling bias, all consecutive participants that met the selection criteria were voluntarily included in the study and no participant meeting the criteria was excluded until the desired sample size (n = 25) was reached, except in the event that a participant did not give written consent.

From January 2016 to November 2016, 169 cataract operations were performed of which 24 cases would have met the inclusion- and exclusion criteria for this research study (Figure 3.1). The researcher herefore assumed that the population size would have remained more or less the same for 2018, but the sudden increase in popularity of multifocal IOLs as well as toric IOLs was unforeseen. It would have been desirable to

have a larger sample size, but due to the time constraints of this study, the researcher was content with 25 participants.

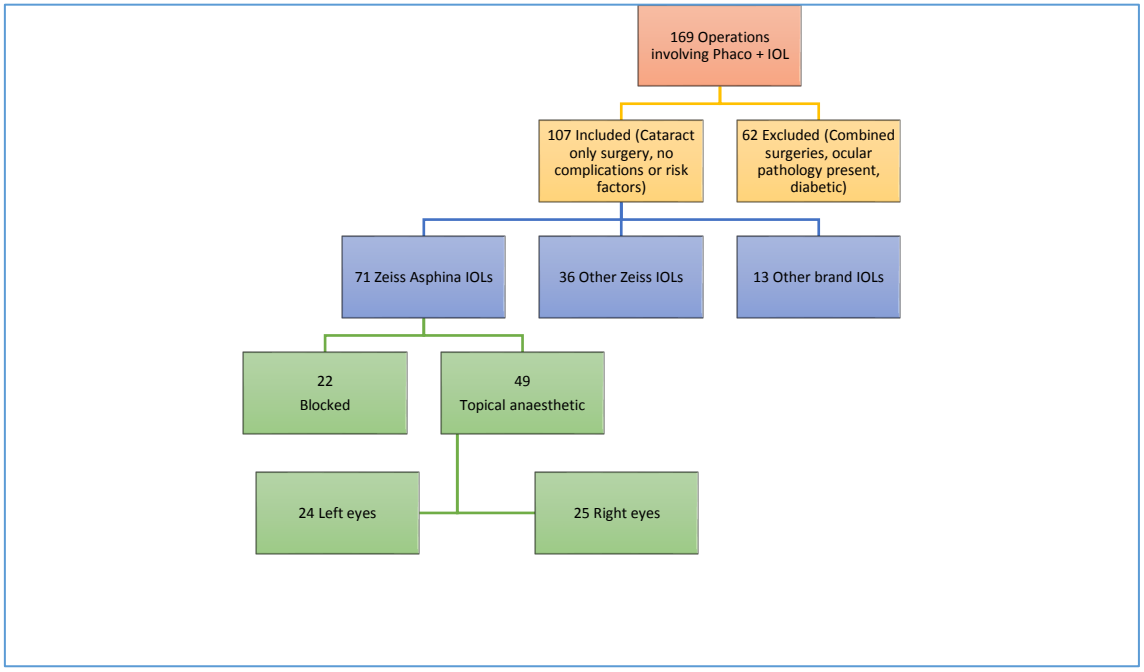

Figure 3. 1: Cataract surgery data of 2016 at the practice where the research study was conducted (compiled by the researcher for the purpose of this study).

The participants were identified and approached by the surgeon to participate in the research study when presenting for an ophthalmology appointment. The names of these participants were then given to the researcher. The researcher discussed the research study with each of the possible participants and provided them with an information sheet (Appendix A). Written consent was also obtained from each possible participant before inclusion in the study (Appendix B). The participants did not receive any remuneration for taking part in this study.

When considering the sample size, it is essential to choose a quantity that will answer the research question and to ensure that the answer is representative of the population being investigated (Pourhoseingholi *et al.*, 2013). These participants were scheduled to have their 'first eye' surgery, i.e. the eye being operated was the first to undergo cataract surgery of the two eyes.

Left eye surgery was done first and the unoperated right eye then served as a control. Data was collected from the right control eye until it had surgery (usually two weeks after the first eye surgery was done) or until six weeks after surgery (if the right eye did not need surgery). Data for both eyes were collected simultaneously over a six week period.

Follow up consultations at the practice where this study took place, were done before surgery and then consecutively at one day, one week, two weeks, four weeks and six weeks after surgery for the left eye. This allowed for data collection to be spread evenly and the participants did not have to attend more visits than participants that were not included in the study. Therefore, the arrangement did not inconvenience the participant in any way.

3.6.3 Description of sample

The sample included any participant that met the inclusion criteria as stipulated below.

3.6.3.1 Inclusion criteria

The following participants were liable for inclusion in this research study:

- The left eye was the first eye that was scheduled for cataract surgery and the control data included data collected from the right eye of the same participant.
- Participants aged between 50 – 75 years were included as study participants.
- The patient had to be diagnosed with an age-related cataract and the diagnosis had to be made by the ophthalmic surgeon.
- Patients were operated by the same experienced surgeon at the same facility and were seen at the same practice for follow-up appointments.
- Patients that had undergone uneventful phacoemulsification cataract surgery, during which no intraoperative complications took place, were included.
- Only participants having surgery done with local anaesthesia were included.
- Participants that had a monofocal IOL implanted were included.

- The same surgical technique was used, with surgical incisions at 0° for left eyes and 180° for right eyes.

3.6.3.2 Exclusion criteria

The following participants were excluded from this research study:

- Patients with diagnosed AMD, uveitis, diabetic macula oedema or any other pre-existing ocular pathology. These conditions are risk factors for complications during surgery (Khan *et al.*, 2015). The existence of a cataract should be the only cause for reduced vision.
- Right eyes were included as the control group if the criteria were met until the right eye had surgery or until the six weeks period had lapsed if no surgery was done on the right eye.
- Traumatic cataracts and congenital cataracts were not included in this study, as surgical methods and prognosis often differ from the 'normal' age-related cataract, due to the possibility of more complications during surgery (Greenberg *et al.*, 2011; Thanigasalam *et al.*, 2015; Thapa *et al.*, 2015).
- Patients that underwent combined procedures, i.e. not only solely cataract surgery, were excluded.
- Patients diagnosed with any corneal pathology or that have received any other corneal surgery or refractive surgery previously. Alio *et al*. (2016) and Greene & Mian (2013) emphasised the importance of identifying pre-existing corneal disease when considering cataract surgery.
- Diagnosed glaucoma patients. It has been proven that glaucoma patients often have unpredictable VA outcomes after cataract surgery (Lee *et al.*, 2017).
- Patients that suffer from any autoimmune disease such as Type 1 Diabetes, Rheumatoid Arthritis, Hepatitis, Lupus, HIV/AIDS etc. These patients often have an increased risk of infection and CMO and also have a longer healing time compared to healthy patients after surgery (Hadda *et al.*, 2014).

- Any other IOL used than a spherical monofocal IOL, for example, a multifocal IOL, excluded the participant from participating in the study.
- Patients that require toric correction. If the astigmatism was more than 1 Dioptre, a toric IOL is used. Different IOLs may have different lens properties that might influence the stabilisation of the eye after cataract surgery. Thus only spherical IOLs were used in this research study to standardise the IOL type for the surgery.
- If any intraoperative complications took place, the cataract surgery for the specific patient was regarded as not being uneventful and the results were not included in this study.

3.6.4 Measurement of ocular parameters required for data analysis

The measuring techniques that were employed for this study were adapted from techniques described by Kanski (2007), Grosvenor (2007) and Elliot (2003) and will be discussed in the following sections.

Participants that met the inclusion criteria were approached by the researcher after seeing the surgeon, to voluntarily take part in the research study when they attended the practice for their consultation before cataract surgery. The research study was explained verbally and an information sheet (Appendix A) was given to the participant as well as a consent form that was signed by the participant and the researcher before the participant was included in the study (Appendix B).

All measurements discussed below were done before surgery. Thereafter, the same measurements were repeated post-operatively on day one, week one, week two, week four and week six after uneventful left eye cataract surgery. These follow-up consultations were done at the same practice.

Measurement and recording of data were done by the researcher herself. All measurements were done in a private room and the same measurements were done in the same room with the same light conditions during every follow-up consultation. Appendix C represents the recording sheet for data capturing.

Four different measurements were done for each participant namely BCVA, CMT, CCT and refraction. These measurements were done to address the objectives of this study.

3.6.4.1 Best Corrected Visual Acuity

Aim of test: Best corrected visual acuity is the most popular used technique to measure visual function. The pinhole visual acuity was measured by the researcher and will be regarded as the BCVA of the participant for this study.

Instruments used: 'SHARP VA' software displaying a Snellen chart from Carl Zeiss, calibrated for a room distance of 3 m at the practice (calibration was done at the installation of the screen in 2013). The operated left eye was measured as well as the right eye where the right eye was used as the control. An occluder was used to cover the eye that was not being tested.

Room setup: Room lights were left on and measured by using the Lux Meter application by My Mobile Tools Developments to ensure a light intensity of 90 – 110 LUX during all examinations. The patient was seated in the participant chair.

Unit of measurement: Visual acuity was recorded in decimal notation (each letter value = 0.02).

Method: The participant was asked to close the right eye to measure the BCVA of the left (operated) eye before and after surgery as described earlier. The test began with the biggest letter on the chart. When the participant correctly identified all the letters in a row, the participant was asked to continue to the next row until the participant failed to identify half of the letters in a row (Elliot, 2014). This was recorded as the VA of the left eye. The same procedure was followed for measurement of the right control eye.

3.6.4.2 Macula thickness

Aim of test: Macula thickness measurement is a common post-operative measurement used to detect any subtle change that may alert the practitioner to a possible complication like cystoid macula oedema.

Instruments used: Macula thickness was measured using the Cirrus OCT from Carl Zeiss, in the OCT room at the practice. Optical coherence tomography is the preferred method for macula thickness measurement (Gharbiya *et al.*, 2013; Giansanti *et al.*, 2013). As discussed in Chapter 2.6.7.2, the OCT is proven to be a reliable method to measure macula thickness with good repeatability (Krader and Pohl, 2011; Lobo, 2012; Yeom *et al.*, 2019). Measurements were done by the researcher.

Room setup: Semi-dark room (measuring 50 LUX) was used to stimulate optimal pupil dilatation for better imaging. 10 seconds was allowed for pupil adjustment. The participant was seated in front of the OCT camera. The researcher was seated opposite the participant to take the measurement.

Unit of measurement: Values were recorded in micrometre (μm).

Method: The participant was asked to put his/her chin in the chinrest and put his/her forehead against the headrest. The correct alignment was ensured and the participant was asked to look at the green fixation cross. The participant kept the eye open and was asked not to blink until the researcher took the OCT scan of the central macula area. An average of three readings was used for this study. After each measurement, the patient was asked to lift his/her head, adjust the head on the chin rest and the instrument was pulled back and refocussed. This ensured 3 independent readings. The same procedure was followed for the right control eye.

3.6.4.3 Corneal thickness

Aim of test: The cornea often shows oedema after cataract surgery due to the mechanical trauma of the operation. This measurement was done to evaluate if any significant corneal oedema occurred.

Instruments used: Central corneal thickness was measured using the Cirrus OCT from Carl Zeiss, at the practice in the OCT room. The Cirrus OCT device has been found to measure CCT with accurate repeatable results in µm (Calvo-Sanz *et al.*, 2018; Metheetrairut *et al.*, 2018). Measurements were done by the researcher.

Room setup: The participant was already seated in front of the OCT camera for central macula thickness measurement and the room setup stayed the same (semi-dark room measuring 50 LUX). The researcher was seated opposite the participant to take the measurement. The central corneal thickness measurement was done after the central macula thickness was measured.

Unit of measurement: Values were recorded in micrometre (µm).

Method: The participant was asked to put his/her chin in the chinrest and put his/her forehead against the headrest as with the previous measurement of central macula thickness. The participant was aligned to the correct height and asked to look at the green fixation cross. The participant kept the eye open and was asked not to blink until the researcher has taken the OCT scan of the central corneal area. An average of three readings was used for this study. Three independent readings were ensured by asking the patient to lift his/her head after each measurement, adjusting the patient's head on the chin rest and also by the researcher pulling back the instrument and refocussing it. The same procedure was followed for the measurement of the right control eye.

3.6.4.4 Refraction

Aim of test: This measurement aimed to objectively establish the refractive error of the eye. The baseline refraction data is regarded as irrelevant as to when stabilisation occurs after cataract surgery, as the refraction after cataract surgery will not return to the pre-operative value and the goal is to determine when stabilisation occurs from one visit to the next

Instruments used: This measurement was done objectively with the Zeiss Visuref 100 operated by the researcher. The Zeiss Visuref has also been used in other studies to

determine the objective refraction of the eye (Waldman *et al.*, 2017; Bennett *et al.*, 2019; Kumar and Woretaw, 2019; Luong *et al.*, 2019; Reed *et al.*, 2020).

Room setup: Room lights were left on and measured by using the Lux Meter application by My Mobile Tools Developments to ensure a light intensity of 90 – 110 LUX during all examinations. The participant was seated in front of the instrument. The researcher was seated opposite the participant to take the measurement

Method: The participant was asked to put his/her chin in the chinrest and put his/her forehead against the headrest. The participant was aligned to the correct height. The participant was instructed to blink several times and then asked to look straight at the top of the balloon imaged on the screen inside the machine while the Visuref automatically took three objective readings. An average is then presented by the instrument as one measurement. Three sets of measurements were taken (9 readings in total). The same procedure was followed for the right control eye.

3.6.5 Methodological and measurement errors

Inconsistent measurements could seriously affect the reliability of test results. To avoid inconsistencies, all measurements were done and recorded by the researcher herself. These measurements included all the measured variables namely VA, refraction, CCT and CMT. To avoid measurement bias, refraction was only done objectively and not subjectively, as described above.

It was important that the surgical technique used was the same for all participants included in the study. Phacoemulsification cataract surgery was done by the same surgeon. The position of the surgeon in theatre relative to the head of the patient caused him to use different angles for the different eyes and laterality also influenced the technique of the surgeon. All patients were therefore operated by the same surgeon. Left eyes were operated first and right eyes served as controls, either for the six week duration of the measurements if not operated or until the right eye was operated.

Corneal incisions for the left eye were made at the lateral aspect of the eye (at 0°). The same surgical materials were used for all participants.

Test conditions were the same for each participant, as described in the previous paragraphs and the same testing room was used to keep distances and illumination constant. Illumination consistency was ensured by measuring the room LUX before each consultation.

To avoid mechanical failure of equipment, all equipment used was serviced and calibrated on schedule as per the supplier requirements. A generator was available in the case of a power failure.

Patients were reminded of all appointments via SMS reminders, appointment cards and were phoned if they were late or did not arrive. Participant data was only included for appointments that were attended. If a follow-up consultation was missed, the data for that appointment was left blank.

3.6.6 Pilot study

A pilot study offers an important 'test run' of what the main research study will be like. Pilot studies assist in evaluating methods, reviewing data collection choices and bringing attention to possible errors and flaws in the study (Arain *et al.*, 2010). The pilot study was done according to the same criteria as discussed for the research study and was done at the same practice.

To ensure all of the above, the pilot study was done on four participants with the same inclusion/exclusion criteria as that specified for the participants of the study (convenience sampling). The pilot study was done from January 2018 to March 2018. No changes were made to the methodology and the data of the pilot study was included in the final research results and analysis.

3.7 Time

The protocol for this research study was developed from April 2017 to August 2017. An evaluation committee meeting was held on 27 September 2017. Ethical approval for this research study was obtained on 27 November 2017. The Pilot study was conducted from January 2018 to March 2018. Data for this research study was collected from April 2018 to December 2018. A meeting was held with the Department of Biostatistics (School of Biomedical Sciences, UFS) on 18 March 2019. The dissertation was written from March 2018 to March 2020.

3.8 Data analysis

Analysis of the data was done by the Department of Biostatistics (School of Biomedical Sciences, UFS). Non-parametric statistical methods were employed for the analysis of all data as the data was found to be not normally distributed. The results were summarised by means of frequencies and percentages (categorical variables) and medians (variables were not normally distributed). Two groups were compared by means of 95% confidence intervals.

3.9 Ethical aspects

The following steps were taken in order to ensure an ethical research study:

- Informed consent was obtained from each participant in the study. The information and consent forms were available in English and Afrikaans (Appendix B and Appendix C).
- All information collected was kept confidential and stored on a personal computer, of which only the researcher had the password. The data collection sheets were locked up in a safe at the researcher's residence for which only the researcher had the password.

- Permission was obtained from the surgeon for the use of the facility where the data collection took place and for approaching his patients to participate (Appendix D).
- Approval was obtained from the Health Sciences Research Ethics Committee (HSREC) at the University of the Free State (Appendix E).
- Participants in the study were not remunerated. However, the results of the study will be made available to the participants after completion of the study upon request.
- No extra costs were involved for the follow-up consultations and tests, as these consultations were part of the standard follow up routine at the practice where the study was conducted.
- The researcher and supervisors have no conflict of interest to declare.

3.10 Conclusion

The quantitative methodological approach discussed in this chapter ensured that the data was collected objectively and efficiently to best reach the objectives for this cohort analytical research study. The results of this data will be discussed in the following chapter.

Chapter 4.

RESULTS

4.1 Introduction

This quantitative, cohort analytical study included participants from 50 to 75 years who underwent uneventful cataract surgery in one or both eyes. The same surgeon performed all surgeries at a specific ophthalmic practice. Convenience sampling was utilised and participants that met the inclusion criteria and gave written consent for this research study were included. Each participant was given a reference number to ensure confidentiality.

A total of 25 participants met the criteria and were included in this research study. Data from the left eye was collected if the left eye was operated first and the right eye was included as the control until the right eye was operated, usually two weeks later if indicated. If the right eye was not operated, it was included as a control for the six week duration of the study. Of these 25 participants, 23 control eyes were included. Two patients were monocular and therefore no right eye data could be included as a control for these two participants. Of the 23 control eyes, 15 had cataract surgery in the right eye two weeks after the left eye was operated, and thus, 23 control eyes reduced to 8 control eyes two weeks after data collection of the left eye started. All participants underwent cataract surgery by the same surgeon and received a monofocal (focus at one distance) IOL implant.

The main aim of this study was to determine the time after uneventful cataract surgery which is optimal for refraction. This was investigated by measuring four variables, namely the best corrected visual acuity (BCVA), central corneal thickness (CCT), central macula thickness (CMT) and the refraction. The objective was to measure these four variables intermittently over six weeks to establish the time that each variable stabilised. The BCVA was measured using the pinhole technique and a Snellen chart. The CCT and

CMT were both measured with an OCT device. The refraction was objectively measured with an autorefractor. All measurements were taken by the researcher with the same instruments, at the same practice and in the same light conditions.

After all the data was collected, the analysis was done by a biostatistician at the Department of Biostatistics (School of Biomedical Sciences, UFS). The data was evaluated for normal distribution. The data was found to be not normally distributed and therefore, non-parametric statistical methods were implemented for the analysis of the data. The results were summarized by means of frequencies and percentages (categorical variables) and medians and percentiles (numerical variables). Groups were compared by means of the Sign rank test to evaluate whether differences were of statistical significance at a 95% confidence interval.

The participants' attendance is presented in Table 4.1. The participants' data was collected at the following time intervals (cf. Section 3.6.4, p.46):

- Pre-operative visit (Pre-op)
- One day after uneventful cataract surgery visit (Day 1)
- One week after uneventful cataract surgery visit (Week 1)
- Two weeks after uneventful cataract surgery visit (Week 2)
- Four weeks after uneventful cataract surgery visit (Week 4)
- Six weeks after uneventful cataract surgery visit (Week 6)

Table 4. 1: The number of participants that attended each visit during the research study are presented in this table.

Visit	Pre-op	Day 1	Week 1	Week 2	Week 4	Week 6
Number of participants that attended	25	25	25	24	23	25
Number of operated eyes	25	25	25	24	23	25
Number of control eyes	23	23	23	8	7	8

From Table 4.1 it can be noted that during the visits of Week 2 and Week 4, not all participants attended the visits due to travel constraints. From Week 2 onwards, the number of control eyes reduced significantly due to most of the right eyes (n = 15) having had surgery at this time and the data of these right eyes was no longer included as control data.

4.2 Demographic data of participants

From January 2018 to December 2018, 25 participants met the research criteria and were included in the research study. The demographic data is represented in Table 4.2 below and includes the age as well as the gender of the included participants.

The majority of participants in this research study were female (68%). The highest number of female participants that underwent cataract surgery was between 70-75 years of age and the highest number of males was between 60-69 years of age, with a median age of 68 years for the sample group. This might indicate that in this research study, female participants tended to wait longer before opting for cataract surgery or that they developed cataracts later in life compared to male participants.

Table 4. 2: The demographic data of each research participant is presented in the table.

Age group	Percentage of participants per age group	Female	Male	Total
50-59	24%	4	2	6
60-69	32%	3	5	8
70-75	44%	10	1	11
Total		**17 (68%)**	**8 (32%)**	n = 25
Median age	**68**			

From January 2018 to December 2018, 240 participants did not meet the research criteria and were not included in the research study. As seen in Figure 4.1 below, the main reason for exclusion (36% of patients) was that a monofocal IOL was not used, but a multifocal or toric IOL was implanted during cataract surgery. Many patients (29%) had surgery of the right eye first and were excluded as left eyes were measured for this study. Some of the patients (17%) did not have only cataract surgery but a combined procedure, for example cataract surgery with a vitrectomy. Other patients were excluded because they had systemic or ocular pathology (10%), some were younger than 50 or older than 75 years (7%) and a few were not willing to participate in the study (1%).

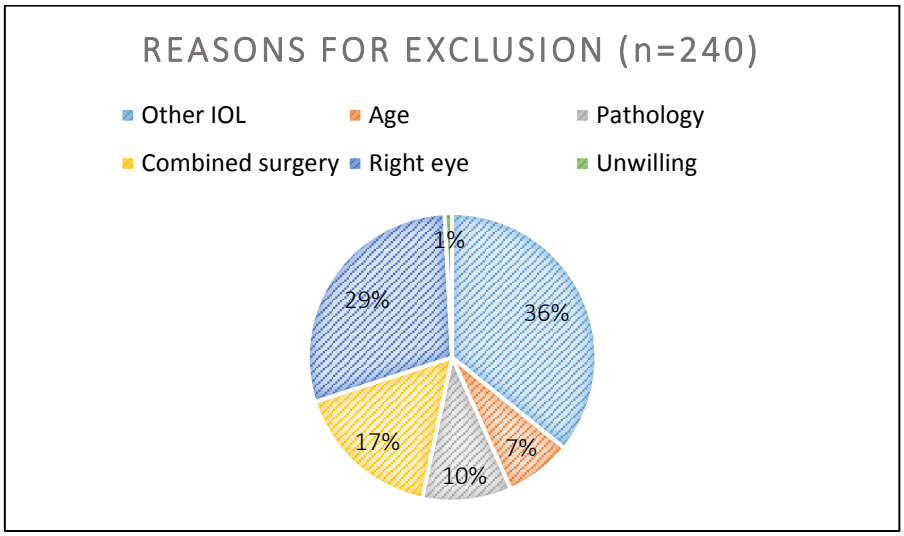

Figure 4. 1: Reasons why patients that underwent cataract surgery were excluded from this study (n=240).

As per the inclusion criteria (cf. Section 3.6.3.1, p.44), local anaesthesia was used for all the cataract surgeries included in this research study. As discussed previously (cf. Section 3.6.1, p.42), participants had a choice between topical anaesthetic or an anaesthetic block as the type of local anaesthesia for the cataract surgery.

Table 4. 3: The anaesthetic choice of the participants (n = 25) having cataract surgery.

Age group	Topical Anaesthetic	Anaesthetic Block
50-59	3	3
60-69	5	3
70-75	10	1
Total	**18 (72%)**	**7 (28%)**

As seen in Table 4.3 above, most of the patients (72%) opted for a topical anaesthetic. The sample size for this research study was relatively small and no differences in the stabilisation of the measured variables was noted between the two anaesthetic choices.

4.3 Best corrected visual acuity results

Best corrected visual acuity (BCVA) was used to assess the visual function of participants in this research study. For this study, the pinhole VA was measured and recorded as the BCVA of the participant. The BCVA results (minimum, maximum and median values) for the operated left eyes can be seen in Figure 4.2 on page 60 and for the control right eyes in Figure 4.3 on page 61.

The results in Figure 4.2 indicate that the BCVA improved for all operated left eyes after uneventful cataract surgery. The median pre-operative BCVA was 0.4 ± 0.17 (interquartile range). On day one after cataract surgery, the BCVA value improved to 0.99 ± 0.07 (interquartile range). The BCVA continued to improve and a median value of 1.0 ± 0.22 was measured at one week and 1.2 ± 0.20 (interquartile range) at two weeks after cataract surgery. Four weeks after cataract surgery the BCVA was 1.17 ± 0.21 (interquartile range) and finally at six weeks after cataract surgery the BCVA was 1.2 ± 0.20 (interquartile range). From this result, it can be seen that a minimal change in values was observed from Week 2 onwards and may indicate that the visual acuity is stable two weeks after uneventful cataract surgery.

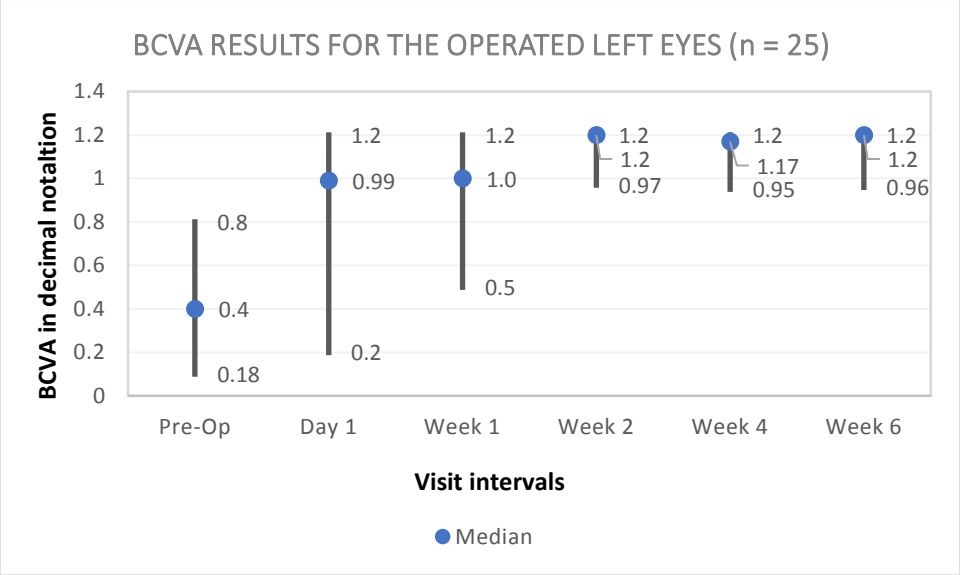

Figure 4. 2: The best corrected visual acuity results in decimal notation for the operated left eyes (n = 25).

The best corrected visual acuity results showed in Figure 4.2 above for the operated left eyes (n = 25) indicate the range (vertical lines), thus minimum to maximum value of the spread of measurements. The blue dots on the vertical lines represent the median of the best corrected visual acuity at each visit. It can be seen that the best corrected visual acuity improved form Day 1 after cataract surgery as compared to the BCVA before surgery.

As expected, the median BCVA for the control right eyes did not show a significant change. The median pre-operative BCVA for the control eyes was 0.9 ± 0.24 (interquartile range). At the final visit six weeks after cataract surgery, the BCVA was very similar and measured a median value of 1.0 ± 0.13 (interquartile range).

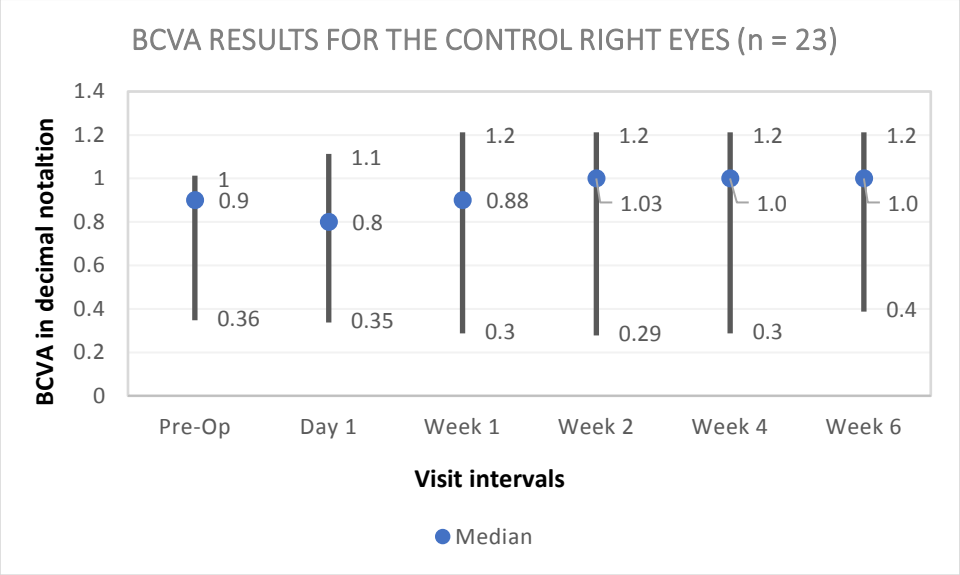

Figure 4. 3: The best corrected visual acuity results in decimal notation for the control right eyes (n = 23).

The best corrected visual acuity results showed in Figure 4.3 above for the control right eyes (n = 23) indicate the range (vertical lines), thus minimum to maximum value of the spread of measurements. The blue dots on the vertical lines represent the median of the control best corrected visual acuity at each visit. It can be seen that the control best corrected visual acuity of the unoperated right eyes, did not show the same improvement as the best corrected visual acuity of the operated left eyes seen in Figure 4.2.

The data from the operated left eyes was further analysed to calculate the difference in BCVA between the scheduled visits. Results were compared during consecutive weeks as the goal was to see at which visit the BCVA values stabilise. For this study, the stabilisation of BCVA is defined as a change in BCVA of 0.1 or less. This constitutes one line or less on the Snellen chart (decimal acuity) which is regarded as significant (Carlson and Kurtz, 2004). Table 4.4 below represents the median difference of BCVA between consecutive visits and the number (and percentage) of operated left eyes that stabilised in terms of visual acuity.

It is clear from Table 4.4 that two weeks after cataract surgery, there were 14 participants with stabilised BCVA. The analysed data therefor indicates that more than half of the participants (56%) had a stable BCVA two weeks after cataract surgery. Four weeks after cataract surgery, seven more participants achieved stabilisation of BCVA with a total of 21 stabilised participants. Finally, at six weeks after cataract surgery, two more participants achieved stabilisation of BCVA. According to the stabilisation criteria for this study, a total of 22 participants (88%) reached stabilisation six weeks after cataract surgery.

Table 4. 4: A representation of the change and stabilisation of the best corrected visual acuity between visits for the operated left eyes (n=25).

	Median	**Stabilised**	**Q25***	**Q75***
Preop / Day 1	-0.55	0 (0%)	-0.75	-0.41
Day 1 / Week 1	-0.02	11 (44%)	-0.21	0
Week 1 / Week 2	0	14 (56%)	-0.15	0
Week 2 / Week 4	0	21 (84%)	0	0.01
Week 4 / Week 6	0	22 (88%)	-0.01	0

**Q25 and Q75 represent the lower quartile and the upper quartile of the median change in measurement respectively.*

Lastly, in order to calculate the statistical significance of the change in BCVA between visits for the operated left eyes as well as the control right eyes, the Sign rank test was used. A *p*-value less than 0.05 (95% confidence interval) was considered a statistically significant difference. As represented in Table 4.5 below, a statistically significant change was found between the pre-operative visit and one day after cataract surgery, which is to be expected as the cataract that caused the vision loss was removed. A statistically significant difference was also noted one day and one week after cataract surgery as well as one week and two weeks after cataract surgery. There was no statistically significant difference between the other remaining visits, indicating that the BCVA for the operated left eyes stabilised two weeks after cataract surgery. In addition,

no statistically significant differences were found between any visits for the control right eye.

Table 4. 5: The statistical significance (*p*-value <0.05) of the best corrected visual acuity between visits.

Visit intervals	Operated left eyes	Control right eyes
Pre-operative and Day 1	<0.0001*	0.7288
Day 1 and Week 1	0.0041*	0.6962
Week 1 and Week 2	0.0098*	0.7500
Week 2 and Week 4	0.2070	1.0000
Week 4 and Week 6	0.6362	0.2500

*statistically significant difference

The collective data presented on BCVA indicates that the BCVA possibly stabilises two weeks after uneventful cataract surgery.

4.4 Central corneal thickness results

Measurement of central corneal thickness (CCT) was done to evaluate if any significant corneal oedema resulted after the cataract surgery. As discussed in Chapter 2.6.6.1 (cf. p.27), the exact increase in corneal thickness that is regarded as significant corneal oedema is not accurately described in the literature at the time of this research study. Any increase within one or multiple layers of the cornea is generally accepted and referred to as corneal oedema. The average central corneal thickness is regarded as 540 µm (Kanski, 2007; American Academy of Ophthalmology, 2013; Bowling, 2016). For this study, the stabilisation of CCT was taken as an average from the values considered significant in other studies and was defined as a difference in CCT of 20 µm or less (Tao *et al.*, 2013; Caglar *et al.*, 2016; Zheng *et al.*, 2016).

Central corneal thickness measurements were done on the operated left eyes, as well as on the control right eyes. The results of CCT thickness measurements are represented in Figure 4.4 for the operated left eyes and Figure 4.5 for the control right eyes.

The median CCT results and the interquartile ranges at the pre-operative visits were within the norm measuring 524.00 ± 40.00 µm (interquartile range). One day after surgery, the median CCT value increased to 574.67 ± 69.34 µm (interquartile range) but then decreased one week after the cataract surgery to 533.33 ± 45.33 µm (interquartile range). A minimal difference is observed from one week onwards. This indicates possible stabilisation of the CCT one week after uneventful cataract surgery.

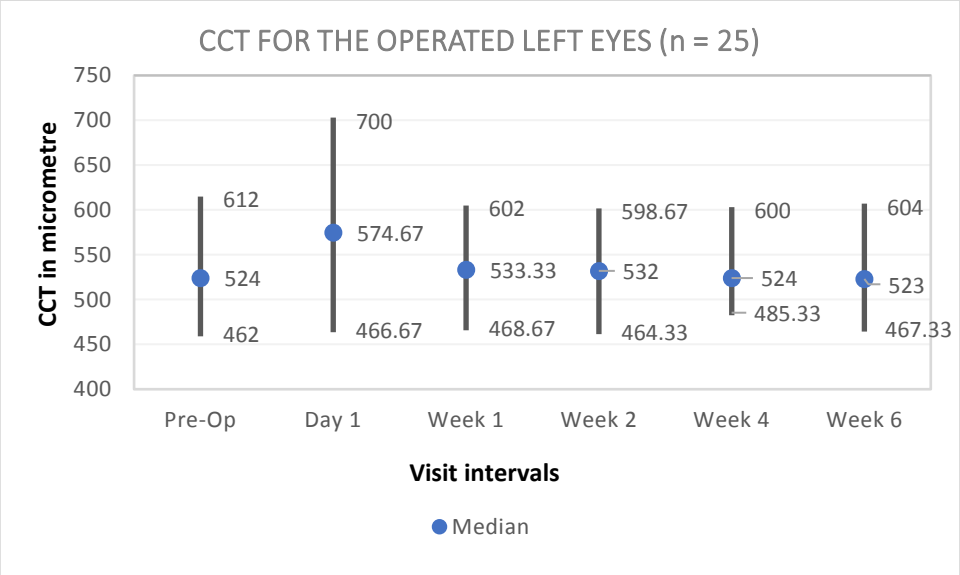

Figure 4. 4: The central corneal thickness results in micrometres for the operated left eyes (n = 25).

The central corneal thickness results in micrometres for the operated left eyes (n = 25) showed in Figure 4.4 above indicate the range (vertical lines), thus minimum to maximum value of the spread of measurements. The blue dots on the vertical lines represent the median of the central corneal thickness at each visit. It can be seen that the central corneal thickness increases one day after cataract surgery and then reduces again.

The CCT for the control right eyes did not show the same pattern of increase in thickness at one day after the cataract surgery that was noted in the data for the operated left eye. No significant pattern of increase or decrease in the CCT measurement is observed in any of the control right eyes. This was expected, as no intervention took place in the control right eyes.

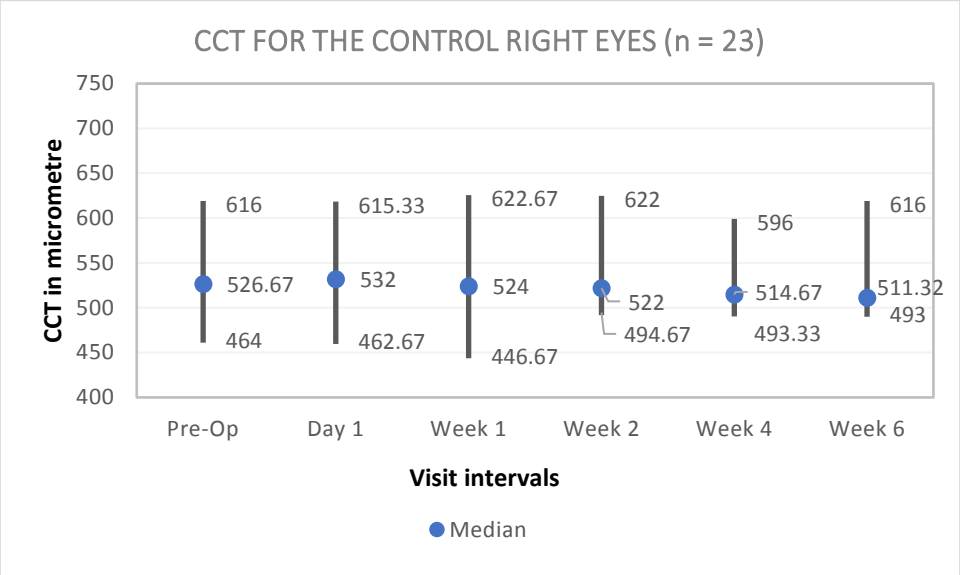

Figure 4. 5: The central corneal thickness results in micrometres for the control right eyes (n = 23).

The central corneal thickness results in micrometres for the control right eyes (n = 23) showe in Figure 4.5 above indicate the range (vertical lines), thus minimum to maximum value of the spread of measurements. The blue dots on the vertical lines represent the median of the control central corneal thickness at each visit. The results showed no noted increase in central corneal thickness one day after cataract surgery as noted in Figure 4.4 above.

The data from the operated left eyes was further analysed to calculate the difference in CCT between the baseline value obtained at the pre-operative visit and the different scheduled visits post-operatively of the operated eyes. Table 4.6 represents the median

difference of CCT between visits as well as the number (and percentage) of eyes that stabilised in terms of CCT by returning to the baseline value.

As presented in Table 4.6 below, one participant already achieved stabilisation of CCT only one day after cataract surgery. One week after surgery, an impressive number of 16 more participants achieved stabilisation of CCT. The data revealed that more than half (68%) of the participants had stable CCT measurements one week after cataract surgery. By Week 2 (72%) and Week 4 (84%), even more participants presented with stable CCT measurements. Almost all participants had stable CCT measurements at Week 6 (96%) after uneventful cataract surgery.

Table 4. 6: A representation of the difference and stabilisation of central corneal thickness between visits for the operated left eyes (n = 25).

	Median	**Stabilisation**	**Q25***	**Q75***
Preop / Day 1	-36.33	1 (4%)	-48.00	-24.00
Preop / Week 1	-2.67	17 (68%)	-8.00	0.67
Preop / Week 2	-3.84	18 (72%)	-7.33	3.67
Preop / Week 4	2.33	21 (84%)	-3.33	9.33
Preop / Week 6	0	24 (96%)	-4.00	5.33

** Q25 and Q75 represent the lower quartile and the upper quartile of the median change in measurement respectively.*

In order to calculate the statistical significance of the difference of CCT between visits for the operated left eyes and the control right eyes, the Sign rank test was used. A *p*-value less than 0.05 was considered statistically significant (confidence interval of 95%). A statistically significant difference was found between the pre-operative visit and one day as well as one week after cataract surgery for the operated left eyes and is represented in Table 4.7. No statistically significant difference was found between the pre-operative visit and two weeks, four weeks or six weeks after cataract surgery.

Interestingly, a statistically significant difference was found in the control right eyes between the pre-operative visit and one day as well as pre-operative visit and six weeks after cataract surgery, as seen in Table. 4.7 below. The reason for the statistically significant difference found in the data of the control eyes between the pre-operative visit and Week 1 is unclear. The cause could be environmental (dryness), drug-related (incorrect eye drop usage) or even idiopathic (Urrego-Díaz *et al.*, 2017).

Table 4. 7: The statistical significance (*p*-value <0.05) of the central corneal thickness between visits for the operated left eyes and the control right eyes.

Visit intervals	Operated left eyes	Control right eyes
Pre-operative and Day 1	<.0001*	0.0102*
Pre-operative and Week 1	0.0074*	0.9375
Pre-operative and Week 2	0.0640	0.4844
Pre-operative and Week 4	0.4583	0.0625
Pre-operative and Week 6	0.9648	0.0156*

*statistically significant difference

From the data presented above in Table 4.7, it may be noted that the CCT may possibly already stabilise one week after uneventful cataract surgery.

4.5 Central macula thickness results

The macula thickness measurement is an important post-operative measurement used to detect any subtle difference in thickness of the macula that may indicate a possible complication like cystoid macula oedema. The centre of the macula measures about 252 µm in thickness and any thickness greater than this may be regarded as macula thickening resulting from oedema (Chan *et al.*, 2006; Ross and Pawlina, 2006; Agarwal, 2012). Central macula thickness (CMT) measurement was done on the operated eye as

well as the control eye. For this study, the stabilisation of CMT is defined as a difference in CMT of 25 µm or less. This stabilisation criteria is an average derived from similar studies by Jagow *et al.* (2007) and Atalay *et al*. (2016). The results of CMT thickness measurement (minimum, maximum and median values) are represented in Figure 4.6 for the operated left eyes and Figure 4.7 for the control right eyes.

As seen in Figure 4.6 below, the median pre-operative CMT was in accordance with the norm, 247.67 ± 24.34 µm (interquartile range) and changed very little for the remainder of the study. The median CMT very gradually increased to 255.33 ± 24.00 µm (interquartile range) by the six week visit, indicating no real difference after surgery in the CMT of the operated left eyes.

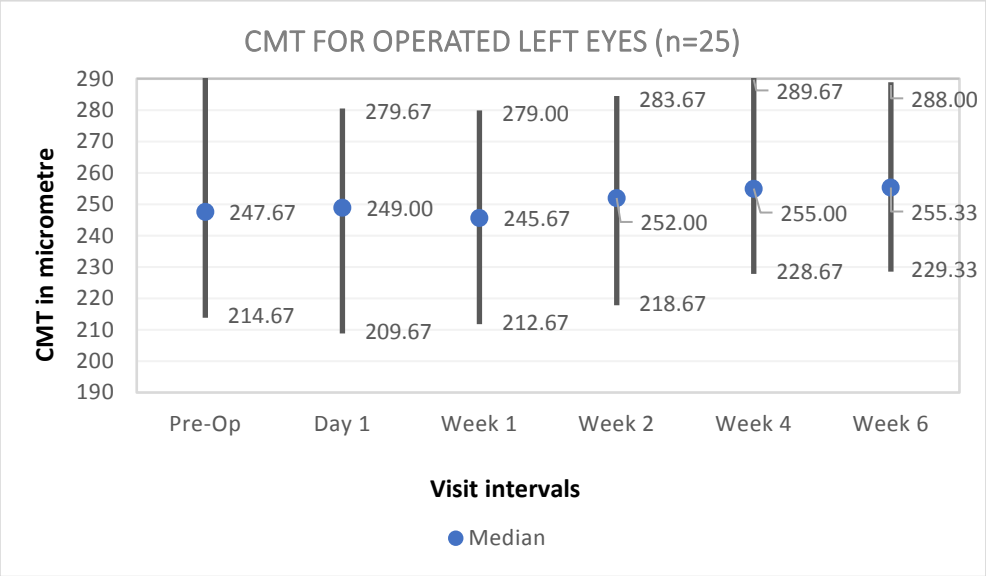

Figure 4. 6: The central macula thickness in micrometres for the operated left eyes (n = 25).

The central macula thickness in micrometres for the operated left eyes (n = 25) showed in Figure 4.5 indicate the range (vertical lines), thus minimum to maximum value of the spread of measurements. The blue dots on the vertical lines represent the median of the central macula thickness at each visit. The results seen in Figure 4.6 do not show a noticeable change in central macula thickness.

As shown in Figure 4.7, the median value before cataract surgery for the control eyes was 251.67 ± 25.67 µm (interquartile range) and six weeks after cataract surgery the CMT was almost identical at a measurement of 253.67 ± 33.33 µm (interquartile range).

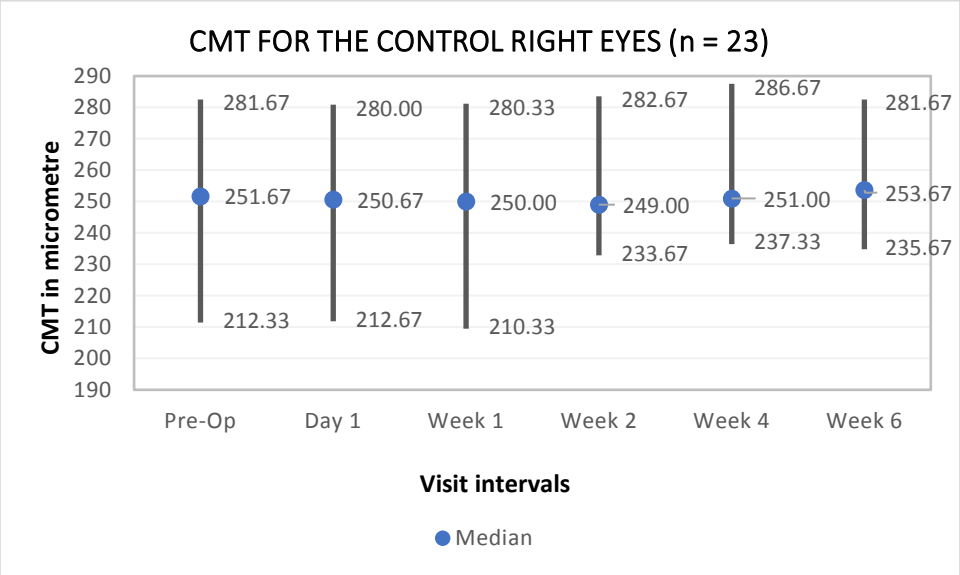

Figure 4. 7: The central macula thickness in micrometres for the control right eyes (n = 23).

The central macula thickness in micrometres for the control right eyes (n = 23) showed in Figure 4.7 above indicate the range (vertical lines), thus minimum to maximum value of the spread of measurements. The blue dots on the vertical lines represent the median of the control central macula thickness at each visit. The results do not show a noticeable difference in central macula thickness.

Table 4.8 below represents the median of the difference of CMT between the pre-operative visit and the scheduled visits post-operatively as well as the number (and percentage) of operated left eyes that stabilised in terms of CMT at each visit. This comparison was made to determine the time after cataract surgery that the CMT value returned to the pre-operative value.

Table 4.8 shows that all, but one participant (96%) achieved stabilisation of CMT by one day after cataract surgery. The remaining participant's CMT returned to baseline value

at two weeks after cataract surgery, indicating that stabilisation of the CMT may occurs at two weeks after uneventful cataract surgery.

Table 4. 8: The difference and stabilisation of central macula thickness between visits (n = 25).

	Median	Stabilisation	Q25*	Q75*
Preop / Day 1	2.66	24 (96%)	-1.00	7.00
Preop / Week 1	2.00	24 (96%)	-1.00	4.67
Preop / Week 2	-1.33	25 (100%)	-3.67	0.17
Preop / Week 4	-6.00	25 (100%)	-11.34	-1.34
Preop / Week 6	-7.00	25 (100%)	-13.33	-2.66

** Q25 and Q75 represent the lower quartile and the upper quartile of the median change in measurement respectively.*

In order to calculate the statistical significance of the difference between the CMT measurements taken at the different visits, the Sign rank test was used. A *p*-value less than 0.05 was considered statistically significant (95% confidence interval). As seen in Table 4.9, no statistically significant difference was found for the operated eye between the pre-operative visit and one week or two weeks after cataract surgery. A statistically significant difference was found between the pre-operative visit and one day, four weeks as well as six weeks after cataract surgery. As expected, no statistically significant difference was found for the control right eyes.

Table 4. 9: The statistical significance (*p*-value <0.05) of the central macula thickness between visits.

Visit intervals	Operated left eyes	Control right eyes
Pre-operative and Day 1	0.0126*	0.4234
Pre-operative and Week 1	0.0444	0.0947
Pre-operative and Week 2	0.0769	0.1719
Pre-operative and Week 4	0.0021*	0.9844
Pre-operative and Week 6	<.0001*	0.3594

*statistically significant difference

The CMT measurements in Table 4.8 showed stabilisation at one day after cataract surgery for most participants. However, in Table 4.9 it may be noted that a statistically significant difference is seen 4 and 6 weeks after uneventful surgery. The reason for this change is unclear and will need further investigation.

4.6 Refraction results

The conventional notation of sphere/cylinder/axis was used for the refraction in this study. The data of the three values were analysed separately to allow for better accuracy.

The pre-operative data is not included in the results. This baseline data is regarded as irrelevant as to when stabilisation occurs after cataract surgery, as the refraction after cataract surgery will not return to the pre-operative value and the goal is to determine when stabilisation occurs from one visit to the next. It is expected that the refraction will change after cataract surgery, mainly due to the surgical incisions made during the procedure and the insertion of an IOL (Bradley *et al*., 2006). The aim of cataract surgery is additionally also to eliminate any pre-operative refractive error that may have been noted in the eye.

4.6.1 Spherical refraction results

The first component of conventional refraction is the spherical value. The spherical refraction was measured objectively on the operated eyes as well as the control eyes. For this study, the stabilisation of spherical refractive results was defined as a difference of 0.25 D or less (Caglar *et al.*, 2016; The Vision Council of America, 2016). The results of the spherical refraction measurement are represented in Figure 4.8 for the operated left eyes and Figure 4.9 for the control right eyes.

The values shown in Figure 4.8 indicated a tendency to plano (zero) in the spherical refraction on the first day after cataract surgery. Less difference has been noted at the

visits after one day post-operatively. One day after cataract surgery, the spherical refraction improved to a median value of +0.25 ± 1.09 D (interquartile range). The improvement continued at one week and two weeks after cataract surgery with median spherical values and interquartile ranges reported of 0.00 ± 0.66 D and 0.00D ± 0.71 D respectively. At four weeks and six weeks after cataract surgery, there was a very slight hyperopic shift in median value with a spherical refraction of 0.08 ± 0.66 D (interquartile range) and 0.17 ± 0.58 D (interquartile range) respectively. This indicates that the cataract surgery was successful in improving the spherical refraction to roughly plano for all participants.

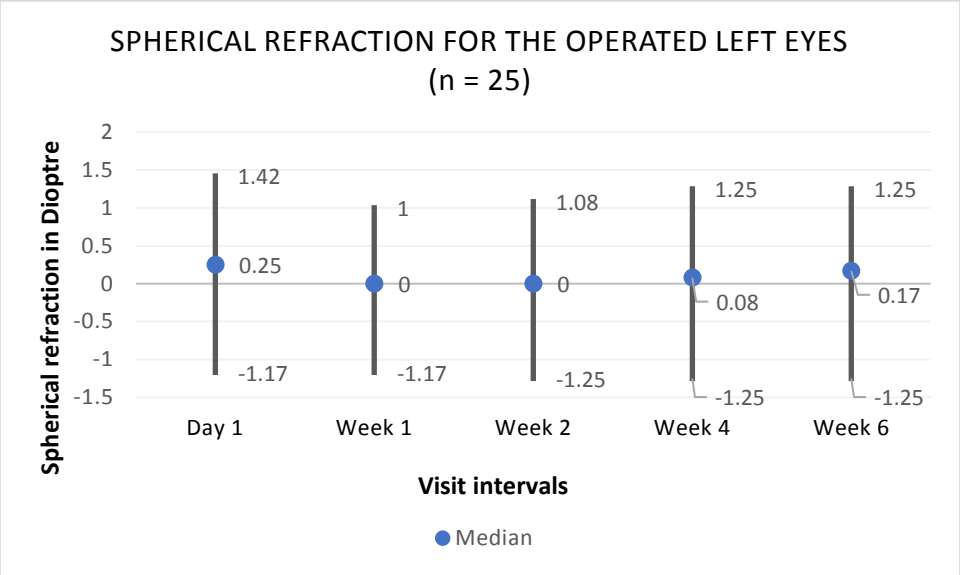

Figure 4. 8 The spherical refraction results in Dioptre for the operated left eyes (n = 25).

The spherical refraction results in Dioptre for the operated left eyes (n = 25) showed in Figure 4.8 above indicate the range (vertical lines), thus minimum to maximum value of the spread of measurements. The blue dots on the vertical lines represent the median of the spherical refraction at each visit.

As expected, the spherical refraction of the control eyes represented in Figure 4.9, did not show the same pattern as the operated eyes represented in Figure 4.8. The change

in measurements observed from Week 1 to Week 2, is the result of 15 right eyes that had cataract surgery two weeks after the left eye and where thus excluded from the sample as of this visit, including future visits. The refractive values, therefore, appear to improve at Week 2, as the remaining right control eyes have relatively good vision with no indication of cataract surgery and were not operated.

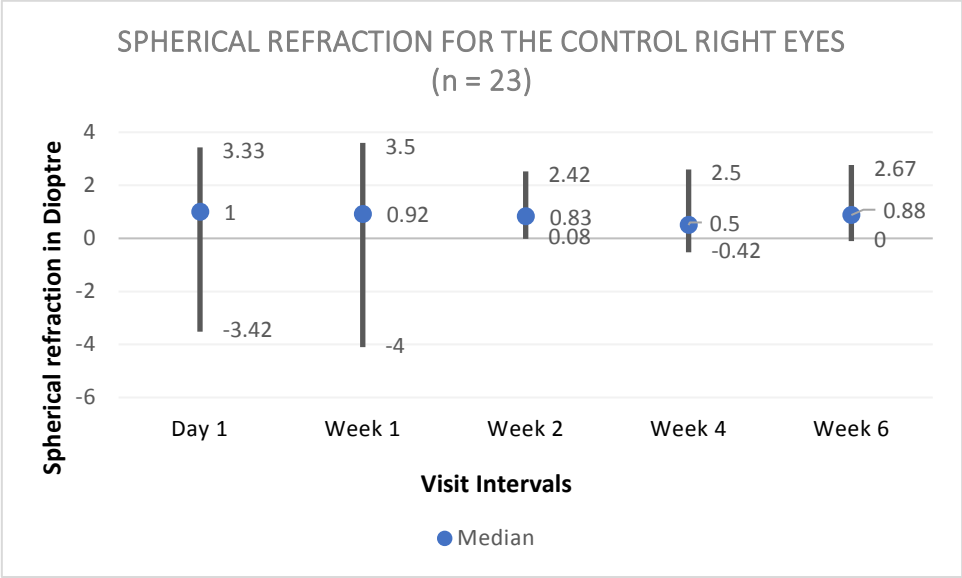

Figure 4. 9 The spherical refraction results in Dioptre for the control right eyes (n = 23).

The spherical refraction results in Dioptre for the control right eyes (n = 23) showed in Figure 4.9 above indicate the range (vertical lines), thus minimum to maximum value of the spread of measurements. The blue dots on the vertical lines represent the median of the control spherical refraction at each visit.

Table 4.10 below represents the median of the difference of spherical refraction between visits as well as the number (and percentage) of operated left eyes that stabilised in terms of spherical refraction over time. Consecutive visits were compared to establish when the spherical refraction is stable.

Seven participants (28%) achieved stabilisation of spherical refraction one week after cataract surgery as seen in Table 4.10 below. At the second week post-operatively, seven

more participants achieved stabilisation of spherical refractive value, bringing the total to 14 (56%) stabilised participants at the time. This indicates that more than half of participants achieved stabilisation of the spherical refraction at two weeks after cataract surgery.

Table 4. 10: The difference and stabilisation of spherical refraction of the operated left eyes between visits (n = 25).

	Median	**Stabilisation**	**Q25***	**Q75***
Day 1 / Week 1	+0.25	7 (28%)	+0.00	+0.59
Week 1 / Week 2	-0.04	14 (56%)	-0.25	-0.09
Week 2 / Week 4	+0.00	18 (72%)	-0.25	+0.25
Week 4 / Week 6	+0.00	22 (88%)	-0.17	+0.00

** Q25 and Q75 represent the lower quartile and the upper quartile of the median change in measurement respectively*

In order to calculate the statistical significance of the difference of spherical refraction between visits, the Sign rank test was used. A *p*-value of less than 0.05 was considered statistically significant (95% confidence interval). As seen in Table 4.11, a statistically significant difference in spherical refraction of the operated left eyes was found between one day and one week after cataract surgery. No statistically significant difference was found between the consecutive visits after one week for the operated eyes, indicating stabilisation at one week after cataract surgery. The control right eyes had no statistically significant difference between any visits.

Table 4. 11: The statistical significance (*p*-value <0.05) of the spherical refraction between visits.

Visit intervals	Operated left eyes	Control right eyes
Day 1 and Week 1	0.0057*	0.8930
Week 1 and Week 2	0.3976	1.0000
Week 2 and Week 4	0.8899	0.4375
Week 4 and Week 6	0.2949	0.3125

*statistically significant difference

The analysis of the data on spherical refraction indicates that an accurate refraction of the spherical component of the refraction can be achieved from one week after uneventful cataract surgery.

4.6.2 Cylinder refraction results

The cylinder value is the second component of the conventional notation of refraction. The cylinder refraction was measured objectively on the operated left eyes as well as the control right eyes. For this study, the stabilisation of cylinder refractive results was defined as a difference of 0.25 D or less, the same criteria used for the spherical stabilisation (Caglar *et al.*, 2016; The Vision Council of America, 2016). The results of the cylinder refraction measurements are represented in Figure 4.10 for the operated left eyes and in Figure 4.11 for the control right eyes.

One day after cataract surgery, the cylinder refraction increased with a median value of -1.00 ± 0.59 D (interquartile range). One week after cataract surgery the cylinder value shifted back to -0.67 ± 0.33 D (interquartile range) and two weeks after surgery the cylinder value was very similar at -0.63 ±0.37 D (interquartile range). At four weeks and six weeks after cataract surgery, there was a very slight decrease in the cylinder refraction of -0.58 ± 0.33 D (interquartile range) and -0.58 ± 0.67 D (interquartile range)

respectively. The cylinder value thus changed minimally during the six weeks of this study.

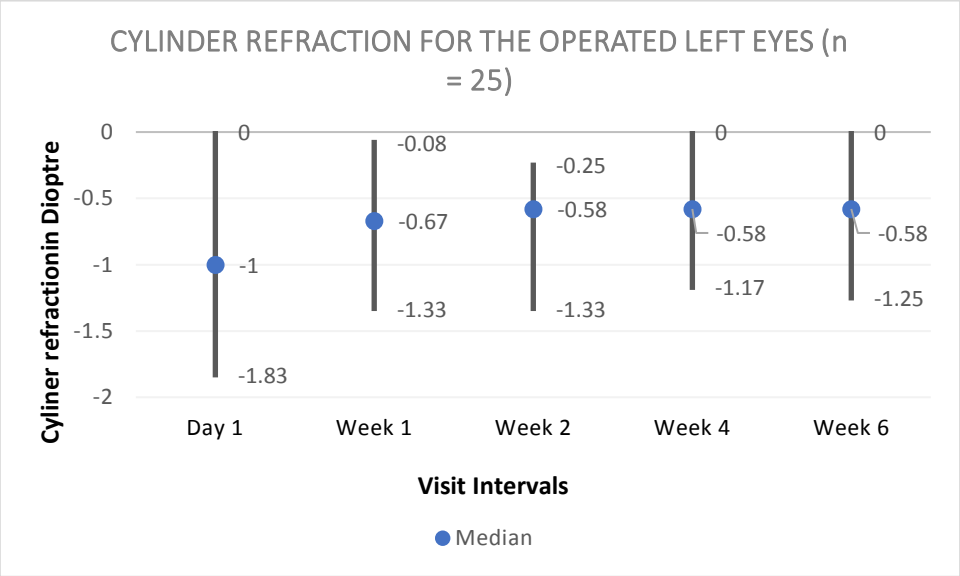

Figure 4. 10: The cylinder refraction results in Dioptre for the operated left eyes (n = 25).

The cylinder refraction results in Dioptre for the operated left eyes (n = 25) showed in Figure 4.10 above indicate the range (vertical lines), thus minimum to maximum value of the spread of measurements. The blue dots on the vertical lines represent the median of the cylinder refraction at each visit. The cylinder value showed a small change from Week 1 after surgery and onwards.

The median cylinder refraction results for the control right eyes seen in Figure 4.11, showed minimal fluctuation and remained constant for the duration of the research study as expected.

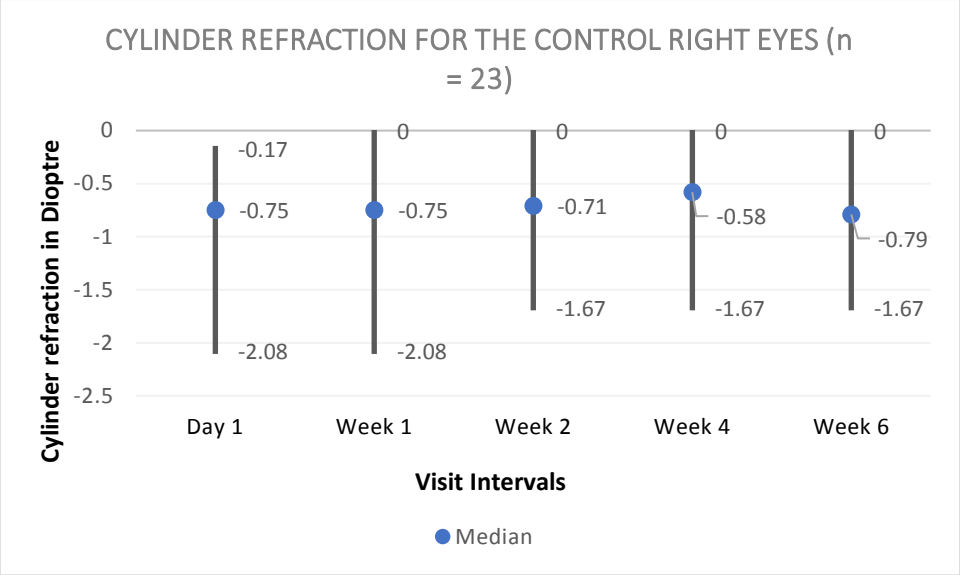

Figure 4. 11: The cylinder refraction results in Dioptre for the control right eyes (n = 23).

The cylinder refraction results in Dioptre for the control right eyes (n = 23) showed in Figure 4.11 above indicate the range (vertical lines), thus minimum to maximum value of the spread of measurements. The blue dots on the vertical lines represent the median of the control cylinder refraction at each visit. Very little change in cylinder value for the control right eye was observed.

The data was further analysed to calculate the difference in cylinder refractive values between the consecutive scheduled weeks for the operated left eyes. Table 4.12 represents the median of the difference of cylinder refraction between visits as well as the number (and percentage) of eyes that stabilised in terms of cylinder refraction.

The cylinder refraction stabilised relatively quickly after surgery. Almost half (44%) of the cylinder refraction of participants stabilised one week after cataract surgery. From week two onwards, most participants had a stabilised cylinder refraction with a median value of +0.00 D, indicating no difference in value.

Table 4. 12: The difference and stabilisation of cylinder refraction between visits for the operated left eyes (n = 25).

	Median	Stabilised	Q25*	Q75*
Day 1 / Week 1	-0.17	11 (44%)	-0.42	0.08
Week 1 / Week 2	+0.00	15 (60%)	-0.17	+0.17
Week 2 / Week 4	+0.00	20 (80%)	-0.17	+0.17
Week 4 / Week 6	+0.00	23 (92%)	-0.17	+0.09

** Q25 and Q75 represent the lower quartile and the upper quartile of the median change in measurement respectively.*

In order to calculate the statistical significance of the difference of cylinder refraction between visits, the Sign rank test was used. A *p*-value less than 0.05 was considered significant (a confidence interval of 95%). It can be seen in Table 4.13 below that the only statistically significant difference was found for the operated eyes between one day and one week after cataract surgery. No statistically significant difference was found between any of the other visits, implying stabilisation one week after surgery. No statistically significant difference was found between visits for the control eye.

Table 4. 13: The statistical significance (*p*-value <0.05) of the cylinder refraction between visits (n = 25).

Visit intervals	Operated eyes	Control eyes
Day 1 and Week 1	0.0065*	0.2074
Week 1 and Week 2	0.9780	0.2500
Week 2 and Week 4	0.7653	0.2500
Week 4 and Week 6	0.7743	0.2500

*statistically significant difference

As with the spherical refraction results, the cylinder component of the refraction was stabilised from one week after uneventful cataract surgery.

4.6.3 Axis results

The final value in the conventional notation of refraction is the axis value of the cylinder. The axis of the cylinder was measured objectively on the operated eyes as well as the control eyes. The results of the axis measurements are represented in Figure 4.12 for the operated left eyes and in Figure 4.13 for the control right eyes.

The median axis values for the operated eyes can be seen in Figure 4.12. One day after cataract surgery, the median axis value was 64.67° ± 60.33° (interquartile range) and six weeks after cataract surgery the median axis was very similar at 64.67° ± 74.33° (interquartile range).

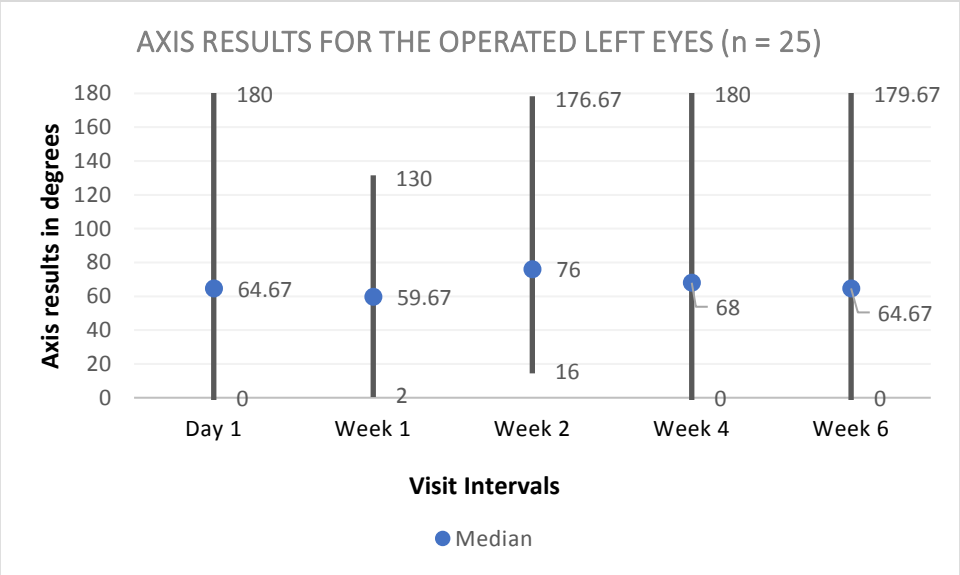

Figure 4. 12: The axis results in degrees for the operated left eyes (n = 25).

The axis results in degrees for the operated left eyes (n = 25) showed in Figure 4.12 above indicate the range (vertical lines), thus minimum to maximum value of the spread of measurements. The blue dots on the vertical lines represent the median of the axis at each visit. The median axis value showed some variation throughout the study.

The axis values for the control eyes changed very slightly during the study, however the difference is mainly insignificant. The median axis value one day after cataract surgery

was 59.67° ± 37.67° (interquartile range) and six weeks after cataract surgery the median axis was 73.67° ± 42.66° (interquartile range).

It must be noted that there are some factors that may influence the axis of the refraction, such as the corneal cylinder or astigmatism of the patient, which would be different in every patient. The data is presented here for the sake of completeness, but it must be emphasized that the sphere and cylinder analysis of the refraction carries a lot more weight when stabilisation is considered.

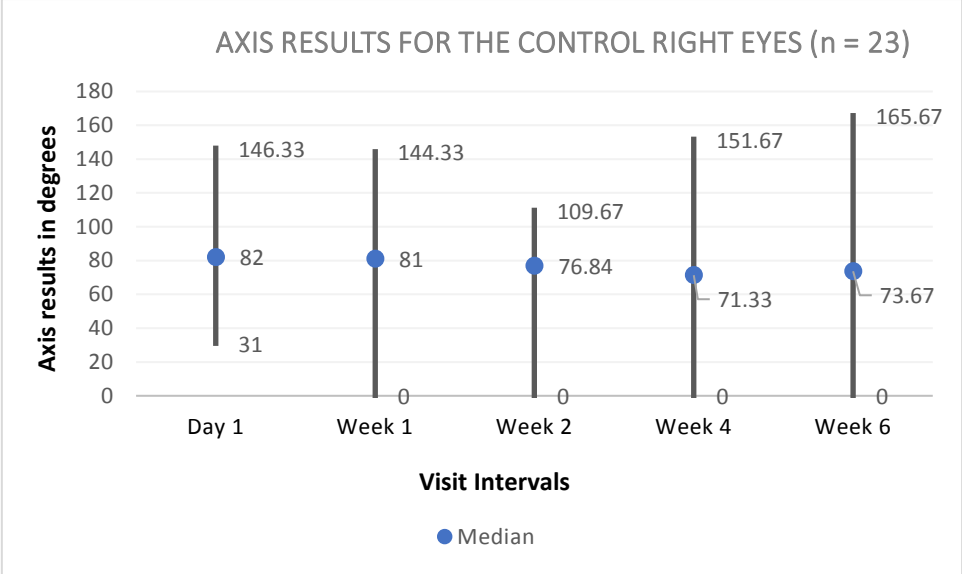

Figure 4. 13: The axis results in degrees for the control right eyes (n = 23).

The axis results in degrees for the control right eyes (n = 23) showed in Figure 4.13 above, indicate the range (vertical lines), thus minimum to maximum value of the spread of measurements. The blue dots on the vertical lines represent the median of the control axis at each visit. Very slight differences in axis value for the control right eye was observed.

The data was further analysed to calculate the difference in the axis between the scheduled weeks. For this research study stabilisation of the axis is defined as 10° or less (Brown, 2006). Table 4.14 represents the median of the difference in the axis between

consecutive visits as well as the number (and percentage) of eyes that stabilised in terms of the axis.

One week after cataract surgery, five participants achieved a stable axis value. A week later at two weeks after cataract surgery, a total number of 10 participants had a stable axis value. Four weeks after cataract surgery two more participants achieved stable axis values, bringing the total to 11. Lastly, at the visit six weeks after cataract surgery, four more participants achieved stable axis values, a total of 15 stable participants. Only 60% of participants achieved a stable axis value according to the criteria used for this study. The axis stabilisation might be irrelevant as the participants included in this study all had low cylinder values and is not very sensitive to change in cylinder axis (the median cylinder value at 6 weeks was -0.58) and the corneal cylinder value also differs for each participant.

Table 4. 14: The difference and stabilisation of the axis between visits (n = 25).

	Median	**Stabilise**	**Q25***	**Q75***
Day 1 / Week 1	0.33	7 (28%)	-14.00	18.00
Week 1 / Week 2	-6.34	10 (40%)	-20.67	1.34
Week 2 / Week 4	1.33	11 (44%)	-4.67	15.33
Week 4 / Week 6	-2.33	15 (60%)	-16.66	3.67

** Q25 and Q75 represent the lower quartile and the upper quartile of the median change in measurement respectively.*

In order to calculate the statistical significance of the difference of axis between visits, the Sign rank test was used. A *p*-value less than 0.05 was considered significant (95% confidence interval). As seen in Table 4.15 below, a statistically significant difference was found between one week and two weeks after cataract surgery. Again, due to the small cylinder value, this can be regarded as irrelevant. No statistically significant difference was found between the other visits for the operated eyes, indicating possible stabilisation at two weeks.

Table 4. 15: The statistical significance (p-value <0.05) of the axis between visits (n = 25).

Visit intervals	Operated eyes	Control eyes
Day 1 and Week 1	0.8244	0.5744
Week 1 and Week 2	0.0019*	0.6875
Week 2 and Week 4	0.3263	0.4375
Week 4 and Week 6	0.2500	1.0000

*statistically significant difference

The cylinder values for the participants in this research study was relatively low as per the inclusion criteria and the stabilisation of the axis value is not as important as the spherical stabilisation result. No statistically significant changed was noted form Week 2 after uneventful cataract surgery and therefor the axis value can be said to stabilise from two weeks after cataract surgery.

4.7 Possible associations between the stabilisation of the four measured variables.

The analysed data were also compared to establish if there are possible associations between the stabilisation of best corrected visual acuity (BCVA), central corneal thickness (CCT), central macula thickness (CMT) and refraction.

Stabilisation of the central corneal thickness (CCT) occurred one week before the stabilisation of the refraction. The stabilisation of the central macula thickness (CMT) did not show the same pattern of change throughout the study period of six weeks as any of the other variables that were measured in this study.

Best corrected visual acuity (BCVA) might be an indication as to when the optimal time for spectacle refraction after surgery is, as the results in this research study showed stabilisation of both the BCVA and the refraction two weeks after the cataract surgery.

The individual participant data did not show any increased or decreased stabilisation time of the four variables for participants of different ages or gender. The stabilisation of the variables was also not clearly linked to the choice of topical anaesthetic or anaesthetic block.

Except for the association between BCVA and refraction, no other associations could be concluded from the analysed data for this research study.

4.8 Conclusion

The analysis of the data collected for this research study was sufficient to make conclusions for the four variables. These conclusions will be further discussed in the following chapter.

Chapter 5.

DISCUSSION

5.1 Introduction

This chapter discusses the results reviewed in Chapter 4. The focus of this discussion is to establish how these results contribute to the aim of the research, which was to determine when the optimal time for refraction after uneventful cataract surgery is. This chapter also reviews previous literature that either supports or opposes the findings of this study.

During this study, best corrected visual acuity (BCVA), central corneal thickness (CCT), central macula thickness (CMT) and the refraction were evaluated as variables. Twenty-five participants complied with the inclusion and exclusion criteria and were voluntarily included in the study. The visits were scheduled for before the cataract surgery (pre-operative) and one day (Day 1), one week (Week 1), two weeks (Week 2), four weeks (Week 4) and six weeks (Week 6) after cataract surgery. Visits were well attended, although not all participants attended the visits scheduled for Week 2 (n=24) and Week 4 (n=23). This was due to travel constraints. Additionally, at the visit scheduled for Week 2, 15 of the 23 control eyes had cataract surgery performed on the right control eye and these were no longer included in the study as control eyes (cf. Table 4.1, p.55).

Although the sample size was restricted, adequate data on the stabilisation of BCVA, CCT, CMT and refraction was collected and analysed for interpretation of the measured variables. The main reasons that patients were excluded from the sample, included the choice of IOL (36%) and that some patients had surgery of the right eye first (29%) and not the left eye as per the inclusion criteria for this study (cf. Figure 4.1, p.58).

5.2 Data collection

All data collected for this study was measured by the researcher at the same practice in the same room setup. Data was kept confidential by the allocation of a reference number for each participant. The data collected consisted of the measurements of BCVA, CCT, CMT and refraction.

Analysis of the data was done by the Department of Biostatistics, School of Biomedical Sciences, UFS. The data was found to be not normally distributed, and therefore, non-parametric statistical methods were used for the analysis of the data. The results were summarised by means of frequencies and percentages (categorical variables) and medians. Two groups were compared by means of 95% confidence intervals using the Sign rank test.

5.3 Demographic data of participants

Inclusion and exclusion criteria were used to identify participants for the study. These criteria are thoroughly discussed in Chapter 3 (cf. 3.6.3, p.44).

Male and female participants between the ages of 50-75 years were included in the study and the median age of the participants was 68 years (cf. Table 4.2, p.56). The reasoning behind the age criteria was due to ageing being the most common cause of cataracts (cf. 2.4.2.1.1, p.8).

In this study, most participants (44%) were in the higher age group (70-75 years), indicating that ageing does have an influence on cataract formation, as expected (Steinert, 2010; Atif *et al.*, 2018; Singh *et al.*, 2019; Taseer *et al.*, 2019). Since the median pre-operative BCVA for this study was 0.4, it could be seen that participants waited until the visual limitations due to the cataracts were more pronounced. This could also explain the higher age of the participants. This idea was also previously researched by Thompson and Lakhani (2015) and Alshamrani (2018) who both agreed that patients

postpone cataract surgery to when the symptoms severely influence their quality of vision.

According to literature, topical anaesthesia is the most cost-effective and least invasive method of anaesthesia for cataract surgery (cf. 2.6.4, p.22). Most of the participants in this study (n=18) chose to have surgery with topical anaesthesia rather than an anaesthetic block (cf. Table 4.3, p.58). The reason for the participants' anaesthetic choice was not investigated as part of this study, but it was interesting to note that in the younger age group (50-59 years), the distribution between topical anaesthesia and anaesthetic block was equal (n=3, n=3), but in the older age group (70-75 years), only one participant chose an anaesthetic block and the vast majority (n=10) chose topical anaesthesia. A possible reason for topical anaesthesia being chosen may be because of the relatively lower risk of complications associated with topical anaesthesia and the fact that the patient can use the eye almost immediately after cataract surgery. This will make mobility for elderly patients more comfortable compared to the akinesia experienced with an anaesthetic block (Thompson and Lakhani, 2015). The relationship between the four variables and the choice of local anaesthetic was investigated. The data analysed for this study revealed no difference in stabilisation between patients who had topical anaesthesia and patients who had an anaesthetic block (cf. Table 4.3, p. 58). Therefore, no definite conclusion could be made, possibly due to the small sample size of the study.

The number of female participants (n=17) in this study was double the number of male participants (n=8). It has been noted in the literature that there are more female than male cataract patients seen and treated in South Africa (Lewallen and Courtright, 2002). In this study, most of the female participants (n=10) were in a higher age group (70-75 years) and most of the male participants (n=5) were in a middle-age group (60-69 years). This could simply be because females live on average six years longer than males (Statistics South Africa, 2019). It could also indicate that females tended to wait longer than males to have cataract surgery done.

In the following sections, the results of the four variables are discussed, starting with BCVA, followed by CCT, CMT and lastly, the refraction.

5.4 Best corrected visual acuity

The first variable investigated with the participants, was the best corrected visual acuity (BCVA). The visual function of the participants was subjectively evaluated by measuring the BCVA with the pinhole technique and a Snellen chart (cf. 3.6.4.1, p. 47). The BCVA improved, as hoped, at Day 1 after cataract surgery.

The analysed data (cf. Table 4.5, p. 62) indicates that in most participants, the BCVA was stable two weeks after cataract surgery. This corresponds with Tinley *et al.* (2003) that found that visual acuity measured two weeks after cataract surgery was not significantly different from the visual acuity measured at later post-operative consultations. In contrast, this is half the time described by Ao *et al.* (2014) who felt it was only possible to accurately measure visual acuity at four weeks after cataract surgery. This is possibly because the participants in their study were older than the participants in this current study.

Statistically significant differences (on a 95% confidence level with $p < 0.05$) in BCVA was seen between pre-operative visit and Day 1 (p=<0.0001), Day 1 and Week 1 (p=0.0041) as well as Week 1 and Week 2 (p=0.0098). No statistically significant differences were measured from Week 2 after surgery onwards (cf. Table 4.5, p.62). At Week 2 as well as Week 6, the BCVA measured 1.2 ± 0.2 (interquartile range), with minimal differences in values in between these two visits (cf. Figure 4.2, p.60). In this study, the BCVA improved after cataract surgery. This improvement in vision is the expected outcome of cataract surgery and therefore has a positive influence on the overall well-being of the participant (cf. 2.6.8.1, p.35).

When considering Table 4.1 (p.55) representing the control right eyes, the control right eyes showed a slight improvement in visual acuity. This improvement is probably due to the change in this particular sample size at Week 2 (n=8) compared to the previous visits (n=23) (cf. Table 4.1, p.55). It is noted from Week 2 onwards, that the control eyes had relatively good vision, as expected for those control eyes which did not have to undergo cataract surgery. This most likely caused the improved median values seen from Week 2 and thereafter (cf. Figure 4.3, p.61).

The presented data then confirms that the BCVA improved after uneventful cataract surgery and it may also be concluded that patients who underwent uneventful cataract surgery can expect to have good and stable vision two weeks after cataract surgery.

5.5 Central Corneal thickness

The first anatomical parameter evaluated, was the central corneal thickness (CCT). The CCT was measured at all visits (pre-operative, Day 1, Week 1, Week 2, Week 4 and Week 6) for all the participants (n=25) using an OCT instrument as described in Chapter 3 (cf. 3.6.4.3, p.48).

A noticeable difference was observed in the measurement (cf. Table 4.6, p. 65) of the CCT with an increase of 36.66 µm at Day 1 after cataract surgery. A similar result was found by Ishikawa *et al.* (2018), Tao *et al.* (2013) and Zheng *et al.* (2016) who also found the greatest increase in CCT on the first day after cataract surgery. Another study reported a significant increase in CCT only six weeks after cataract surgery, but as explained by Matsuura *et al.* (2017), this delayed increase was due to an external cause unrelated to the cataract surgery. These results indicate how sensitive the cornea is to surgical intervention as the median CCT of the control eyes did not reflect many variations.

Although cataract surgery caused corneal oedema, as seen in this study, the CCT rapidly returned to almost baseline values at Week 1 after surgery (cf. Figure 4.4, p.64). This recovery was quicker compared to that of Ahmad *et al.* (2013), Caceres (2015) and Caglar *et al.* (2017) who found recovery only at two and three weeks after surgery respectively. Their increased recovery time might be due to patient risk factors such as the older ages of the participants (Caceres, 2015) or the different surgical techniques used (Ahmad *et al.*, 2013) or a different IOL material implanted that took longer to stabilise (Caglar *et al.*, 2016).

If considering the stabilisation criteria of 20 µm (Tao *et al.*, 2013; Caglar *et al.*, 2016; Zheng *et al.*, 2016), most participants (n=17, 68%) had a stable CCT one week after

cataract surgery. There was no statistical significance at a 95% level of confidence in the difference of CCT from Week 2 (p=0.0640) after cataract surgery and later (cf. Table 4.7, p.66). This indicated that stabilisation of the CCT for the participants in this study was achieved from one week after cataract surgery.

A similar recovery time of one week was described by Tao *et al.* (2013) and Ward and Ajamian (2009) in patients with uneventful cataract surgery with no predisposing ocular or systemic diseases.

It can be concluded from the data collected for this research study, that most participants had a minimal difference in CCT from one week after cataract surgery and therefore, the stabilisation of the CCT was achieved from one week after cataract surgery.

5.6 Central macula thickness

An important post-operative complication that was evaluated in this study was the central macula thickness (CMT). The OCT measurement of the CMT was performed on the operated (n=25) and the control (n=23) eyes at all visits.

The CMT stabilised early in the study with only one participant out of all the operated eyes (n=25) who did not return to baseline value CMT at Day 1 and Week 1 after cataract surgery (cf. Table 4.8, p.69). This named participant did however, have a stabilised CMT from Week 2 onwards as per the stabilisation criteria of 25 µm (Jagow *et al.,* 2007; Atalay *et al*. 2016). A statistically significant difference was, however, found between the pre-operative visit and Day 1 (p=0.126) for the operated eyes.

Almost no variation in the median CMT values for the operated eye was measured from the pre-operative visit to Week 4. It is interesting to note that the biggest difference in CMT from baseline value was measured at Week 4 (6.00 µm) and Week 6 (7.00 µm). When comparing this data from Table 4.8 (cf. p.69) to the statistical significance displayed in Table 4.9 (cf. p.69), statistically significant differences were found at Week

4 (p=0.0021) and Week 6 (p=<0.0001). This may indicate a subclinical difference in CMT at Week 4 and Week 6 that did not affect the vision of the participants, since BCVA stabilised at Week 2 as discussed earlier in section 5.4. (cf. p.86), these findings are in agreement with the fact that CMO usually occurs at four to six weeks after cataract surgery (Scholl et al., 2011; Vukicevic et al., 2012; Carricondo et al., 2015), although it has been reported to sometimes occur earlier, for example in diabetic patients. Instances of increased CMT have been reported as late as 12 weeks after cataract surgery, but for this study the CMT measurements were only taken until six weeks after cataract surgery (cf. 2.6.7.5, p.34).

In summary, a statistically significant difference in CMT was noted on Day 1, Week 4 and Week 6.

5.7 Refraction results

The components of a refraction for spectacles consist of the spherical refractive power, the cylindrical refractive power and the axis of the cylindrical power. Each one of these three components of the refraction will be discussed, however, the spherical values are of greater importance for this study as participants with low cylindrical values were used. The axis values depend greatly on the corneal toricity and even though the data is presented, it must be noted that its value contributes in the context of this study, has less value as compared to the spherical component.

The pre-operative data is not included in the discussion. This baseline data is regarded as irrelevant as to when stabilisation occurs after cataract surgery, because the refraction after cataract surgery will not return to pre-operative value as the IOL is calculated to correct all refractive error present and the goal is to determine when stabilisation occurs and not when the value returns to baseline.

5.7.1 Spherical refraction

The median spherical results displayed in Figure 4.8 (cf. p.72) indicate that a minimal spherical value was measured at Day 1 after surgery (+0.25 ± 1.09 D interquartile range). This is a positive result as the goal of cataract surgery is to leave the patient as close to emmetropia (0 D) as possible. From Week 1 (0.00 ± 0.66 D interquartile range) to Week 6 (+0.17 ± 0.58 D interquartile range), the difference in spherical refraction was minimal. This may indicate, as also found by Juan *et al.* (2013) and Kessel *et al.* (2015), that one day to one week after cataract surgery, the refraction in some participants did not change and can thus be regarded as stable.

Although some participants already had a stable spherical refraction one week after surgery, even more participants had a stabilised spherical refraction two weeks after cataract surgery. From Week 2, as seen in Table 4.10 (cf. p.74), slightly more than half of the participants achieved stabilisation of the spherical refraction (n=14, 56%). A comprehensive study by Riaz *et al.* (2006) recommended a waiting time of six weeks after cataract surgery for refraction. This is possibly due to the fact that the study was done on a much bigger sample and also that different surgical techniques were used. The difference in spherical refraction value for this study was, however, minimal between Week 1 and Week 2 (-0.04), indicating that the spherical refraction possibly stabilises between one and two weeks after cataract surgery for most participants. The same stabilisation of two weeks was found in a similar study by Caglar *et al.* (2016).

To establish if the spherical refraction was stable, the measurements at each visit were compared to the visit before. Interestingly, there was a statistically significant difference from Day 1 to Week 1 (p=0.0057) after the cataract surgery. No statistically significant differences were found between the visits thereafter (cf. Table 4.11, p.75).

The presented data on the differences between the visits as well as the statistical significance, indicates that the spherical value after uneventful cataract surgery was stable from one week after uneventful cataract surgery. This finding supports Juan *et al.* (2013) who recommended that refraction can be done one week after cataract surgery.

5.7.2 Cylinder refraction

The cylinder refraction compensates for the astigmatism of the eye. The participants in this study had monofocal IOL's implanted, which does not compensate for astigmatism. The patients who presented with high astigmatism and wanted a toric IOL, were excluded from this study. Therefore, it was expected that the cylinder values of the participants in this study were relatively low.

Almost half of the participants had a stable cylinder refraction at Week 1 (a difference of 0.25 D or less). The median difference between the visits was 0.00 D from Week 1 and thereafter (cf. Table 4.12, p. 78). This stabilisation is three weeks earlier than the period for refraction described by Porter *et al.* (2012), Schuster *et al.* (2013) and Karpecki and Cunningham (2015) who did the spectacle refraction at four weeks after cataract surgery. An improvement in refractive stabilisation time has been noted to be as a result of improved surgical equipment and technique (cf. 2.6.8.2, p.35) and this might be why the stabilisation period for this study is sooner than studies done a few years ago.

By comparing the measurements of the consecutive visits, the biggest difference and statistically significant difference was found between Day 1 and Week 1 (cf. Table 4.13, p. 78). No statistically significant differences were found between the visits thereafter (p=0.0065).

The presented data on the differences between the visits as well as the statistical significance, indicates that the cylinder value was stable from one week after uneventful cataract surgery.

5.7.3 Axis

The axis value of the refraction determines where in the spectacles the cylinder power is positioned. Median axis values were calculated for the operated as well as the control eyes. The axis of the operated eyes changed minimally from Day 1 to Week 6.

As with the spherical and cylinder components of the refraction, the measurement of the axis value was compared to the previous visit's measurement to establish when

stabilisation occurs. The only statistically significant difference in axis value was found at Week 2 (p=0.0019) after cataract surgery. The differences in axis value were insignificant after Week 2 (cf. Table 4.15, p. 82). This indicates stabilisation of the axis only two weeks after cataract surgery.

For the axis value, the statistical significance could be the best indication as to when stabilisation occurs. The only statistically significant change was found between Week 1 and Week 2 (cf. Table 4.15, p82). The axis value can thus be regarded as being stable form two weeks after uneventful cataract surgery.

5.7.4 Refraction summary

As expected with cataract surgery, all participants in this research study had a difference in refraction after cataract surgery. Although the spherical and cylinder components stabilised one week after uneventful cataract surgery, the axis value stabilised only two weeks after uneventful cataract surgery. The total refraction consists of all three these values (sphere, cylinder and axis). If the results of the spherical refraction, cylinder refraction and the cylinder axis is then regarded as a whole, this indicates that it is possible to do an accurate refraction for spectacles two weeks after cataract surgery.

5.8 Associations between the four variables

No definite associations were found between any of the four variables (best corrected visual acuity (BCVA), central corneal thickness (CCT), central macula thickness (CMT) and refraction).

Best corrected visual acuity (BCVA), although a subjective measurement, can be an indication as to when the optimal time for spectacle refraction after surgery is as the results in this research study showed stabilisation of both the BCVA and the refraction from two weeks onwards after cataract surgery.

The stabilisation of CCT occurred one week before the stabilisation of BCVA and refraction. The stabilisation of CCT can be said to have stabilised a week before the BCVA and refraction for this study.

No possible associations between the CMT and the other variables measured in this research study could be made. If the sample size was larger or the duration of data collection longer, more associations might have been made.

5.9 Conclusion

The results indicate that it is possible to do a spectacle refraction from two weeks after uneventful cataract surgery that would be deemed accurate and stable. This certainly has a very practical implication in the field of optometry. It is, however, important in the clinical setting to evaluate each patient's visual stabilisation in a holistic manner, keeping the patient's general health (for example diabetes) and ocular health (for example dry eye) in mind. Patients with diagnosed AMD, uveitis, diabetic macula oedema or any other pre-existing ocular pathology are at a higher risk for complications during surgery (Khan *et al.*, 2015) and any operative or post-operative complications can delay the stabilisation of post-surgical refraction for spectacles. The surgical methods used for the removal of traumatic cataracts and congenital cataracts are often more complicated. The prognosis in these cases often differ from the 'normal' age-related cataract due to an increased possibility of complications during surgery. Any complications that occur can delay the healing and the stabilisation for spectacle refraction (Greenberg et al., 2011; Thanigasalam et al., 2015; Thapa et al., 2015). Patients that suffer from any autoimmune disease such as Type 1 Diabetes, Rheumatoid Arthritis, Hepatitis, Lupus, HIV/AIDS etc., often have an increased risk of infection and CMO and also have a longer healing time compared to healthy patients after surgery (Hadda et al., 2014). Combined surgeries, for example vitreoretinal cataract surgery or the insertion of a glaucoma stent, is a more intricate surgery and the clinical stabilisation of the refraction will be prolonged. The statistical significance of the results of this study should therefore always be regarded as results found in patients without any increased risk for slower healing

and subsequently delayed stabilisation of refraction. Patients with the presence of the named factors, should therefore be approached in a more holistic manner and should possibly be refracted slightly later, given slower healing times in these patients. The clinical significance is important in these patients, as statistics found in this study may not necessarily be applicable to these patients. Complete clinical evaluation is necessary in these patients before refraction and the prescribing of the new spectacles after cataract surgery takes place. The next chapter will summarise the importance of the refractive stabilisation after uneventful cataract surgery for this research study.

Chapter 6.

CONCLUSION

6.1 Introduction

A difference in refraction is expected after cataract surgery. Although the modern trend is to leave the patient as independent as possible from spectacles, most patients will still need spectacles for optimal vision, mostly for near activities like reading.

The main aim of this study was to determine when in the first six weeks after uneventful cataract surgery, the operated eye stabilises for the refraction of the new spectacles needed. As discussed in Chapter 2 (cf. 2.6.8.2, p.35), there is great discrepancy in current literature as to when the correct time is to do a refraction for spectacles after cataract surgery.

This final chapter will provide an overview of the study as well as the final findings. The conclusions, limitations and the significance of this study will also be discussed.

6.2 Overview of the study

Four variables were measured at six visits to acquire the data after uneventful cataract surgery. The full measurement procedures were discussed in Chapter 3 (cf. 3.6.4, p.46). The four variables that were investigated, included the best corrected visual acuity (BCVA), central corneal thickness (CCT), central macula thickness (CMT) and the refraction.

These visits took place before cataract surgery and then at one day, one week, two weeks, four weeks and lastly six weeks after cataract surgery. The data was analysed to

determine the difference between these variables consecutively over the six weeks that the study took place.

Chapter 4 represented the results that were discussed in Chapter 5. One variable remained inconclusive as to when stabilisation occurs, namely the central macula thickness. The other three other variables (best corrected visual acuity (BCVA), central corneal thickness (CCT) and refraction) were found to stabilise within two weeks after cataract surgery, indicating that, taking these variables into consideration, spectacles can be prescribed as early as two weeks after uneventful (no complications occurred during cataract surgery) cataract surgery.

6.3 Conclusions

6.3.1 Main Aim

The main aim of this study was to determine when in the first six weeks after uneventful cataract surgery, the operated eye stabilises for the refraction of the new spectacle needed.

By assessing the results of this study, the conclusion can be made that the refraction stabilises two weeks after cataract surgery. This indicates that spectacles may be optimally prescribed two weeks after uneventful cataract surgery.

6.3.2 Objectives

The first objective was to measure the difference in BCVA before uneventful cataract surgery and consecutively over a period of six weeks thereafter. Stabilisation of BCVA was defined as a difference in measurement of 0.1 (one line on Snellen chart) or less. The BCVA was found to stabilise two weeks after uneventful cataract surgery for the participants in this research study.

The next objective was to measure the difference in CCT consecutively over the period from pre-operative visit until six weeks after uneventful cataract surgery. A difference

of 20 µm or less in CCT was decided on as the stabilisation criteria for this research study. It was found that the CCT returned to baseline values from two weeks after uneventful cataract surgery.

A stabilisation criteria of a difference of 25 µm or less was decided on for the third objective measured, namely the CMT. This measurement was also done before uneventful cataract surgery and consecutively over a period of six weeks thereafter. Although the CMT showed stabilisation at one day after cataract surgery for most participants, a statistically significant difference was observed at Week 4 and Week 6, rendering the data inconclusive as to when stabilisation occurs.

The most important objective was the measurement of the refraction. The refraction was measured from one day after uneventful cataract surgery until six weeks thereafter. During this time, it was noted that the refraction stabilises two weeks after cataract surgery.

Lastly, the possible associations between the stabilisation of the four measured variables were investigated. The results showed no definite associations between any of the four variables. Stabilisation of the BCVA may be an indication as to when the optimal time for spectacle refraction after surgery is, as the results in this research study showed stabilisation of both BCVA and refraction two weeks after cataract surgery.

6.4 Limitations of the study

The researcher recognises the following limitations in the study:

- Due to the small sample size, fewer associations could be made between the four variables.
- Strict criteria were adhered to for this study, for example the left eye had to be the first eye that was operated, resulting in a small sample size.
- The time period that participants were measured for this study was six weeks. Measurements of the variables, specifically the central macula thickness, might

have shown a significant difference if measured for a longer time period after cataract surgery.

6.5 Contribution of the research

This study contributes greatly to the current literature on the topic of refractive stabilisation after uneventful cataract surgery. It is important to note that this study was done on healthy individuals of a certain age group that underwent uncomplicated cataract surgery, as many factors can influence the stabilisation of the refraction after cataract surgery.

The results of this research study make a very useful recommendation that can be applied by optometrists and ophthalmologists namely that spectacles may possibly be prescribed two weeks after uneventful cataract surgery. It is important that optometrists are aware of this possibility to be able to assist their patients optimally.

6.6 Recommendations

Future suggestions for this study include:

- Identifying a population that uses mostly spherical IOLs for cataract surgery, so that a larger sample size can be used.
- A similar study can be conducted using multifocal or toric IOLs to establish what the difference in stabilisation time of the refraction is when specialised IOLs are used.
- Extra follow up visits after cataract surgery up to 12 months, to specifically investigate if an increase in central macula thickness or central macula oedema occurs at a later stage after cataract surgery.
- The reason why patients choose topical anaesthesia for cataract surgery and the reason why patients choose an anaesthetic block for cataract surgery should be assessed.

- The relationship between the anaesthetic choice (anaesthetic block or topical anaesthesia) and BCVA, CMT, CCT and refraction.
- The reason why females seemed to have cataract surgery at a higher age than males can be investigated.
- The reason why a statistically significant difference in central corneal thickness was found in the control eyes at one day and six weeks after cataract surgery of the contralateral eye.

6.7 Conclusive remark

As mentioned, the literature is greatly divided on the topic of when a refraction for spectacles after cataract surgery should be done. No research on the optimal time for spectacle refraction was found to be done in South Africa at the time of this study. This study, therefore, contributes greatly to the field of optometry by suggesting that two weeks after uneventful cataract surgery may be the optimal time for spectacle refraction. The statistical significance of the study findings should however always be regarded as results found in patients without any increased risk for slower healing after cataract surgery. The clinical significance is important in these patients with risk factors, as statistics found in this study may not necessarily be applicable to these patients. A complete clinical evaluation is necessary in these patients before refraction and the prescribing of the new spectacles takes place.

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LIST OF APPENDICES

APPENDIX A

PATIENT DATA COLLECTION SHEET

PATIENT DATA COLLECTION SHEET

Eye:		Date:	
Age:		Visit:	
Gender:		Ref no:	
Refraction 1:		CMT 1:	
Refraction 2:		CMT 2:	
Refraction 3:		CMT 3:	
Average refraction:		Average CMT:	
BCVA 1:		CCT 1:	
BCVA 2:		CCT 2:	
BCVA 3:		CCT 3:	
Average BCVA:		Average CCT:	
Anaesthesia:			
Lens:			
Surgeon:			
Pre-existing pathology:			
Chronic conditions (autoimmune/eye):			
Uneventful surgery:			
Solely cataract surgery:			

APPENDIX B

CONSENT AND INFORMATION DOCUMENT

***Study Title*: The measurement and evaluation of visual acuity, corneal thickness, central macula thickness and refractive error after uneventful cataract surgery.**

Dear Participant

I am inviting you to voluntarily participate in my research study. I am currently a postgraduate student at The University of the Free State doing the Master of Optometry degree.

Researcher: Mrs. Cara Biddulph *Contact: cara@kloofeye.co.za*

Purpose of the research: The aim of this research study is to determine the correct time to do a refraction after uneventful cataract surgery, i.e. when to have spectacles made after cataract surgery.

What you will be asked to do in the research study: You will be expected to attend all your follow up consultations after surgery: day 1, week 1, week 2, week 4 and week 6. Dates for these consultations will be conformed once you have booked your cataract surgery date. At these consultations the following tests will be done: Visual Acuity, Refraction and Optical Coherence Tomography (OCT) scans of the macula and cornea. Please ask the researcher if you require any information on these tests.

Risks: There are no risks involved in this research study. All the necessary tests are done on all patients, even if they are not part of this research study.

Benefits of the research: You will assist in determining the correct time to have spectacles made after surgery. Your refraction (script for glasses) will be provided to you at your last consultation (6 weeks after cataract surgery).

Data collection: All the results from your tests will be recorded by the researcher.

Confidentiality: Confidentiality will be provided to the fullest extent possible by law. No personal detail (name, address, etc.) will be made available to any other parties (other than the researcher) in order to create absolute anonymity. Organisations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the Ethics Committee at the University of the Free State.

Voluntary participation: Your participation in the study is completely voluntary and you may choose to stop participating at any time. Your decision not to volunteer will not influence the relationship you may have with the researcher or staff at Kloof Eye either now, or in the future.

Withdrawal from the study: You can stop participating in the study at any time, for any reason, if you so decide. Your decision to stop participating, or to refuse to do certain tests or measurements, will not affect your relationship with the researcher or staff at Kloof Eye, or any other group associated with this project. In the event you withdraw from the study, all associated data collected will be immediately destroyed wherever possible.

Research results: If you as participant would like access to the result of the research study, you can contact the researcher directly.

I,_____ , voluntarily consent to participate in the following research study as explained above: *The measurement and evaluation of visual acuity, corneal thickness, central macula thickness and refractive error after uneventful cataract surgery.* I understood the nature of this research project and wish to participate. My signature below indicates my consent.

_____	_____	_____
Participant signature	Participant name	Date
_____	_____	_____
Researcher signature	Researcher name	Date
_____	_____	_____
Witness signature	Witness name	Date

APPENDIX C

TOESTEMMING- EN INLIGTINGSDOKUMENT

***Studie Titel*: 'The measurement and evaluation of visual acuity, corneal thickness, central macula thickness and refractive error after uneventful cataract surgery.'**

Geagte deelnemer

Ek nooi u uit om vrywilliglik aan my navorsingstudie deel te neem. Ek is huidig 'n nagraadse student aan die Universiteit van die Vrystaat en is besig met my Meester in Optometrie graad.

Navorser: Mev. Cara Biddulph *Kontak: cara@kloofeye.co.za*

Doel van die navorsingstudie: Die doel van hierdie navorsing is om te bevestig wanneer die korrekte tyd na katarak chirurgie is om 'n refrakasie te doen, i.e. wanneer om 'n bril te laat maak na katarak chirurgie.

Wat van u verwag word in die studie: U sal verwag word om al u opvolg besoeke by te woon na chirurgie: dag 1, week 1, week 2, week 4 en week 6. Die datums van hierdie konsultasies sal bevestig word wannner u die katarak chirurgie datum bespreek het. Die volgende toetse gaan by die konsultasies gedoen word: Gesigskerpte (visie), refraksie en OCT van die macula en kornea. Vra asb. die navorser as u enige vrae oor enige van hierdie toetse het.

Risiko's: Daar is geen risiko's betrokke by hierdie navorsingstudie nie. Al die nodige toetse word op alle pasiënte gedoen, al neem hulle nie deel aan die navorsingstudie nie.

Voordeel van die navorsing: U bydrae help die navorser om te bevestig wanneer die korrekte tyd is om 'n bril te laat maak na katarak chirurgie. U refraksie (bril voorskrif) sal aan u verskaf word na u laaste konsultasie (week 6 na chirurgie).

Data insameling: Al die toets resultate gaan deur die navorser self neergeskryf word op die data insamelingsblad.

Vertroulikheid: Vertroulikheid sal ten volle toegepas word binne wetgewing. Geen persoonlike informasie (naam, adres, ens.) sal verskaf word an enige eksterne party nie en u identeit sal anoniem gehou word. Organisasies wat wel die navorsingsdata mag nasien/kopiëer vir kwaliteitsbeheer en data analise sluit in die Etiek Kommitee van die Universiteit van die Vrystaat.

Vrywillige deelname: U deelname in die navorsingstudie is geheel en al vrywillig en u mag enige tyd besluit om nie meer deel te wees van die navorsingstudie nie. As u besluit om nie deel te neem nie sal u keuse op geen manier u verhouding, huidiglik of in die toekoms, met die navorser of enige personeel van Kloof Oog beinvloed nie.

Onttrekking van die studie: U kan enige tyd gedurende die navorsingstudie besluit om nie meer deel van die studie te wees nie, ongeag die rede. U besluit om nie sekere toetse en metings te doen nie, sal op geen manier u verhouding, huidiglik of in die toekoms, met die navorser of enige personeel van Kloof Oog beinvloed nie. Sou u van die navorsingstudie onttrek, sal al die data verwyder word van die studie rekords.

Navorsingstudie resultate: As u as deelnemer belangstel in die uitkoms van die navorsingstudie, kan u die navorser direk kontak.

Ek,_____ , gee hiermee vrywilliglik toestemming om deel te neem aan die bogenoemde navorsingstudie: *The measurement and evaluation of visual acuity, corneal thickness, central macula thickness and refractive error after uneventful cataract surgery.* Ek verstaan die omvang van die

navorsingsprojek en wil deelneem aan die studie. My handtekening hier onder verteenwoordig my vrywilliglike toestemming tot deelname.

_____	_____	_____
Deelnemer handtekening	Deelnemer naam	Datum
_____	_____	_____
Navorser handtekening	Navorser naam	Datum
_____	_____	_____
Getuie handtekening	Getuie naam	Datum

APPENDIX D

PERMISSION: USE OF FACILITY AND PATIENTS

PERMISSION: USE OF FACILITY AND PATIENTS

***Study Title*: The optimal time for post-operative refraction after uneventful cataract surgery.**

Dear Dr. de la Bat

I am asking your permission to use your facility (Kloof Eye) to do the tests and measurement needed for my research study. As you are aware,I am currently a postgraduate student at The University of the Free State doing the Master of Optometry degree.

Researcher: *Mrs. Cara Biddulph* *Email: cara@kloofeye.co.za*

Tel: 012 347 0500 *Address: 506 Jochemus Street, Erasmuskloof, Pretoria*

Study leader: *Dr. Marsha Oberholzer* *Email: oberholzerm@ufs.ac.za*

Tel: 051 405 2536 *Address: Room 112, White Block, National Hospital, Roth Avenue, Bloemfonetin*

The aim of this research study is to determine the correct time to do a refraction after uneventful cataract surgery, i.e. when to have spectacles made after cataract surgery.

The patients at Kloof Eye will be approached to voluntarily take part in this research study. 40 pateints will be used in this research study. Patients will attend their follow-up consultations after surgery as follow: day 1, week 1, week 2, week 4 and week 6. Dates for these consultations will be conformed once the subject has booked their cataract surgery date.

The following tests will be done:

- Visual Acuity with use of the Sharp VA software from Zeiss
- Refraction will objectively be determined with the Zeiss Visuref 100.
- The Zeiss Cirrus will be used to take OCT scans of the macula and cornea.

For any queries regarding the ethics approval of this study, please feel welcome to contact the HSREC office at UFS: Mrs. M Marais at 051 444 4359.

Attached you will find a copy of my protocol. You are welcome to contact me with any concerns or uncertainties.

I, Gov de la Rat, give consent for the use of my facility (Kloof Eye) for the following research study as explained above: *The optimal time for post-operative refractive error after uneventful cataract surgery.* I also give consent that my patients may be approached to voluntarily take part in this research study. My signature below indicates my consent.

Signature	Gov de la Rat Name	2017-10-18 Date
Researcher signature	Cara Biddulph Researcher name	2017 10 18 Date
Witness signature	Margaret Botha Witness name	18/10/2017 Date

APPENDIX C

HSREC APPROVAL

UNIVERSITY OF THE FREE STATE
UNIVERSITEIT VAN DIE VRYSTAAT
YUNIVESITHI YA FREISTATA

UFS-UV
HEALTH SCIENCES
GESONDHEIDSWETENSKAPPE

IRB nr 00006240
REC Reference nr 230408-011
IORG0005187
FWA00012784

27 November 2017

C BIDDULPH
DEPT OF OPTOMETRY
FACULTY OF HEALTH SCIENCES
UFS

Dear C Biddulph

HSREC 152/2017 (UFS-HSD2017/1422)
PRINCIPAL INVESTIGATOR: C BIDDULPH
PROJECT TITLE: OPTIMAL TIME FOR POST-OPERATIVE REFRACTION AFTER UNEVENTFUL CATARACT SURGERY

APPROVED

1. You are hereby kindly informed that the Health Sciences Research Ethics Committee (HSREC) approved this protocol after all conditions were met. This decision will be ratified at the next meeting to be held on 05 December 2017.
2. The Committee must be informed of any serious adverse event and/or termination of the study.
3. Any amendment, extension or other modifications to the protocol must be submitted to the HSREC for approval.
4. A progress report should be submitted within one year of approval and annually for long term studies.
5. A final report should be submitted at the completion of the study.
6. Kindly use the **HSREC NR** as reference in correspondence to the HSREC Secretariat.
7. The HSREC functions in compliance with, but not limited to, the following documents and guidelines; The SA National Health Act. No. 61 of 2003; Ethics in Health Research: Principles, Structures and Processes (2015); SA GCP(2006); Declaration of Helsinki; The Belmont Report; The US Office of Human Research Protections 45 CFR 461 (for non-exempt research with human participants conducted or supported by the US Department of Health and Human Services-(HHS), 21 CFR 50, 21 CFR 56; CIOMS; ICH-GCP-E6 Sections 1-4; The International Conference on Harmonization and Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH Tripartite), Guidelines of the SA Medicines Control Council as well as Laws and Regulations with regard to the Control of Medicines, Constitution of the HSREC of the Faculty of Health Sciences.

Yours faithfully

MS MGE MARAIS
HEAD: HEALTH SCIENCES RESEARCH ETHICS COMMITTEE ADMINISTRATION

Health Sciences Research Ethics Committee
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