School of Public Health

Impact of Cataract Surgery on Driving Difficulty and Quality of Life for Older Drivers

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Declaration

To the best of my knowledge and belief this thesis contains no material previously published by any other person except where due acknowledgment has been made.

This thesis contains no material which has been accepted for the award of any other degree or diploma in any university.

Signature: ……… ……..

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ABSTRACT

The demand for cataract surgery is set to increase due to the ageing population of Australia. Cataracts are usually bilateral, but cataract surgery is almost always performed one eye at a time. Previous investigations of the impact of cataract surgery seldom analysed the separate effects of each surgery. Instead, patients who underwent first, second or both eye surgeries were combined in the analyses. In Western Australia, public hospital patients wait substantial periods of time between first and second eye cataract surgeries. For these patients, understanding the separate effects of first eye surgery on driving difficulty, vision-related quality of life and depressive symptoms is of considerable importance for their safety and well-being.

This before and after study aimed to gain a better understanding of the impact of first eye cataract surgery on self-reported driving difficulty, vision-related quality of life and depressive symptoms for older drivers. It also aimed to investigate how changes in these outcomes were associated with changes in objective visual measures after cataract surgery.

The sample consisted of 99 bilateral cataract patients who drove and were about to undergo first eye cataract surgery. Participants were recruited consecutively from the Ophthalmology Departments of Royal Perth, Sir Charles Gairdner and Fremantle Hospitals in Perth, Western Australia. Participants were assessed during the week before and approximately 12 weeks after first eye cataract surgery. Data on major study outcomes including self-reported driving difficulty, vision-related quality of life and depressive symptoms, were collected using previously developed questionnaires, administered by the researcher. Three objective visual measures, namely visual acuity, contrast sensitivity and stereopsis, and two cognitive tests, namely the Mini Mental State Examination and a useful field of view test, were also conducted. In addition, demographic and health information were collected from participants.

Separate generalised linear estimating equations were used to ascertain the changes in driving difficulty, vision-related quality of life and depressive symptoms after first eye surgery. Multiple linear regression modelling was then undertaken to determine whether changes in the major outcomes after surgery were associated with changes in objective visual measures.

After first eye cataract surgery, there were significant mean improvements of approximately 10 points in overall driving difficulty ($p<0.001$) and vision-related quality of life ($p<0.001$) scores. There was a statistically significant but not clinically meaningful improvement in depressive symptoms of approximately one point after surgery ($p=0.024$). Before first eye surgery, 18% of participants did not meet the visual standards for licensing in Western Australia. After surgery this proportion was reduced to 4%.

After controlling for confounding factors, change in surgery eye contrast sensitivity was the only objective visual measure significantly associated with change in driving difficulty after first eye cataract surgery ($p<0.001$). Change in surgery eye contrast sensitivity was also the only visual measure associated with change in vision-related quality of life ($p<0.001$). Stereopsis was the only visual measure associated with change in depressive symptoms after first eye surgery ($p<0.032$). Only 22% of participants received new glasses after first eye cataract surgery. Receiving new glasses after surgery was significantly associated with greater improvement in driving difficulty ($p<0.001$), vision-related quality of life ($p<0.001$) and depressive symptoms ($p=0.001$).

Despite overall improvements, some participants did not improve or even declined in driving difficulty (19%), vision-related quality of life (14%) or depressive symptoms (47%) after first eye cataract surgery. For all three of the major outcomes, those who did not improve experienced significant improvements in surgery eye visual acuity and surgery eye contrast sensitivity after surgery, but not in stereopsis.

Results found that first eye cataract surgery had significant benefits in terms of driving difficulty, vision-related quality of life and maintenance of levels of vision required for driver licensing, but not depressive symptoms. This provides strong grounds for Ophthalmologists to recommend cataract surgery to all suitable drivers with bilateral cataract, and for funding to be increased to reduce the waiting period for cataract surgery for public patients. Contrast sensitivity and/ or stereopsis, but not visual acuity, were associated with changes in the major outcomes after surgery. This challenges the current reliance on visual acuity for assessment and prioritisation of cataract patients for surgery, and in driver licensing. In addition, results suggest that the stereopsis measure may be useful for identifying bilateral cataract patients who do not improve after first eye cataract surgery, so they can be advised and possibly prioritised for second eye surgery.

Further research is required to determine the additional effects of second eye cataract surgery for older drivers, to further uncover factors associated with non-improvement of cataract patients after first eye surgery and to develop appropriate visual tests for driver licensing.

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LIST OF ABBREVIATIONS

ADVS	Activities of Daily Vision Scale
BDI	Beck's Depression Inventory
CES-D	Centre for Epidemiologic Studies Depression Scale
CI	confidence interval
DASS	Depression Anxiety Stress Scale
ETDRS	Early Treatment Diabetic Retinopathy Study
GEE	generalised estimating equation
GDS	Geriatric Depression Scale
HADS	Hospital Anxiety and Depression Scale
HRQOL	health-related quality of life
ICOM	Impact of Cataract on Mobility
logMAR	logarithm of the minimum angle of resolution
MMSE	Mini Mental State Examination
ms	milliseconds
n	sample size
NEI VFQ-25	25 Item National Eye Institute Visual Function Questionnaire
NHVQoL	Nursing Home Vision-Targeted Health-Related Quality of Life Questionnaire
OR	odds ratio
PASW	Predictive Analytics Software
PIADS	Psychosocial Impact of Assistive Devices Questionnaire
POMS	Profile of Mood States
RCT	randomised controlled trial
RR	relative risk
SD	standard deviation
SF-12	12 Item Short Form Health Survey
SF-36	36 Item Short Form Health Survey
SIP	Sickness Impact Profile
UK	United Kingdom
USA	United States of America
VF-14	Visual Function Index
VRQOL	vision-related quality of life

CHAPTER 1

Introduction

1 INTRODUCTION

1.1 Background

The first cataract extraction was performed in the year 1747. Since then, cataract surgery has evolved into an extremely effective, modern procedure that can be performed as outpatient surgery (Jaffe 1998). Cataract surgery is the most commonly performed operative procedure in Australia and it can be credited with preventing blindness in millions of people around the world each year (Tan et al. 2004). Due to the ageing population of Australia, the demand for cataract surgery is set to increase (Rochtchina et al. 2003). Therefore, gaining a thorough understanding of the impact of cataract surgery on wide range of health and safety outcomes is of great significance.

1.2 Rationale

It is widely accepted that cataract surgery brings about significant improvements in vision (Barañano et al. 2008; Elliott et al. 2000). In addition, it has been reported to impact on a broad range of physical, mental and social outcomes, although some potential effects remain unclear (McGwin et al. 2003a). Cataracts are usually bilateral, affecting both eyes (Asbell et al. 2005), but cataract surgery is almost always performed one eye at a time (Meuleners et al. 2006). Public hospital patients in Western Australia experience long waiting periods before the first eye surgery and again before the second eye surgery. Although each surgery may have quite different effects on the overall functioning of bilateral cataract patients (Castells et al. 1999; Castells et al. 2006), the majority of evidence to date has not examined first or second eye surgery separately. Instead, patients who underwent first, second or both eye surgeries have been combined in the analyses or it has not been specified. In addition, both unilateral and bilateral patients have commonly been included in study samples.

While first eye surgery can bring about significant visual improvements, for some bilateral cataract patients, it can also result in large differences in vision between the operated and un-operated eyes, and in poor stereopsis (a form of depth perception) (Comas et al. 2007; Castells et al. 2006). Second eye surgery usually resolves this defect (Comas et al. 2007). Limited evidence has suggested that a proportion of patients do not improve or even decline on different self-reported outcomes after first eye cataract surgery (Black et al. 2009; Castells et al. 1999). Since many bilateral cataract patients have to function for substantial periods of time with only one cataract operated on, it is essential for their safety and well-being to thoroughly understand the effects of first eye surgery.

1.2.1 Cataract Surgery and Self-Reported Driving Difficulty

The proportion of drivers aged 60 years and over on Australian roads is projected to double by the year 2051 (King et al. 2007), meaning the effect of cataract surgery on driving outcomes is of particular concern. While cataract surgery has been shown to have overall benefits for self-reported driving difficulty (Subzwari et al. 2008), little is known about the separate effects of first and second eye surgery. Driving is also a complex activity and no information exists on the specific components of driving affected before and after first eye surgery, or the impact of the surgery on these tasks. In Western Australia, drivers with cataract are subjected to the same visual standards for licensing as the general population, largely based on visual acuity testing. Despite reviews concluding that evidence for a link between visual acuity and driving risk is inconclusive or weak at best, visual acuity remains the most commonly used screening test for licensing around the world (Bohensky et al. 2008; Desapriya et al. 2011). Some evidence has indicated the need for more appropriate visual measures for predicting driving ability in cataract patients (McGwin, Chapman & Owsley 2000; Owsley et al. 2001).

1.2.2 Cataract Surgery and Vision-Related Quality of Life

Vision-related quality of life (VRQOL) is an important outcome in the evaluation of cataract surgery and may be especially relevant for older drivers. The ability to drive can provide older adults with mobility, social activity and independence, and influence their health and well-being (Oxley & Whelan 2008; Windsor et al. 2007). Various self-report instruments have been developed to measure VRQOL or the impact of visual impairment on daily activities and emotional and social well-being (Mangione et al. 2001; Steinberg et al. 1994). Although multiple studies have reported improvements in VRQOL after cataract surgery, little research has been conducted in Australia and few drivers have been included in the samples. In addition, VRQOL is a multi-dimensional construct and little is known about which dimensions are affected at different stages of cataract surgery or the impact of surgery on these. Few studies have investigated the association between visual measures and VRQOL and those that have, reported conflicting results.

1.2.3 Cataract Surgery and Depressive Symptoms

The impact of cataract surgery on depressive symptoms is currently unclear, possibly due to small sample sizes and lack of separate investigations of those who underwent first, second or both eye surgeries in the analyses. Depression is a serious health issue for older Australians and evidence indicates that driving cessation and driving self-restriction may be associated with increased depressive symptoms (Fonda, Wallace & Herzog 2001; Ragland, Satariano & MacLeod 2005; Windsor et al. 2007). However, studies examining the impact of cataract surgery on depressive symptoms have included low numbers of drivers. The separate effects of first and second eye cataract surgery on depressive symptoms in older drivers and visual measures associated with depressive symptoms require further examination.

1.3 Study Objectives

The overall aim of this study is to gain a better understanding of the impact of first eye cataract surgery on self-reported driving difficulty, VRQOL and depressive symptoms, and how changes in these outcomes are associated with changes in visual measures after cataract surgery.

The specific study objectives are:

1. To examine changes in objective visual measures (visual acuity, contrast sensitivity and stereopsis) before and three months after first eye cataract surgery for older drivers with bilateral cataract in Perth, Western Australia.

2. To determine the impact of first eye cataract surgery on self-reported driving difficulty, VRQOL and depressive symptoms for older drivers with bilateral cataract.

3. To investigate the association between changes in objective visual measures (visual acuity, contrast sensitivity and stereopsis) and changes in self-reported driving difficulty, VRQOL and depressive symptoms after first eye cataract surgery.

1.4 Significance of the Study

Previous studies investigating the impact of cataract surgery have not separately analysed the effects of first, second or both eye surgeries. Public hospital patients in Western Australia wait substantial periods of time between the two cataract surgeries. For these patients, understanding the separate effects of first eye surgery is of considerable importance for their safety and well-being. This study contributes to the literature by increasing our understanding of the effects of first eye cataract surgery on self-reported driving difficulty, VRQOL and depressive symptoms for older drivers with bilateral cataract. It also has the potential to provide new information about the specific components of driving difficulty and VRQOL affected before and after first eye surgery and the impact of surgery on these. Thirdly, the study will determine visual measures that may be associated with changes in driving difficulty, VRQOL and depressive symptoms after first eye surgery.

This research has several clinical implications. Firstly, information on the specific impacts of first eye cataract surgery and how patients function after this surgery would assist clinicians in determining the need for second eye surgery in cases of bilateral cataract. It may also provide a rationale for reducing waiting times between surgeries for particular groups of patients who do not improve after first eye surgery. Secondly, the findings could allow bilateral patients to be appropriately advised on specific driving difficulties they may experience before and after their first eye surgery. Thirdly, identification of visual measures associated with change in driving difficulty, VRQOL or depressive symptom outcomes could allow clinicians to assess patients' degree of functional limitation and to identify those who may have improved or declined after first eye surgery. Patients could then be targeted for safety advice or prioritised for second eye surgery. Finally, information on visual measures related to changes in driving difficulty would be useful for clinicians and licensing authorities responsible for assessing fitness to drive in older drivers at different stages of surgery.

1.5 Outline of the Thesis

Chapter 2 reviews existing literature on the impact of cataract surgery and is sectioned into outcomes of interest. Evidence on the impact of cataract and cataract surgery on visual, driving difficulty, VRQOL and depressive symptom outcomes is critically reviewed. In addition, research to date on the association between objective measures of vision and driving difficulty, VRQOL and depressive symptoms is discussed.

Chapter 3 describes the methodology of the study. This chapter details the study design, participant recruitment, data collection methods, ethical issues, instruments used to collect visual, cognitive and self-reported data and statistical analysis of the data.

Chapter 4 presents the results of the study. Results of the pilot test of the questionnaire and participation rates of the study are reported. A description of the sample is then provided including demographic and cataract treatment information. Next, descriptive statistics are provided for cognitive and visual characteristics of the sample and univariate analyses presented. Findings are then presented with respect to the three major outcomes of interest; self-reported driving difficulty, VRQOL and depressive symptoms. Each outcome is presented as follows: 1) descriptive statistics, 2) univariate analyses, 3) a generalised estimating equation (GEE) model examining the effect of the cataract surgery and 4) a multiple linear regression model examining how changes in visual measures are associated with changes in the outcome of interest.

Chapter 5 discusses the results of the study in relation to previous research. Clinical implications of the findings are explained and recommendations for further research are made. In addition, the strengths and limitations of the current study are addressed and conclusions drawn.

CHAPTER 2

Literature Review

2 LITERATURE REVIEW

This literature review provides the background to the study and reviews current evidence on the effects of cataract surgery. Initially, information on cataract and cataract surgery in Western Australia is provided. The review is then sectioned into visual, driving, VRQOL and depressive symptom outcomes and research to date on the impact of cataract and cataract surgery on each of these outcomes is discussed. In addition, evidence on the association between objective measures of vision and driving difficulty, VRQOL and depressive symptom outcomes is reviewed.

2.1 Incidence and Pathophysiology of Cataract

Cataract is the leading cause of blindness worldwide (Pascolini et al. 2004; Resnikoff et al. 2004), and in Australia, it is the second most common cause of low vision, following refractive error (Taylor et al. 2005). The single most important risk factor for cataract is increasing age (Abraham, Condon & West Gower 2006), with over half of Australians developing cataract by their seventies and nearly 90% by their eighties (McCarty, Keeffe & Taylor 1999). Due to the ageing population, it is predicted that by 2021, approximately 2.7 million Australians will have cataract (Rochtchina et al. 2003).

Cataract is an opacification or clouding of the usually transparent crystalline lens of the eye (Asbell et al. 2005). It occurs as a result of the denaturation of the lens proteins, and can take months to several years to develop (Riaz et al. 2006). There are three main types of cataract including nuclear, cortical and subcapsular (anterior and posterior) cataracts (Asbell et al. 2005). They can occur alone or in combination and affect different anatomical locations of the lens (Asbell et al. 2005). The shape, clarity and refractive index of the lens affects how light is focused on the retina of the eye (Asbell et al. 2005). Therefore, the development of cataract usually involves a gradual, painless loss of near and/or distance vision. Other common symptoms include blurred vision, photophobia (sensitivity to light), diplopia (double vision), change in colour perception and myopic shift (The Royal Australian and New Zealand College of Ophthalmologists 2006). Cataracts are most commonly bilateral but may be of different severities and can also occur unilaterally (Asbell et al. 2005).

2.2 Cataract Surgery

2.2.1 Incidence and Projections

To date, no method of preventing or reversing the formation of cataracts has been identified and surgery is the only treatment option for cataract. Cataract surgery is the most commonly performed operative procedure in Australia (Tan et al. 2004) and is highly successful at improving vision in the operated eye(s) (Riaz et al. 2006). The incidence of cataract surgery is rapidly increasing in Australia (Clark et al. 2011)

2.2.2 Procedure

In Australia, phacoemulsification is the most commonly used method of cataract extraction (Clark et al. 2011). This modern technique uses an ultrasonic device to break up and remove the lens of the eye. An artificial lens (intraocular lens) is then inserted into the lens capsule through a very small incision (Riaz et al. 2006). This procedure is usually performed as outpatient surgery under local anaesthetic and visual recovery following surgery is very rapid (Riaz et al. 2006). The possible complications of cataract surgery can be serious and include postoperative endophthalmitis, retinal detachment, dislocation of the intraocular lens, retained pieces of lens and corneal oedema (Clark et al. 2011). However, these complications are rare, only affecting 1% of cataract surgeries performed in Western Australia in 2001 (Clark et al. 2011).

Although the majority of cataract cases are bilateral, cataract surgery is almost always performed one eye at a time. This is to eliminate the risk of sight-threatening complications occurring bilaterally, to avoid bilateral postoperative visual impairment and to allow Ophthalmologists to plan the second eye surgery based on the results of the first (Meuleners et al. 2006).

There are no set criteria for eligibility for cataract surgery but recommendations are based on factors including lens opacity, visual acuity, patient-reported symptoms, ocular co-morbidities and the expected outcome of the surgery (The Royal Australian and New Zealand College of Ophthalmologists 2006). In Western Australia, all suitable candidates are offered cataract surgery through the public hospital system, free of charge. However, those who elect to have cataract surgery through this system face long waiting periods. Although waiting times vary widely, bilateral cataract patients frequently wait more than 12 months for first eye surgery and then wait more than six months for second eye surgery, if they elect to have it (Ng, J 2009, pers. comm., 1 Oct).

2.3 Cataract Surgery and Objective Visual Outcomes

Cataract can affect several different aspects of vision. Visual acuity is the traditional measure used to assess impairment, however using this measure alone may miss aspects of impairment (Bal et al. 2011; Rubin et al. 2007). The impact of cataract on visual acuity, contrast sensitivity, stereopsis and other visual measures will be described and evidence on the impact of cataract surgery on these measures reviewed.

2.3.1 Visual Acuity

2.3.1.1 Impact of Cataract on Visual Acuity

Visual acuity is a measure of the clearness of vision and is commonly affected by the presence of cataract (McGwin et al. 2003b). Decreased visual acuity can affect both near and distance vision and may impact on tasks such as reading, fine handiwork and watching television (Walker, Anstey & Lord 2006). Evidence also suggests that poor visual acuity may affect the performance of visually demanding driving tasks such as driving at night and in high traffic (McGwin et al. 2000), as well as sign recognition and hazard detection (Wood 1999; Wood 2002).

2.3.1.2 Impact of Cataract Surgery on Visual Acuity

It is well known that cataract surgery can bring about significant improvements in visual acuity in the operated eye (Baranano et al. 2008). However, because the world is viewed with two eyes, the impact of cataract surgery on binocular measures of vision is also important. For bilateral cataract patients, binocular visual acuity has been shown to significantly improve following first eye cataract surgery (Castells et al. 2006; Comas et al. 2007). Second eye surgery has also shown to bring about significant, though much smaller improvements (Laidlaw et al. 1998). A Spanish randomised controlled trial (RCT) by Castells et al. comparing outcomes of first and both eye cataract surgeries estimated that 88% of the improvement in binocular visual acuity could be attributed to first eye surgery and only 12% to second eye surgery (Castells et al. 2006). Despite having clear benefits for visual acuity, it has also been found that first eye surgery can increase the difference in visual acuity between the two eyes and that second eye surgery can reduce this discrepancy (Comas et al. 2007).

2.3.2 Contrast Sensitivity

2.3.2.1 Impact of Cataract on Contrast Sensitivity

Contrast sensitivity (the ability to see contrast or shading differences) also frequently decreases as a result of cataract (McGwin et al. 2003b). It is also possible for cataract patients who have reasonably good visual acuity to have quite poor contrast sensitivity (Bal et al. 2011). Studies have suggested that contrast sensitivity plays a role in the performance of near and distance activities such as reading, face recognition, using stairs and activities performed in dim light (McCulloch et al. 2011; West et al. 2002). Evidence also suggests that reduced contrast sensitivity may affect several driving tasks including night driving (McGwin et al. 2003b), turning across traffic (McGwin, Chapman & Owsley 2000), driving in the rain or fog (Horswill & Plooy 2008; Mantyjarvi & Tuppurainen 1999), detecting pedestrians, cyclists or the edge of the road (Mantyjarvi & Tuppurainen 1999; West et al. 2002) and judging vehicle speeds (Horswill & Plooy 2008).

2.3.2.2 Impact of Cataract Surgery on Contrast Sensitivity

Cataract surgery has also been shown to bring about significant improvements in contrast sensitivity in the operated eye (Elliott et al. 2000). Similar to visual acuity, binocular contrast sensitivity has been reported to significantly improve following first eye surgery with only small improvements observed after second eye surgery (Castells et al. 2006; Comas et al. 2007; Laidlaw et al. 1998). The study described above by Castells et al. estimated that 96% of the overall improvement in binocular contrast sensitivity could be attributed to first eye cataract surgery and only 4% to second eye surgery (Castells et al. 2006). Again, it has been found that first eye surgery can increase the difference in contrast sensitivity between the two eyes and second eye surgery can reduce this difference (Comas et al. 2007).

2.3.3 Stereopsis

2.3.3.1 Impact of Cataract on Stereopsis

Stereopsis is a form of depth perception that results from receiving two slightly different projections onto the retinas of the two eyes and requires a minimum level of visual acuity and contrast sensitivity (Comas et al. 2007). Therefore, reductions in these measures due to cataract may lead to reduced stereopsis. Stereopsis is most important at near distances and can affect fine manipulative skills such as threading a needle, as well as gross motor skills and the judgement of stairs (O'Connor et al. 2010). In terms of driving, stereopsis may contribute to judging the distance of objects located closer than 40 metres (Bauer et al. 2001), affect the onset of braking and stopping distance (Tijtgat et al. 2008).

2.3.3.2 Impact of Cataract Surgery on Stereopsis

Stereopsis commonly improves following first eye cataract surgery, as a result of improved visual acuity and contrast sensitivity (Comas et al. 2007; Elliott et al. 2000; Laidlaw et al. 1998). However, contrary to findings regarding visual acuity and contrast sensitivity, second eye surgery has been reported to bring about an even greater improvement in stereopsis (Comas et al. 2007). The study by Castells et al.

estimated that only 46% of the overall improvement in stereopsis was attributable to first eye surgery and 54% to second eye surgery (Castells et al. 2006). Given that stereopsis is a binocular measure, it can be negatively affected by differences in visual acuity, contrast sensitivity and refractive error (the difference between the focal length of the cornea and lens, and the length of the eye) between the two eyes (Comas et al. 2007). Improvement in stereopsis after the second surgery is most likely due to a reduction in these differences between eyes (Comas et al. 2007).

2.3.4 Other Objective Visual Measures

The presence of cataract can also make the eye more susceptible to glare, which affects outdoor activities (McGwin et al. 2003b). Disability glare may affect ability to drive at night due to headlights, in early morning or late afternoon due to sun position (West et al. 2002) and also to detect hazards and pedestrians under these conditions (Theeuwes, Alferdinck & Perel 2002). One study suggested an improvement in disability glare after first eye cataract surgery (Superstein, Boyaner & Overbury 1999) but the effects of the second surgery are unknown.

Visual field is another measure affected in some cataract cases (Arvind et al. 2005). In terms of driving, visual field restriction may affect maintenance of lane position and detection of hazards in the peripheral vision (Bohensky et al. 2008; Bowers et al. 2005) Cataract surgery can improve horizontal and vertical visual fields in affected patients and evidence suggests that second eye surgery may be particularly important for this improvement (Arvind et al. 2005; Liu, Xu & He 2006; Talbot & Perkins 1998).

2.3.5 Vision after First Eye Cataract Surgery

While it has been established that first eye cataract surgery can bring about significant visual improvements, for some bilateral patients it can also result in large differences in vision between the operated and un-operated eyes, differences which may compromise stereopsis (Comas et al. 2007; Castells et al. 2006). For example, one study reported that when the difference in visual acuity between eyes was greater than 0.4 logarithm of the minimum angle of resolution (logMAR) units, stereopsis was negatively affected (Comas et al. 2007). In addition, this difference can lead to the phenomenon of binocular inhibition, where binocular visual acuity or contrast sensitivity is significantly worse than the visual acuity or contrast sensitivity of the better eye (Azen et al. 2002). After first eye surgery the un-operated eye can "interfere" with vision, potentially affecting the performance of various tasks, including driving (Comas et al. 2007).

2.4 Cataract Surgery and Driving Difficulty

Driving is a complex task, requiring many different aspects of visual functioning (Owsley & McGwin 2010). It has been suggested that vision is responsible for 90 to 95% of the sensory input required for driving (Bohensky et al. 2008; Hills 1980; Shinar & Schieber 1991). As previously described, cataract can negatively affect different aspects of vision, potentially having serious consequences for driving ability. Therefore, evidence surrounding the association between cataract and driving outcomes will be discussed. In addition, existing evidence on the impact of cataract surgery on crash risk, driving performance and self-reported driving difficulty, as well as visual measures associated with these outcomes will be reviewed.

2.4.1 Impact of Cataract on Driving Outcomes

A growing body of evidence suggests that older adults with cataract are less safe to drive. The prospective Impact of Cataract on Mobility (ICOM) Project conducted in the United States of America (USA), found that older drivers with cataract were almost 2.5 times as likely to have had an at-fault crash in the previous five years than those without cataract (relative risk (RR)=2.46, 95% confidence interval (CI)= 1.00-6.16) (Owsley et al. 1999). This study also found that participants with cataract were four times more likely to report difficulty with driving (RR=4.07, 95% CI= 2.39-6.94). Specific areas of difficulty included driving in the rain, driving alone, making turns across traffic, driving on interstates, in high traffic and at night (Owsley et al. 1999).

Several Australian on-road performance and perception-based studies also consistently demonstrated poorer performance on driving tasks for people with cataract. For example, Wood et al. compared the performance of 29 older drivers with bilateral cataract to 18 controls with normal vision on a closed road circuit (Wood & Carberry 2006). Those with cataract had significantly poorer driving performance overall and poorer road sign recognition, hazard recognition and hazard avoidance (Wood & Carberry 2006). Three studies of visually normal participants using simulated cataract goggles also found that participants performed poorer on video-based hazard perception tests (Marrington, Horswill & Wood 2008), closed-circuit day-time driving (Wood, Chaparro & Hickson 2009) and closed-circuit night-time driving (Wood et al. 2010), while wearing the goggles. It should be noted that in all three of these studies, while using the cataract goggles, participants' vision still met Australian legal standards for driving.

2.4.2 Impact of Cataract Surgery on Crash Risk

To date, only the ICOM study discussed above has assessed the association between cataract surgery and crash risk (Owsley et al. 2002). Over a four to six year follow-up period, cataract patients who underwent surgery experienced only half the crash risk of cataract patients who did not have surgery (RR=0.47, 95% CI= 0.23-0.94). (Owsley et al. 2002). While results are promising, this study is limited by the small sample size (n) of 174 drivers who had surgery and 103 controls, and the subsequent low number of at-fault crashes recorded. This study also combined those who had first eye cataract surgery (44%) and those who had both eye surgeries (56%) during the study period in the analysis (Owsley et al. 2002). Since the majority of cataract cases are bilateral, it still remains unclear whether first eye surgery alone reduces crash risk, or whether two surgeries are required for this effect.

2.4.3 Impact of Cataract Surgery on On-Road Driving Performance

One small Australian study examined the driving performance of 29 drivers with bilateral cataract aged 50 and above and 18 controls on a closed road circuit. Driving performance significantly improved after bilateral cataract surgery in terms of overall driving score, road sign recognition, road hazards recognised and avoided (Wood & Carberry 2006).

2.4.4 Impact of Cataract Surgery on Self-Reported Driving Difficulty

The majority of studies examining the effect of cataract surgery on driving focused on self-reported driving difficulty as the outcome. A meta-analysis of one retrospective (Chang-Godinich, Ou & Koch 1999) and four prospective cohort studies (Monestam, Lundquist & Wachtmeister 2005; Monestam & Lundqvist 2006; Monestam & Wachtmeister 1997; Mamidipudi et al. 2003) reported that the risk of driving difficulty was reduced by 88% following cataract surgery (odds ratio (OR)=0.12, 95% CI= 0.10 to 0.16) (Subzwari et al. 2008). Table 2.1 details the studies examining self-reported driving difficulty as an outcome of cataract surgery. Although driving difficulty has not been examined as part of a RCT, all identified studies suggested an association between cataract surgery and decreased self-reported driving difficulty. The majority of studies however, did not define whether participants had undergone surgery on the first, second or both eyes, or analysed all participants together (Bevin, Derrett & Molteno 2004; Mamidipudi et al. 2003; McGwin et al. 2003b; Monestam, Lundquist & Wachtmeister 2005; Monestam & Lundqvist 2006; Monestam & Wachtmeister 1997; Owsley et al. 2002).

Results from a prospective study by Castells et al. revealed that among those who underwent only first eye surgery, 89% reported improved driving difficulty during the day and 79% at night (Castells et al. 1999). For second eye patients, 100% reported improvement with day and night driving after surgery. Interestingly, among first eye patients, 11% and 7% respectively reported more difficulty with day and night driving after surgery and 14% reported no change with night driving (Castells et al. 1999). Another small study reported significant improvements in both day and night driving following first eye surgery but improvements only in night driving following second eye surgery (Elliott et al. 2000). Finally, Monestam et al. found no significant difference in driving difficulty depending on whether a patient had surgery on one or both eyes during a five year follow up period (Monestam &

Lundqvist 2006). However, this study included participants with both unilateral and bilateral cataract and the authors acknowledge that this finding most likely occurred because those who elected to have only one surgery during the study period, probably only had one cataract (Monestam & Lundqvist 2006).

The majority of studies measured driving difficulty with general questionnaires that contained only two driving-related items addressing day and night driving (Bevin, Derrett & Molteno 2004; Castells et al. 1999; Elliott et al. 2000; Mamidipudi et al. 2003; McGwin et al. 2003b). Others added further driving-related items including distance estimation, traffic signs, glare and pedestrians but did not provide reliability or validity estimates (Monestam, Lundquist & Wachtmeister 2005; Monestam & Lundqvist 2006; Monestam & Wachtmeister 1997). Only Owsley et al. used the validated, eight item Driving Habits Questionnaire (Owsley et al. 2002).

2.4.5 Visual Standards for Driving in Western Australia

In Western Australia, all drivers are required to pass a vision test at initial licensing, at age 75, age 78, annually from age 80 and at any other time a visual condition is reported to the Department of Transport, Western Australia (Austroads 2006). The test is a simple measure of visual acuity and drivers meet the criteria for licensing if they are able to read the 0.30 logMAR line of the chart, making no more than two errors, with the better eye or with both eyes together. Drivers may also be referred to an Ophthalmologist or Optometrist for visual field testing but only if visual field defect is actually suspected and reported (Austroads 2006). Drivers with cataract are subjected to the same visual standards for licensing. These standards remain a contentious issue and have been widely criticised for being “arbitrary” and not reflective of the complex visual skills necessary for driving (Bohensky et al. 2008; Owsley & McGwin 1999; Desapriya et al. 2011).

2.4.6 Visual Measures and Driving Outcomes for Cataract Patients

Five studies have examined visual measures associated with driving outcomes for cataract patients, with conflicting results. A cross-sectional analysis of 274 older drivers with cataract and 103 without cataract performed as part of the ICOM study, reported that log contrast sensitivity worse than 1.25 was the only independent predictor of crash involvement in the previous five years (Owsley et al. 2001). This relationship was stronger for worse eye contrast sensitivity (OR=7.86; 95% CI= 1.55- 39.79) than better eye (OR=3.78; 95% CI= 1.15-12.48) and impaired contrast sensitivity increased crash risk even when only one eye was affected (Owsley et al. 2001). Visual acuity and disability glare measures were not independently associated with crash risk (Owsley et al. 2001). However, the retrospective design of this analysis only allowed participants' vision to be measured at the end of the five-year study period (Owsley et al. 2001).

An Australian study including 48 drivers with cataract also reported that the contrast sensitivity measure was most strongly associated with self-reported driving difficulty, followed by worse eye visual acuity (Walker, Anstey & Lord 2006). In a cross-sectional analysis of 384 drivers (three quarters with cataract), independent associations between different visual measures and difficulty on specific driving items on the Driving Habits Questionnaire were assessed (McGwin, Chapman & Owsley 2000). In contrast, this analysis reported that visual acuity was the only measure associated with overall driving difficulty. Specifically, a better-eye visual acuity of worse than 0.2 logMAR was associated with difficulty on more visually demanding driving tasks including driving in high traffic, in peak hour, at night and making turns across traffic (McGwin, Chapman & Owsley 2000). Better eye contrast sensitivity was associated with difficulty making turns and disability glare was not associated with any tasks (McGwin, Chapman & Owsley 2000). This contrast in findings may be due to only better eye values being included in the analysis.

A prospective analysis of 156 participants who underwent cataract surgery as part of the ICOM study later reported that changes in visual acuity and contrast sensitivity in the first operated eye after surgery, were significantly associated with change in night driving but not day driving difficulty (McGwin et al. 2003b). Change in disability glare was not associated with either day or night driving. This analysis included patients who had undergone cataract surgery on one or both eyes (McGwin et al. 2003b). A closed-circuit study reported that changes in driving performance of 29 drivers following bilateral cataract surgery were only associated with change in contrast sensitivity in the second-operated eye but not changes in visual acuity, disability glare or kinetic field measures (Wood & Carberry 2006).

2.4.7 Driving Difficulty: Gaps in the Evidence

While evidence suggests that cataract surgery is beneficial for driving outcomes, the separate effects of first and second eye surgery on self-reported driving difficulty is currently unclear. Only two studies have examined first or second eye surgery separately and both included only two simple questions concerning day and night driving (Castells et al. 1999; Elliott et al. 2000). Further research using a detailed and validated driving difficulty questionnaire would provide valuable information on the specific driving difficulties bilateral cataract patients experience before and after first eye surgery and how surgery influences these. It is also reported that a number of bilateral cataract patients continue to experience some visual impairment after first eye surgery (Acosta-Rojas et al. 2006; Comas et al. 2007) and that a visual acuity test may be inadequate for identifying those who are at risk on the road (Desapriya et al. 2011). It would therefore be useful to determine which visual factors are associated with improvement and non-improvement in driving difficulty after first eye surgery. Finally, although it has been demonstrated that stereopsis often remains affected after first eye surgery (Castells et al. 2006), to date no studies examining cataract surgery and self-reported driving difficulty have collected data on this visual measure.

Table 2.1 Studies Examining Cataract Surgery and Self-Reported Driving Difficulty

Study	Country	Study Design	Participants (drivers)	Instrument	First or Second Eye Surgery	Findings
Bevin et al. 2004	New Zealand	Prospective cohort	- 29 surgery - No controls	- VF-14	Not specified	- Significant decrease in proportion experiencing difficulty with day and night driving after surgery
Castells et al. 1999	Spain	Cohort analysis of RCT	- 249 first eye surgery - 66 second eye surgery	- VF-14	First and second eye analysed separately	- Majority of first eye and all of second eye group improved in day and night driving score after surgery
Elliot et al. 2000	Canada	Prospective cohort	- 17 first eye surgery - 25 second eye surgery - 25 no cataract	- ADVS	First and second eye analysed separately	- Significant improvement in day and night driving scores after first eye surgery - Significant improvement in night driving score only after second eye surgery
Mamidipudi et al. 2003	India	Prospective cohort	- 116 surgery - No controls	- NEI VFQ-25 (modified)	Not specified	- Significant improvement in day and night driving after surgery
McGwin et al. 2003b[1]	USA	Prospective cohort	- 156 surgery - 89 no surgery	- ADVS	First or both eyes combined	- Significant improvement in day and night driving scores for surgery group after surgery - No significant change in scores for non-surgery group

Study	Country	Study Design	Participants (drivers)	Instrument	First or Second Eye Surgery	Findings
Monestam & Wachtmeister 1997	Sweden	Prospective cohort	- 19 surgery - No controls	- Not specified	First, second or both eyes combined	- Significant decrease in proportion experiencing visual problems while driving after surgery
Monestam et al. 2005; Monestam & Lundqvist 2006	Sweden	Prospective cohort	- 189 surgery - No controls	- VF-14 - Additional items	First, second or both eyes combined	- Significant decrease in proportion experiencing any difficulty with day and night driving five years after surgery - No significant difference in driving difficulty between those who had first or both eye surgeries
Owsley et al. 2002[1]	USA	Prospective cohort	- 174 surgery - 103 no surgery	- Driving Habits Questionnaire	First or both eyes combined	- No significant difference between groups in driving difficulty at first annual follow up after surgery - Significantly less driving difficulty for surgery group at second annual follow up

Instrument abbreviations: ADVS, Activities of Daily Vision Scale; NEI VFQ-25, 25 Item National Eye Institute Visual Function Questionnaire; VF-14, Visual Function Index

[1] Results from same study using different measurement instruments

2.5 Cataract Surgery and Vision-Related Quality of Life

Objective visual measures have often been used to describe impairment due to cataract and improvement after cataract surgery. It is recognised though, that these measures may not accurately reflect the impact of visual impairment on an individual's performance of everyday tasks, participation in social activities or mental health (Margolis et al. 2002). Health-related quality of life (HRQOL) is now recognised as an important element in the evaluation of health interventions, including cataract surgery (Elliott, Pesudovs & Mallinson 2007). It can be defined as the "physical, psychological and social domains of health, seen as distinct areas that are influenced by a person's experiences, beliefs, expectations and perceptions" (Testa & Simonson 1996).

This attention on HRQOL has led to the development of self-report instruments that aim to specifically measure the impact of visual impairment on daily activities and HRQOL; an outcome often referred to as vision-related quality of life (VRQOL) (de Boer et al. 2004; Elliott, Pesudovs & Mallinson 2007; Margolis et al. 2002). While several cataract-specific VRQOL instruments have been developed, a recent review found weaknesses with these scales including poor validity, ceiling effects and suboptimal targeting (Lundstrom & Pesudovs 2011). In addition, the majority of VRQOL questionnaires focus only on the impact of vision on daily activities. However, recent questionnaires have included more multidimensional assessments of HRQOL, incorporating emotional and social well being (de Boer et al. 2004; Mangione et al. 2001; Margolis et al. 2002). The 25 item National Eye Institute Visual Function Questionnaire (NEI VFQ-25) has been validated for cataract patients; it addresses a wide range of visual concerns and includes social and mental outcomes of visual impairment (Mangione et al. 2001). VRQOL and the more generic HRQOL have been widely assessed as outcomes of cataract surgery. Evidence on the impact of cataract and cataract surgery on these outcomes will be discussed and visual measures associated with VRQOL reviewed.

2.5.1 Impact of Cataract on Vision-Related Quality of Life

The majority of studies confirm that cataract negatively impacts VRQOL (Broman et al. 2002; Nanayakkara 2009; Wu et al. 2008). Evidence also suggests an association between cataract and poorer outcomes on more general HRQOL measures (Knudtson et al. 2005; Nanayakkara 2009; Polack et al. 2008). This implies that cataract can lead to impairment beyond vision-specific functioning and can impact on general health and well being (Polack et al. 2008). Poorer quality of life outcomes have also been demonstrated for those with only one cataract (Knudtson et al. 2005) and increased cataract severity has been associated with decreased VRQOL (Nischler et al. 2010).

2.5.2 Impact of Cataract Surgery on Vision-Related Quality of Life

Twenty studies were identified examining change in VRQOL or HRQOL after cataract surgery and details are presented in Table 2.2. Ten studies reported that first eye cataract surgery was associated with significantly improved VRQOL (Castells et al. 1999; Castells et al. 2006; Elliott et al. 2000; Gray et al. 2006; Gutierrez et al. 2009; Harwood et al. 2005; Javitt et al. 1995; Mamidipudi et al. 2003; Norregaard et al. 2003; Walker et al. 2006). Four studies also reported improved VRQOL following second eye cataract surgery (Castells et al. 1999; Elliott et al. 2000; Foss et al. 2006; Gray et al. 2006) and five after surgery in both eyes (Castells et al. 2006; Ishii, Kabata & Oshika 2008; Javitt et al. 1995; Oshika et al. 2005; Zhang et al. 2011). Other studies combined first, second or both eye patients in the analyses but all still reported significant improvements in VRQOL following surgery (Black et al. 2009; McGwin et al. 2003b; Owsley et al. 2007; Pager, McCluskey & Retsas 2004; Lundqvist & Monestam 2008). Only one study examining cataract surgery in both eyes did not support these findings, however this study contained only seven participants who had both surgeries (Gray et al. 2006).

Studies examining the association between cataract surgery and more generic HRQOL outcomes have reported mixed results. Three studies reported a significant improvement in HRQOL after first eye surgery (Castells et al. 1999; Castells et al. 2006; Harwood et al. 2005) but a small RCT by Elliot et al. found no significant change (Elliott et al. 2000). This trial however, did find a significant improvement in HRQOL after second eye surgery (Elliott et al. 2000), while two other RCTs did not find any change (Foss et al. 2006; Laidlaw et al. 1998). A Spanish prospective study reported improved psychosocial HRQOL scores after second surgery but no change in physical or overall HRQOL scores (Castells et al. 1999). Only one study examined the impact of cataract surgery in both eyes and reported a significant improvement (Castells et al. 2006). Other studies combining first, second or both eye surgeries in the analyses also provided mixed results regarding impact on HRQOL (Black et al. 2009; Owsley et al. 2007; Pager, McCluskey & Retsas 2004; Lundqvist & Monestam 2008).

Evidence clearly indicates that first eye cataract surgery is beneficial for VRQOL and suggests that second eye surgery brings about additional benefits (Lamoureux et al. 2010). A Spanish RCT comparing the effects of first or both eye cataract surgery reported that after controlling for confounding factors, those who had both eye surgeries had significantly better Visual Function Index (VF-14) scores than those who had first eye surgery only (Castells et al. 2006). The authors estimated that first eye surgery contributed to 70.9% of the overall change in VF-14 score while the second surgery contributed 29.1% (Castells et al. 2006). While a large United Kingdom (UK)-based prospective study found that VF-14 scores improved overall after first or second eye cataract surgery, they noted that 25% of participants actually experienced no change or got worse (Black et al. 2009).

2.5.3 Visual Measures and Vision-Related Quality of Life for Cataract Patients

Fewer studies have investigated the association between objective measures of vision and VRQOL for cataract patients. A prospective study of 104 bilateral cataract patients from Spain reported that the influence of visual measures on VRQOL actually changed throughout the different stages of cataract surgery (Acosta-Rojas et al. 2006). Before first eye surgery when participants' vision was the worst, binocular visual acuity was strongly associated with VF-14 score. However, after first and after second eye surgery, when participants' vision was better, stereopsis was most strongly associated with VF-14 score, followed by binocular contrast sensitivity, with visual acuity showing only a weak association (Acosta-Rojas et al. 2006).

Similarly, a study of 289 elderly women with bilateral cataract in the UK reported that binocular visual acuity was the measure most strongly associated with VF-14 score before surgery. (Datta et al. 2008). The association between change in visual measures and change in VF-14 score was then examined for 154 women who underwent first eye surgery (Datta et al. 2008). Change in VF-14 score after surgery was found to be most strongly associated with change in stereopsis, followed by binocular contrast sensitivity and least associated with change in visual acuity (Datta et al. 2008). A low correlation between change in visual acuity and change in VRQOL was also reported in a study from Finland (Uusitalo et al. 1999). The only conflicting results were from the McGwin et al. study which found that change in visual acuity in the first surgery eye and disability glare but not contrast sensitivity were associated with change in Activities of Daily Vision Scale (ADVS) score in 156 patients who underwent first or both eye cataract surgeries. Stereopsis was not examined in this study (McGwin et al. 2003b).

2.5.4 Vision-Related Quality of Life: Gaps in the Evidence

While cataract surgery is clearly beneficial for VRQOL, little research has been conducted in Australia and most studies have included few drivers in their samples. In addition, the majority of research has used the VF-14 to measure VRQOL. This instrument has been criticised for not addressing all the visual concerns of cataract patients (Bellan 2005), being highly focused on activities that require visual acuity (Datta et al. 2008) and having ceiling effects (Acosta-Rojas et al. 2006; Castells et al. 1999; Datta et al. 2008). The NEI VFQ-25 addresses a wider range of visual concerns and includes social and mental outcomes of visual impairment (Mangione et al. 2001).

Further research using such instruments would allow investigation into which specific aspects of VRQOL improve after cataract surgery and which remain affected. Finally, further research is required to determine visual measures associated with change in VRQOL after surgery. Such information could be used to identify patients who improve or decline in VRQOL after first eye surgery.

Table 2.2 Studies Examining Cataract Surgery and Vision-Related or Health-Related Quality of Life

Study	Country	Study Design	Participants	Instrument	First or Second Eye Surgery	Findings
Bilbao et al. 2009	Spain	Prospective cohort	- 4356 surgery - No controls	- VF-14 - SF-36	First or second eye combined	- Significant improvement in VF-14 and SF-36 scores after surgery
Black et al. 2009	UK	Prospective cohort	- 861 surgery - No controls	- VF-14 - EuroQol	First or second eye combined	- Significant improvement in VF-14 score after surgery - Significant decline in EuroQol score after surgery
Castells et al. 1999	Spain	Prospective cohort	- 249 first eye surgery - 66 second eye surgery	- VF-14 - SIP	First or second eye compared	- Significant improvement in VF-14 and psychosocial SIP scores after surgery for first and second eye groups - Significant improvement in global and physical SIP scores after surgery for first eye group only
Castells et al. 2006	Spain	RCT	- 135 first eye surgery - 139 both eye surgeries	- VF-14 - SF-12	First or both eyes compared	- Significant improvement in VF-14 and SF-12 scores for first and both eye surgeries groups - Significantly better VF-14 and mental SF-12 scores for both eye surgeries group at follow up - No significant difference between groups for physical SF-12 scores

Study	Country	Study Design	Participants	Instrument	First or Second Eye Surgery	Findings
Elliott et al. 2000	Canada	Prospective cohort	- 17 first eye surgery - 25 second eye surgery - 25 no cataract	- ADVS - PIADS (modified)	First or second eye analysed separately	- Significant improvement in ADVS score for first and second eye surgery groups - No significant improvement in PIADS score for first eye surgery group - Significant improvement in PIADS score for second eye surgery group
Foss et al. 2006	UK	RCT	- 120 surgery - 119 no surgery (women aged over 70 years)	- VF-14 - EuroQol	Second eye	- Significantly better VF-14 scores for surgery group at follow up - No significant difference between groups for Euroqol score at follow up
Gray et al. 2006	UK	Prospective cohort	- 46 first eye surgery - 39 second eye surgery - 7 both eye surgeries	- VF-14	First, second or both eyes analysed separately	- Significant improvement in VF-14 scores for first and second eye groups after surgery - No significant change in VF-14 score for both eye surgery group
Gutiérrez et al. 2009	Spain	Prospective cohort	- 4336 surgery - No controls	- VF-14	First eye	- Significant improvement in VF-14 score after surgery

Study	Country	Study Design	Participants	Instrument	First or Second Eye Surgery	Findings
Harwood et al. 2005	UK	RCT	- 154 surgery - 152 no surgery (women aged over 70 years)	- VF-14 - EuroQol	First eye	- Significantly better VF-14 and Euroqol scores for surgery group at follow up
Ishii et al. 2008	Japan	Prospective cohort	- 102 surgery - No controls	- NEI VFQ-25	Both eyes	- Significant improvement on all NEI VFQ-25 subscales after surgery except general health
Javitt et al. 1995	USA	Prospective cohort	- 425 first eye surgery - 243 both eye surgeries	- VF-14	First or both eyes compared	- Significant improvement in VF-14 score for first and both eye surgery groups - Significantly greater improvement in VF-14 score for both eye surgeries group
Laidlaw et al. 1998	UK	RCT	- 105 surgery - 103 no surgery	- SF-36 - Additional questions	Second eye	- No significant difference between groups for SF-36 score - Significantly better outcomes for surgery group on additional questions
Mamidipudi et al. 2003	India	Prospective cohort	- 300 surgery - No controls	- NEI VFQ-25 (extensively modified)	First eye	- Significant improvement on modified NEI VFQ-25 subscale scores after surgery
McGwin et al. 2003b	USA	Prospective cohort	- 156 surgery - 89 no surgery	- ADVS	First or both eyes combined	- Significantly better ADVS score for surgery group at follow up

Study	Country	Study Design	Participants	Instrument	First or Second Eye Surgery	Findings
Norregaard et al. 2003	Canada, Denmark, Spain, USA	Prospective cohort	- 1073 surgery - No controls	- VF-14	First eye	- Significant improvement in VF-14 after surgery for all four countries
Oshika et al. 2005	Japan	Prospective cohort	- 110 surgery - 30 no cataract	- NEI VFQ-25	Both eyes	- Significant improvement in NEI VFQ scores after surgery to levels of no cataract group
Owsley et al. 2007	USA	Prospective cohort	- 30 surgery - 15 no surgery (nursing home residents)	- NHVQoL - VF-14 - SF-36	First or second eyes combined	- Significantly better NHVQoL and VF-14 scores for surgery group at follow up - No significant difference between groups for SF-36 scores
Pager et al. 2004	Australia	Prospective cohort	- 111 surgery - No controls	- VF-14 - SF-36	Not specified	- Significant improvement in VF-14 scores after surgery - No significant change in SF-36 scores after surgery
Walker et al. 2006	Australia	RCT	- 25 surgery - 20 no surgery	- VF-14	First eye	- Significantly better VF-14 scores for surgery group at follow up
Zhang et al. 2011	USA	Prospective cohort	- 43 surgery - No controls	- NEI VFQ-25	Both eyes	- Significant improvement in all NEI VFQ-25 subscales after surgery except general health

Instrument abbreviations: ADVS, Activities of Daily Vision Scale; NEI VFQ-25, 25 Item National Eye Institute Visual Function Questionnaire; NHVQoL, Nursing Home Vision-Targeted Health-Related Quality of Life Questionnaire; PIADS, Psychosocial Impact of Assistive Devices Questionnaire; SF-12, 12 Item Short Form Health Survey; SF-36, 36 Item Short Form Health Survey; SIP, Sickness Impact Profile; VF-14, Visual Function Index.

2.6 Cataract Surgery and Depressive Symptoms

Depression is a major health issue for older Australians and it is estimated that between six and 20% of community-dwelling older people experience depression (Cole & Dendukuri 2003; Pirkis et al. 2009). Depression can seriously affect the physical and mental health of older people and may exacerbate medical conditions, increase mortality and result in higher use of health services (National Ageing Research Institute 2009). The relationship between cataract, cataract surgery and depressive symptoms is currently less clear than for VRQOL. This may be due to depression being a complex construct with multi-factorial causes and pathways (Cole & Dendukuri 2003). While cataract surgery may restore vision, this may not necessarily exert a significant impact on depressive symptoms. Length of time with visual impairment due to cataract may also affect depressive symptoms in older adults. Evidence on the impact of cataract and cataract surgery on depressive symptoms will be discussed and visual measures associated with depressive symptoms reviewed.

2.6.1 Impact of Cataract on Depressive Symptoms

While a strong association between visual impairment and increased depressive symptoms in older adults has been established (Hayman et al. 2007; Huang et al. 2010), the relationship between cataract and depressive symptoms is unknown. Freeman et al. reported that among 672 patients awaiting first eye cataract surgery in Canada, 26% showed signs of depressive symptoms (Freeman et al. 2009). They also found that those with poor visual acuity in the surgery eye had 59% higher odds of depressive symptoms after adjustment for confounding factors (OR= 1.59, 95% CI= 1.09-2.33) (Freeman et al. 2009).

2.6.2 Impact of Cataract Surgery on Depressive Symptoms

Table 2.3 details the studies examining depressive symptoms as an outcome of cataract surgery. Four studies have examined the association between first eye cataract surgery and depressive symptoms and report mixed results. A small RCT conducted in Australia compared 25 bilateral cataract patients aged 55 years and over who underwent first eye surgery to 20 controls who did not and reported no significant change in depressive symptoms from baseline to three month follow up (Walker, Anstey & Lord 2006). The authors acknowledge that the power to detect clinically meaningful changes in this study was low (Walker, Anstey & Lord 2006). Similarly, a longitudinal study conducted in the USA followed 122 cataract patients aged 55 years and over who had first eye cataract surgery and 92 who did not for one year and also reported no significant difference between groups in depressive symptoms (McGwin et al. 2006). However, a large UK-based RCT of women aged over 70 years reported a small improvement in depressive symptoms after first eye surgery, compared to a no surgery group who deteriorated over the follow up period (Harwood et al. 2005). Another prospective study in the UK including 46 first eye cataract patients aged over 65 years reported significant decreases in depressive symptoms following surgery. However, there was no control group for comparison (Gray et al. 2006). Results indicate that first eye surgery may potentially have a small impact on depressive symptoms but to date, only studies including more elderly participants have reported significant results.

Two studies examined the association between second eye cataract surgery and depressive symptoms. The study by Gray et al. also included 39 second eye cataract patients and reported a significant improvement in depressive symptoms after surgery (Gray et al. 2006). However, another UK-based RCT reported no significant difference in depressive symptoms between 120 women aged over 70 years who underwent second eye surgery and 119 who did not (Foss et al. 2006).

Other studies examining cataract surgery and depressive symptoms included patients who received first, second or both eye surgeries in the analysis and again, reported mixed results. The study by Gray et al. (2006) also reported a significant improvement in depressive symptoms for seven patients who received surgery in both eyes (Gray et al.

2006), while a Japanese study reported no significant improvement following surgery in both eyes (Ishii, Kabata & Oshika 2008). Three additional studies included both first and second eye patients in their analysis and reported small or no changes in depressive symptoms (Pesudovs, Weisinger & Coster 2003; McGwin et al. 2003a; Owsley et al. 2007).

In summary, the best evidence to date on the impact of first eye cataract surgery on depressive symptoms comes from the RCT by Harwood et al. (2005) which reported a small but significant improvement in depressive symptoms. It should be noted that this study included only women in the sample. The vast majority of other studies to date have found no significant change in depressive symptoms after first and/or second eye cataract surgery. However, this may be due to study limitations including small samples of less than 50 patients per group (Gray et al. 2006; Owsley et al. 2007; Pesudovs, Weisinger & Coster 2003; Walker et al. 2006), lack of control group (Ishii, Kabata & Oshika 2008; Pesudovs, Weisinger & Coster 2003) or the combination of patients undergoing first, second or both eye surgeries in the samples (Pesudovs, Weisinger & Coster 2003; McGwin et al. 2003a; Owsley et al. 2007).

2.6.3 Visual Measures and Depressive Symptoms for Cataract Patients

Very few studies have investigated the association between objective measures of vision and depressive symptoms or change in depressive symptoms after surgery. In fact, the majority have only measured visual acuity. In a secondary analysis of the previously described RCT of women aged over 70 years, poorer binocular visual acuity was found to be associated with depressive symptoms before first eye surgery, while contrast sensitivity and stereopsis were not (Datta et al. 2008). However, change in depressive symptoms after surgery was not associated with changes in any of the visual measures (Datta et al. 2008). A larger, Canadian prospective study of 672 cataract patients awaiting first eye surgery also reported that poor visual acuity in the worse eye was associated with higher odds of depressive symptoms (OR=1.59; 95% CI= 1.09-2.33), but better eye visual acuity was not associated with depressive symptoms (Freeman et al. 2009). This study did not examine any other visual measures (Freeman et al. 2009).

2.6.4 Depressive Symptoms: Gaps in the Evidence

Further research is required to separately analyse the impact of first and second eye surgery on depressive symptoms for bilateral cataract patients. In addition, existing studies have included few drivers in their samples. Since driving cessation and driving limitation have been linked to depressive symptoms in older adults (Fonda, Wallace & Herzog 2001; Windsor et al. 2007), it is possible that cataract surgery may have a more pronounced effect on depressive symptoms in patients who drive. Finally, further research into whether any visual measures are associated with depressive symptoms or change in depressive symptoms after surgery would be beneficial.

2.7 Summary

Overall, current literature suggests that cataract surgery is beneficial for self-reported driving difficulty and VRQOL, but its impact on depressive symptoms is unknown. Despite possible benefits, to date, the separate effects of first and second eye cataract surgery on these outcomes are unclear. In terms of measurement, self-reported driving difficulty has predominantly been examined using only two simple questions concerning day and night driving. Therefore, a gap in the evidence exists surrounding the impact of first eye cataract surgery on specific driving difficulties experienced by bilateral cataract patients. Similarly, the majority of research on cataract surgery and VRQOL has used instruments that focus on the impact of visual impairment on daily activities, without including social and mental aspects of quality of life. How cataract surgery impacts on VRQOL and depression for cataract patients who drive is also not well understood, as studies have included few drivers in their samples. Finally, it has been reported that some bilateral cataract patients continue to experience driving difficulty, poor VRQOL or depressive symptoms after first eye surgery. Although it is known that stereopsis often remains affected after first eye surgery, few studies have collected data on this visual measure. It would therefore be useful to examine whether changes in driving difficulty, VRQOL and depressive symptoms after surgery (including improvement and non-improvement) are associated with particular changes in objective visual measures.

Table 2.3 Studies Examining Cataract Surgery and Depressive Symptoms

Study	Country	Study Design	Participants	Instrument	First or second eye surgery	Findings
Foss et al. 2006	UK	RCT	- 120 surgery - 119 no surgery	- HADS	Second eye	- No significant difference between groups in HADS score after surgery
Gray et al. 2006	UK	Prospective cohort	- 46 first eye surgery - 39 second eye surgery - 7 both eye surgeries	- BDI	First, second or both eyes analysed separately	- Significant improvement in BDI score after surgery in first, second and both eye surgeries groups
Ishii et al. 2008	Japan	Prospective cohort	- 102 surgery - No controls -	- BDI	Both eyes	- Significant improvement in BDI score after surgeries
Harwood et al. 2005	UK	RCT	- 154 surgery - 152 no surgery - (women over 70)	- HADS	First eye	- Small but significant improvement in HADS score for surgery group
McGwin et al. 2003a	USA	Prospective cohort	- 146 surgery - 104 no surgery - 92 no cataract	- CES-D	First or both eyes combined	- No significant change in CES-D score for surgery group - No significant change in CES-D score for no surgery group - Significant worsening of CES-D score for no cataract group

Study	Country	Study Design	Participants	Instrument	First or second eye surgery	Findings
McGwin et al. 2006	USA	Prospective cohort	- 122 surgery - 92 no surgery	- CES-D	First eye	- No significant difference between groups in CES-D score after surgery
Pesudovs et al. 2003	Australia	Prospective cohort	- 13 surgery - No controls	- Cantrill Ladder - POMS	First or second eye combined	- Significant improvement in Cantrill Ladder score after surgery - No change in POMS score after surgery
Owsley et al. 2007	USA	Prospective cohort	- 30 surgery - 15 no surgery (nursing home residents)	- GDS	First or second eye combined	- No significant difference between groups in GDS score after surgery
Walker et al. 2006	Australia	RCT	- 25 surgery - 20 no surgery	- DASS	First eye	- No significant difference between groups in DASS score after surgery

Instrument abbreviations: BDI, Beck's Depression Inventory; CES-D, Centre for Epidemiologic Studies Depression Scale; DASS, Depression Anxiety Stress Scale; GDS, Geriatric Depression Scale; HADS, Hospital Anxiety and Depression Scale; POMS, Profile of Mood States.

CHAPTER 3

Methodology

3 METHODOLOGY

3.1 Study Design

This research utilised a before and after study design. Bilateral cataract patients who were drivers and were about to undergo first eye cataract surgery were recruited. Data were collected from study participants before they underwent the intervention of interest, first eye cataract surgery and again approximately 12 weeks after the surgery. The study was observational in nature as participants were already on the waiting list for cataract surgery and their cataract treatment or waiting time for surgery was not influenced in any way.

In Western Australia, all eligible patients with clinically significant cataract are offered surgery through the public hospital system at no financial cost. Cataract patients who drive rarely refuse this surgery. It was therefore impossible to recruit a group of drivers with bilateral cataract who did not undergo the surgery as a comparison group. It also would have been unethical to delay surgery in a group of drivers for the purposes of the study. Recruiting a group of older drivers without cataract may have provided information about the stability of the outcome variables over time, in the absence of visual impairment or cataract surgery. However, direct comparisons between groups could not have been made due to differences between groups on important baseline variables. Based on this, as well as time and resource constraints, a decision was made to not include such a comparison group. The absence of a comparison group is acknowledged as the main weakness of this study. Since it was not possible to compare those who received first eye cataract surgery with those who did not, changes in major outcomes of interest including self-reported driving difficulty, VRQOL and depressive symptoms were compared within the individual before and after surgery.

3.2 Recruitment

The study participants were recruited at pre-admission ophthalmology clinics attended by all cataract patients of Royal Perth, Sir Charles Gairdner and Fremantle Hospitals prior to cataract surgery. Each of the three hospitals held these clinics on different days or times of the week, allowing the same researcher to attend each clinic. On arrival to the clinic, the researcher received a list of all pre-admission cataract surgery appointments scheduled for the day. As each listed patient arrived at the clinic, the researcher approached them consecutively, explained the study, established eligibility, provided them with the corresponding hospital's Participant Information Sheet (Appendix A) and attempted to recruit them to the study. The hospitals' Ophthalmologists played no role in selecting participants for the study but assisted in confirming that patients met study eligibility criteria. It is acknowledged that the researcher could not attend every clinic held over the 14 month recruitment period so a small number of eligible cataract patients may have been missed. Participants were recruited consecutively until the desired total number was reached. The researchers did not intend to enrol an equal number of participants from each hospital.

3.3 Inclusion and Exclusion Criteria

The inclusion criteria for enrolment in the study were:

- Bilateral cataract as diagnosed by an Ophthalmologist
- Scheduled to undergo first eye cataract surgery within one month
- Aged 55 years or older
- Licensed to drive in Western Australia at time of recruitment
- Drove at least once a week at time of recruitment.

Exclusion criteria were:

- A diagnosis of Dementia, Alzheimer's Disease, Parkinson's Disease or significant psychosis

- Wheelchair bound
- Did not live independently in the community (e.g. in nursing home or prison)
- Had significant ocular conditions including advanced glaucoma, retinopathy or macular degeneration
- Were undergoing combined ocular surgery (e.g. cataract and vitrectomy)
- Were undergoing cataract surgery for the second time on the same eye
- Resided outside the Perth metropolitan area
- Non-English speaking.

3.4 Sample Size

Target enrolment of approximately 100 participants was based on the self-reported driving difficulty outcome obtained from the Driving Habits Questionnaire (Owsley et al. 1999). Sample size was estimated using an equation for comparing two means for repeated measures.

$$n = \frac{(z_{\alpha} + z_{\beta})^2 \sigma^2}{(\mu_t - \mu_p)^2}$$

(Chow, Shao & Wan 2008)p. 56)

Self-reported driving difficulty was measured on a scale of zero to 100 (Owsley et al. 1999). Previous studies indicated that a five point change on the driving difficulty scale represented a clinically meaningful difference ($\mu_t - \mu_p = 5$). This was defined as the mean score at second data collection (μ_t) minus the mean score at the first data collection (μ_p). The estimated standard deviation (SD) of the scale (σ) was 17% (Owsley et al. 2002; Ross et al. 2009). The above equation indicated that a sample size of approximately 100 participants assessed before and after surgery (n=91) would be sufficient to detect a five point change between assessments at a 5% significance level ($z_{\alpha} = 1.96$) with 80% power ($z_{\beta} = 0.84$). Recruiting approximately 100 cataract patients allowed for a drop-out rate of 9%.

The VRQOL outcome measured by the NEI VFQ-25 was also scored on a scale of one to 100 and the composite score was reported to have a SD of 20 points (Mangione et al. 2001). The sample size calculation indicated that recruiting 100 participants would be adequate to detect a clinically significant change of six points on the composite VRQOL score (n=89) and on the 12 subscale scores ($\alpha = 0.05$; power = 80%) (Mangione et al. 2001). Depressive symptoms, measured by the Centre for Epidemiologic Studies Depression Scale (CES-D) was scored on a scale of zero to 60 and had an estimated SD of 13 points (Radloff 1977). Calculations also indicated that 100 participants would be adequate to detect a change of four points on this scale at a 5% significance level with 80% power (n=83).

3.5 Study Sample

The final study sample of 99 cataract patients were recruited between 15 October 2009 and 15 December 2010 from Royal Perth (n=55, 55.6%), Sir Charles Gairdner (n=32, 32.3%) and Fremantle Hospitals (n=12, 12.1%) in Perth, Western Australia. All participants were on the waiting list for first eye cataract surgery and were scheduled to undergo the surgery within the next month. A convenience sampling method was used to recruit eligible participants from the Ophthalmology Departments of the three hospitals. These three major hospitals perform approximately half of the cataract surgeries within the public hospital system in Perth, Western Australia.

During this period, 830 cataract patients were reviewed for eligibility (Figure 3.1). Those undergoing second eye surgery were immediately excluded (n=383). Remaining patients undergoing first eye surgery were excluded for reasons including: aged under 55 years (n=56), non-English speaking (n=28), other significant ocular conditions (n=27), residing outside the Perth metropolitan area (n=22), intellectual/ mental disability or not living independently in the community (n=20) undergoing combined cataract and other ocular surgery (n=17), unilateral cataract (n=12) and second cataract surgery in the same eye (n=4).

Of the remaining 261 patients, 58% were excluded due to being non-drivers (n=152), leaving 109 patients who met all eligibility criteria. The response rate was high (93%) and 101 patients agreed to participate. The drop-out rate was 2% with only two of the 101 participants completing the data collection before but not after surgery. These two were eliminated from the analyses, leaving a final sample size of 99 participants.

Figure 3.1 Flowchart of Study Sample

830
Listed for cataract surgery

Ineligible: 383
Listed for second eye surgery

447
Listed for first eye surgery

Ineligible: 186
Met exclusion criteria

261
Met inclusion criteria

Ineligible: 152
Not current drivers

109
Current drivers

8
Declined to participate

101
Recruited

2
Lost to follow-up

99
Completed study

3.6 Data Collection

The principal researcher performed all participant recruitment and data collection. Data were collected at two points for each participant. The initial data collection was performed, on average, one week before each participant's first eye cataract surgery. This ranged from zero to 5.9 weeks due to a small number of scheduled surgeries being postponed. Follow-up data collection occurred, on average, 12.4 weeks after first eye cataract surgery with the majority (78.8%) occurring between 11 and 14 weeks after surgery. However, this ranged from 4.4 to 21.6 weeks because some patients were scheduled for early second eye cataract surgery and others were not available for data collection until later. No participant had undergone second eye cataract surgery at the time of the follow-up data collection.

Cataract patients who met study eligibility criteria and agreed to participate were enrolled during their pre-admission clinic visit. At this time the researcher recorded the participant's name, address and phone number and made an appointment to conduct the initial data collection during the week prior to cataract surgery. For the second data collection, the researcher phoned participants one week prior to the assessment due date at 12 weeks after surgery, and made an appointment for a convenient time. The researcher collected all data in the participants' own homes.

Data collection could not take place at recruitment during the pre-admission clinic visits because the clinics ran on tight schedules and patients were given dilating eye drops on arrival that affected their vision for several hours. Data collection was conducted in participants' homes rather than asking them to travel back to the hospital or to Curtin University. This increased convenience for participants, decreased road safety risks associated with older cataract patients driving to an unfamiliar location and increased the study's response rate.

The before and after surgery data collection procedures were identical and took between 60 and 75 minutes to complete. Participants received a Participant Information Sheet, had the chance to ask questions and signed a consent form (Appendix B) at recruitment, before any data were collected. Each data collection consisted of visual and cognitive tests and a researcher-administered questionnaire. Participants' medical records were reviewed following surgery to confirm self-reported chronic health conditions, other ocular conditions and to obtain information on intra-operative or post-operative complications of cataract surgery.

3.7 Ethical Considerations

The project was approved by the Curtin University, Royal Perth Hospital, Sir Charles Gairdner Hospital and the South Metropolitan Area Health Service Human Research Ethics Committees (Appendix C). Ethics approval allowed researchers to recruit and assess participants and to review their medical records. This research conformed to the principles of the Declaration of Helsinki (World Medical Association 2008) and the National Health and Medical Research Council's National Statement on Ethical Conduct in Human Research (NHMRC 2007).

At recruitment, prior to any data being collected, the purpose of the study was explained to all participants. They were given a Participant Information Sheet, had the opportunity to ask questions and their written consent was obtained. To ensure participants were cognitively able to provide consent, those diagnosed with dementia or Alzheimer's Disease or who did not live independently in the community (in a nursing home or in prison) were excluded. All cataract patients were informed that participation was entirely voluntary and they could withdraw from the study at any time without consequence for their current or future cataract treatment. Participants were also assured that all information collected would be kept strictly confidential and used purely for the purpose of this study. No information was passed onto treating Ophthalmologists, general practitioners or the Department of Transport, Western Australia in charge of driver licensing.

Participants were also informed that if low visual acuity that did not meet the criteria for an unconditional drivers licence in WA (worse than 0.30 logMAR) was found by the researcher, they would be advised not to drive until they had been seen by their Ophthalmologist. The Ophthalmologists met their duty of care obligations by informing the patient that they should not drive until they had their vision re-assessed after cataract surgery. If the patient's visual acuity was unlikely to improve in the near future, the Ophthalmologist informed the patient that under Western Australia's mandatory reporting of medical conditions legislation, it was the patient's obligation to inform the Department of Transport. It was then the Department of Transport's responsibility to decide if a medical or practical driving assessment was necessary, a licence with conditions should be granted or no further action was required.

All visual assessments conducted as part of this study were non-invasive, simply asked participants to identify letters or pictures and posed no risk. Identified information was used in this study but was accessed only by the principal researcher to allow home visits to be arranged. All raw data were securely stored in a locked filing cabinet in the School of Public Health, Curtin University and will be retained for a period of five years. Lists linking participant identification numbers to participants' identifying details were destroyed once data collection was complete and remaining raw and electronic data were de-identified and contained only participant identification numbers.

3.8 Study Instruments

Data were collected on visual, cognitive, demographic, health, driving, VRQOL and depressive symptom variables. The instruments used for data collection in this study are summarised in Table 3.1. Approval for instrument use was obtained from the author/s where required.

Table 3.1 Study Instruments

Variables	Measurement Instrument
Objective visual tests	
Visual acuity	Early Treatment Diabetic Retinopathy Study (ETDRS) chart (Ferris et al. 1982)
Contrast sensitivity	Pelli-Robson chart (Pelli, Robson & Wilkins 1988)
Stereopsis	Titmus Fly Stereotest (Stereo Optical Co., Inc.)
Cognitive tests	
Cognition	Mini Mental State Examination (MMSE) (Folstein, Folstein & McHugh 1975)
Useful field of view	UFOV® test software (Visual Awareness, Inc.)
Self-reported variables	
Demographic and health information	Researcher- administered questionnaire and medical record review
Driving difficulty and exposure	Driving Habits Questionnaire (Owsley et al. 1999)
VRQOL	NEI VFQ-25 (Mangione et al. 2001)
Depressive symptoms	CES-D (Radloff 1977)

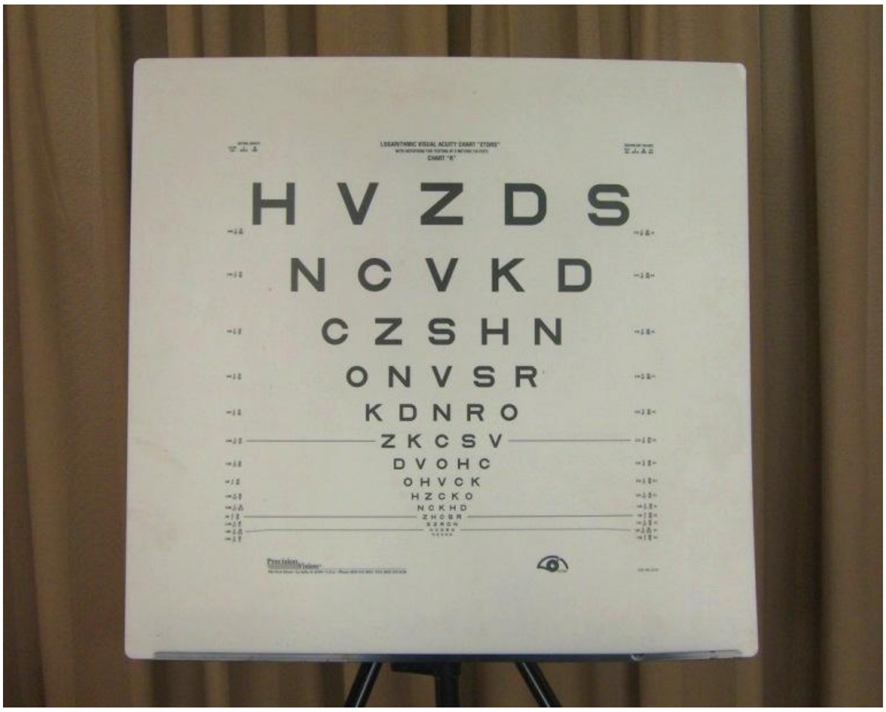
3.8.1 Objective Visual Tests

Three visual tests were performed by the researcher at each data collection. None of these tests required administration by an Ophthalmologist but the researcher was trained in their use by Royal Perth Hospital Ophthalmologists. The use of a light, light meter and tape measure ensured that tests were administered under identical conditions each time.

3.8.1.1 Visual Acuity

Visual acuity, a widely used measure of the clearness of vision was assessed using an ETDRS chart (Ferris et al. 1982). The chart was calibrated for a three metre distance, externally illuminated to approximately 913 lux and scored using a letter by letter method (Ferris et al. 1982). Each eye was assessed separately as well as binocularly (using both eyes) while participants wore the lens correction they typically used for distance activities. The ETDRS chart incorporated specific design criteria that made it more accurate than other commonly used visual acuity charts and it is the gold standard for visual acuity measurement in vision research (Ferris et al. 1982). Surgery eye (the eye scheduled for first eye cataract surgery), non-surgery eye and binocular visual acuity were analysed as continuous variables, expressed on a linear scale as logMAR units. Possible scores ranged from -0.3 to 1.0 logMAR units with lower scores indicating better visual acuity. Participants who could not read any letters on the chart were assigned a value of 1.3 logMAR units.

Figure 3.2 Picture of Early Treatment Diabetic Retinopathy Study Chart used to Measure Visual Acuity



3.8.1.2 Contrast Sensitivity

Contrast sensitivity, the ability to see shading differences was assessed using a Pelli-Robson chart (Pelli, Robson & Wilkins 1988). The test was administered as per standard protocol at a distance of one metre, externally illuminated to approximately 913 lux and scored using a letter by letter method. Each eye was assessed separately as well as binocularly while participants wore the lens correction they typically used for distance activities. Surgery eye, non-surgery eye and binocular contrast sensitivity were analysed as continuous variables with a possible range of 0.00 to 2.25 log units with higher scores representing better contrast sensitivity (Pelli, Robson & Wilkins 1988).

Figure 3.3 Picture of Pelli-Robson Chart used to Measure Contrast Sensitivity

3.8.1.3 Stereopsis

Stereopsis is a form of depth perception that results from receiving two slightly different projections onto the retinas of the two eyes. This was assessed using the Titmus Fly Stereotest (Stereo Optical Co., Inc.) held at a distance of approximately 40.6 centimetres. This test used the vectograph technique, where polarised glasses were used to view pictures that differed in horizontal disparity. This allowed participants to view certain images three dimensionally. Polarised glasses were worn over the participants' normal lens correction typically used for reading and the test performed binocularly. This test could measure disparity from 1.602 to 3.447 log seconds of arc with lower scores indicating better stereopsis. This score was analysed as a continuous variable. Participants who could correctly identify one to nine of the circles on the first test were assigned values between 1.602 and 2.903 log seconds of arc. Those who could not see any of the circles but could see the fly test received a value of 3.447 and those who could not see the fly were assigned a value of 3.653 log seconds of arc.

Figure 3.4 Picture of the Titmus Fly Stereotest used to Measure Stereopsis

3.8.2 Cognitive Tests

3.8.2.1 Mini Mental State Examination

The MMSE is a widely used, reliable and valid measure of cognitive impairment developed by Folstein et al. and contains questions relating to orientation to place, attention, calculation and recall (Folstein, Folstein & McHugh 1975). The MMSE can be used as a screening tool for cognitive impairment but cannot be used to diagnose dementia or other cognitive disorders. The test was administered and scored according to the standardised guidelines developed by Molloy and Standish (Molloy & Standish 1997). Responses on the test were totalled to produce a score between zero and 30 points with higher scores representing better cognitive ability. A score of 23 or lower on the MMSE is a common cut-off used to indicate the presence of some cognitive impairment (Folstein, Folstein & McHugh 1975). The MMSE score was used to control for cognitive ability in this study and was analysed as a continuous variable. It is protected by copyright and not included in the appendices.

3.8.2.2 Useful Field of View

Useful field of view is a test of information processing ability that relies both on visual sensory information and on higher-order processing abilities (Ball & Owsley 1993). The useful field of view is defined as the area from which a person can quickly extract visual information without head or eye movement. This area can be limited by several factors including poor vision, difficulty with dividing attention or ignoring distraction or by slower processing ability (Owsley, Ball & Keeton 1995). Useful field of view was tested using the computer-based UFOV® test software (Visual Awareness, Inc.) with the PC mouse-based format. The test consisted of three subtests assessing speed of visual processing under increasingly complex task demands. The first subtest examined visual processing, the second examined divided attention and the third, selective attention. The scoring system assigned a score between 17 and 500 milliseconds (ms) for each subtest based on the duration the participant required an object to be presented on screen to achieve correct identification of the object 75% of the time.

The test took approximately 15 minutes and was administered in a quiet, dark environment, with the 17 inch computer monitor positioned 46 to 61 centimetres from the participant's eyes. Participants wore their normal lens correction typically used for viewing information at similar distances and performed the tests with both eyes open. Test-retest reliability of the mouse-based PC version has been reported to be high (r = 0.681 to 0.884) (Edwards et al. 2005) and substantial evidence exists that the UFOV® test is a valid predictor of driving performance and crash involvement (Clay et al. 2005; Owsley et al. 1998). The three subtest scores were analysed separately as continuous variables and examined as potential confounders in analyses of driving difficulty only.

3.8.3 Researcher-Administered Questionnaire

A researcher-administered, face to face, structured questionnaire collected information on demographic and health characteristics (Appendix D; q. 1 to 7). It also collected data on driving exposure, self-reported driving difficulty, VRQOL and depressive symptoms using previously developed and validated instruments. The whole questionnaire was assessed by a panel of road safety experts and Ophthalmologists. The questionnaire was then pilot tested on a separate sample of 37 older drivers with or without cataract, through the Royal Perth Hospital Ophthalmology Department. Pilot participants completed the questionnaire twice at an interval of four weeks. Four weeks has been described as an acceptable time interval for test-retest of self-reported outcomes in visually impaired people (Ronbeck, Lundstrom & Kugelberg 2011). The questionnaire was evaluated for face and content validity and test-retest reliability of each item and composite score of the questionnaire was calculated using Pearson, Spearman or Kappa coefficients for continuous, ordinal and categorical responses respectively. Results are presented in Chapter Four.

3.8.3.1 Self-Reported Driving Difficulty

Self-reported driving difficulty was assessed using one section of the researcher-administered Driving Habits Questionnaire (Appendix D; q. 11 to 18). This questionnaire was developed from earlier prototypes by Owsley et al. for the ICOM Project in Alabama, USA (Owsley et al. 1999). It has been quite widely used for the examination of driving with visual impairment (DeCarlo et al. 2003; Owsley et al. 2004) and in Australian studies (Baldock et al. 2006; Pereira, Jull & Treleaven 2008). Using only one section of the questionnaire did not affect the interpretation because each section was scored separately. The self-reported driving difficulty scale contained eight items including driving in the rain, driving alone, parallel parking, making turns across traffic, driving on the freeway, in high traffic, at peak hour and at night. Each item was measured on a five point scale with a score of "one" indicating the participant had stopped driving in that situation due to vision and "five" indicating they had no difficulty in that situation. To obtain the overall driving difficulty score, the mean score of the eight items was calculated, one was subtracted and then multiplied by 25 to give a score between zero and 100. Lower scores represented more driving difficulty.

Construct validity of the scale has been established and the test-retest reliability has been reported to range from 0.44 to 0.74 for the scale items (Owsley et al. 1999). Minor changes were made to the Driving Habits Questionnaire to reflect the Australian driving context. Three separately scored driving difficulty items were also added (Appendix D; q. 19 to 21). These items addressed reading street signs, judging the distance of objects and vehicles and positioning of the vehicle in the lane. Items were chosen due to anecdotal reports of driving difficulties experienced by cataract patients. Self-reported driving difficulty was a major outcome of interest for this study and was analysed as a continuous variable. Each individual item of the scale was converted into a binary variable with responses of "any difficulty" or "no difficulty". This was because the categories of some of the items had very low numbers. Those responding that they had "a little difficulty", "moderate difficulty", "extreme difficulty" or "stopped due to vision" were classified as having "any difficulty". Those who responded "no difficulty" were classified as having "no difficulty".

Information on the number of days and kilometres driven per week was also collected using a section of the Driving Habits Questionnaire (Appendix D, q. 8 to 9) (Owsley et al. 1999) so that driving exposure could be controlled for in the analysis. Test-retest reliability of the exposure items has been reported to range between 0.73 and 0.92 (Owsley et al. 1999).

3.8.3.2 Vision-Related Quality of Life

VRQOL was assessed using the researcher-administered NEI VFQ-25 (Appendix D, q. 22 to 47) (Mangione et al. 2001). This shortened version of the original 51-item questionnaire (Mangione et al. 1998) developed in the USA, included vision-targeted and general items to assess the influence of visual impairment on quality of life. The questionnaire provided an overall composite score and 12 subscale scores including general health, general vision, near vision, distance vision, driving, peripheral vision, colour vision, ocular pain, role limitations, dependency, social function and mental health. Each item on the questionnaire was measured on a five or six point scale giving scores of zero to 100 points. Each subscale contained between one and four items. To obtain each subscale score, its individual item scores were averaged. To obtain the composite score, 11 of the subscale scores were averaged. As per the author's instructions, the general health subscale was not included (Mangione et al. 2001). The composite and subscale scores were measured on a scale of zero to 100 with higher scores representing better VRQOL (Mangione et al. 2001).

Versions of the NEI VFQ-25 have been widely used in countries around the world including Australia, and its psychometric properties assessed (Chia et al. 2006; Stamatiadis 1996; Swamy et al. 2008). The internal consistency of the subscales has been reported to be high (α = 0.71 to 0.85) (Mangione et al. 1998) and content and construct validity have been demonstrated for visual disability including cataract

(Clemons et al. 2003; Mangione et al. 2001; Marella et al. 2010). Finally the scale has shown to have the ability to detect a meaningful change over time (responsiveness) (Lindblad & Clemons 2005; Suzukamo et al. 2005) and a clinically meaningful change has been found to be approximately six points on the composite score (Submacular Surgery Trials Research Group 2007; Suner et al. 2009). The NEI VFQ-25 composite score was a major outcome of interest for this study and was analysed as a continuous variable.

3.8.3.3 Depressive Symptoms

Depressive symptoms were measured using the CES-D (Appendix D; q. 48 to 67) (Radloff 1977), a 20-item scale designed to measure depressive symptoms experienced in the general population. It is not a vision-specific scale and is not intended for use in the diagnosis of clinical depression (Radloff 1977). The scale contained 20 items addressing ways participants may have felt or behaved during the past week. Each item was measured on a scale of zero to three from "rarely" to "all of the time". Scores on the 20 items were totalled to give an overall score between zero and 60, with higher scores representing more depressive symptoms. It is generally considered that a score of 16 or higher on the scale represents the presence of significant depressive symptoms (Radloff 1977). The CES-D has been widely used among the older population including cataract patients (McGwin et al. 2003a). The scale has been shown to have moderate test-retest reliability (0.45 to 0.70), high internal consistency ($\alpha = 0.71$) and good responsiveness (Radloff 1977). In addition, construct and criterion validity of the scale has been established (Beekman et al. 1997; Fountoulakis et al. 2007; Radloff 1977) and it has been shown to be valid for older Australians (McCallum et al. 1995). Depressive symptoms score was the third major outcome of interest for this study and was analysed as a continuous variable.

3.9 Statistical Analysis

3.9.1 Descriptive and Univariate Analyses

All data were coded and analysed using Predictive Analytics Software (PASW) (formerly SPSS Statistics) for windows, version 17.0 (SPSS Inc, Chicago, USA). Firstly, means and SDs or frequency distributions were used to describe the sample at baseline in terms of their demographic, health and cataract treatment characteristics.

Descriptive statistics were also generated for all variables collected before and after surgery. Cognitive variables included the MMSE and useful field of view tests. Visual variables included visual acuity, contrast sensitivity and stereopsis. Driving-related variables included driving exposure, composite driving difficulty score and individual driving items. VRQOL variables included the composite score and 12 subscale scores. Depressive symptom variables included the CES-D composite score. These were all interval variables. For each continuous outcome variable, paired t-tests were used to compare mean values before and after cataract surgery and provide an initial indication of whether there was a significant change. Similarly, McNemar's tests were used to compare distributions of categorical outcome variables before and after surgery. Two sided p-values less than 0.05 were considered significant. The proportion of participants who met WA licensing standards based on vision before and after first eye cataract surgery was also ascertained.

3.9.2 Generalised Linear Estimating Equations

For the three major study outcomes, namely, driving difficulty composite score, VRQOL composite score and depressive symptoms score, separate linear GEE models were constructed. The GEE models analysed whether there was a significant change in these outcomes after cataract surgery, while controlling for potential confounding factors. The visual measures were not included in these models because vision changed as a result of the surgery. Instead, a multiple linear regression was used to investigate whether changes in particular measures of vision were associated with changes in the major outcomes. The GEE method, developed by Zeger and Liang, is suitable for longitudinal or repeated measures study designs where observations within each participant are not independent (Zeger & Liang 1986). GEEs permit specification of a certain working correlation matrix that accounts for this within-subject correlation, thus providing more robust regression coefficients (Ballinger 2004). Normal linear GEEs were constructed because each major outcome was analysed as a continuous variable and an exchangeable working correlation structure was adopted.

The major study outcomes (driving difficulty, VRQOL or depressive symptoms) were entered as outcome variables in each linear GEE model and time (before or after surgery) was added to the model as an explanatory variable. All potential confounding factors were then entered into the linear GEE model and the before and after surgery outcomes were modelled while controlling for these. In each of the three final models, explanatory variables with two sided p-values less than 0.05 were considered significant.

The linear GEE models examined the effect of cataract surgery on the major outcomes of interest but visual variables were not entered and controlled for in the models. This is because the visual measures also changed simultaneously as a direct result of the surgery.

3.9.3 Multiple Linear Regression

To investigate whether changes in particular measures of vision were associated with changes in driving difficulty composite score, VRQOL composite score or depressive symptoms score from before to after surgery while controlling for potential confounding factors, three multiple linear regression models were constructed.

Calculating the difference in the major outcome variable between the before and after surgery measurements and modelling this as the outcome variable in a linear regression model is a simple way to examine change. However, such analyses are vulnerable to the phenomenon of "regression to the mean" where values that are extreme at first measurement tend to be closer to the centre of the distribution on subsequent measurements, making change highly related to the initial value (Twisk 2003). Therefore, for each multiple linear regression model, the major outcome (Y_{i2}) after surgery was modelled as the outcome variable with the major outcome (Y_{i1}) at before surgery being included as an explanatory variable in the model. This approach, known as "analysis of covariance", is a method of examining change that more or less corrects for regression to the mean (Twisk 2003). Using this method, change was defined relative to the value of Y at the before surgery data collection and this relativity was expressed in the regression coefficient β_1, below:

$$Y_{i2} = \beta_0 + \beta_1 Y_{i1} + \beta_2 X_{i1} + \beta_{j+1} X_{ij} + \ldots + \varepsilon_i$$

Where:

Y_{i2}: observation for subject *i* at second data collection

Y_{i1}: observation for subject *i* at first data collection

ε_i: error for subject *i*.

X_{ij}: j^{th} covariate for subject *i*

i: 1, ... , n

For each visual measure including surgery eye visual acuity, non-surgery eye visual acuity, surgery eye contrast sensitivity, non-surgery eye contrast sensitivity and stereopsis, a new variable was calculated representing the change in each visual score from before to after surgery. All visual variables and potential confounders were then added to the model. Significance of the visual and other variables were examined using two model fitting strategies, i.e. the full model and the stepwise approach. Explanatory variables with two sided p-values less than 0.05 were considered significant. If inconsistencies in significant variables were evident between the two modelling strategies, hierarchical linear regression analysis was performed to ascertain whether the inclusion of a particular variable improved the fit of the model. For all three final models, the stepwise method provided the best model fit and was reported in the results.

CHAPTER 4

Results

4 RESULTS

4.1 Pilot Test of Questionnaire

Information on driving outcomes, VRQOL and depressive symptoms were collected through a researcher-administered questionnaire. Prior to study commencement, the whole questionnaire was pilot tested on a separate sample of 37 older drivers with or without cataract, through the Royal Perth Hospital Ophthalmology Department. Pilot test participants ranged in age from 57 to 86 years with a mean of 68.6 years (SD: 7.9) and 62.2% were female. Pilot participants completed the questionnaire twice at an interval of four weeks. The questionnaire was evaluated for face and content validity and very minor modifications were made as a result of this process to reflect the Australian context. The reliability of each questionnaire item was calculated using Pearson, Spearman or Kappa coefficients for continuous, ordinal and categorical responses respectively. The reliability coefficient for the driving difficulty composite score was 0.96 with individual items ranging from 0.41 to 1.0. For the VRQOL composite score, the coefficient was 0.97 with subscale scores ranging from 0.58 to 1.0 and for the depressive symptoms score the coefficient was 0.83. The pilot test of the questionnaire demonstrated good test-retest reliability on all major outcomes of interest for this study.

4.2 Study Participants

The final sample consisted of 99 older drivers about to undergo first eye cataract surgery. The response rate for the study was 93% with eight eligible patients from the 109 initially approached, declining to participate. Two participants were lost to follow-up. Those who declined to participate in the study all agreed to answer a few questions on key variables allowing potential selection bias to be examined. Using independent t-tests for normally distributed and Mann-Whitney U tests for not normally distributed continuous variables and Fisher's exact test for categorical variables, there was no significant difference between the 99 participants and 10 non-participants (including the two drop-outs) in age (p=0.843), sex (p=0.326), country of birth (p=1.000) marital status (p=0.508), living situation (p=0.743), education level (0.064), number of chronic health conditions (p=0.856), number of days driven per week (p=0.806) or kilometres driven per week (p=0.725).

4.3 Demographic Information

Demographic and health characteristics of the 99 study participants are presented in Table 4.1. Age at the first data collection ranged from 55 to 88 years with a mean of 72 years (SD: 7.88). Approximately half the participants were male (n=50, 50.5%) and the majority were not born in Australia (n=53, 53.5%). Those not born in Australia were most commonly born in the UK (n=19, 35.8%), New Zealand (n=6, 11.3%) and Italy (n=6, 11.3%). Fifty-four participants were married or in a de-facto relationship (54.5%) while the remainder were single, divorced or widowed (n=45, 45.5%). The majority of participants did not live alone (n=62, 62.6%). Twenty-seven participants had completed some form of higher education including TAFE or a university degree (27.3%) but primary or high school was the highest level of education obtained for the majority (n=72, 72.7%).

The total number and type of chronic conditions possessed by each participant were obtained through self-report and confirmed via medical record review. The number of chronic conditions ranged from zero to seven with a mean of 3.1 conditions (SD: 1.58). The majority of participants had between one and four chronic conditions (n=77, 77.8%), the most common being circulatory conditions (n=79, 79.8%), musculoskeletal conditions (n=55, 55.6%) and diabetes (n=31, 31.3%). For 85 participants (85.9%), cataract was the only diagnosed eye condition (other than refractive error) and 14 (14.1%) had mild co-morbid eye conditions. Six of these had a diagnosis of glaucoma, five had macular degeneration and three had diabetic retinopathy. For each of these participants however, it was confirmed by an Ophthalmologist the condition was either controlled or non-advanced and that cataract was the principal reason for vision loss.

Table 4.1 Demographic and Health Characteristics Before First Eye Surgery (n=99)

Characteristic	n (%)
Age (years)	
55- 64	18 (18.2%)
65-74	43 (43.4%)
75-84	34 (34.3%)
≥85	4 (4.0%)
Gender	
Male	50 (50.5%)
Female	49 (49.5%)
Country of birth	
Australia	46 (46.5%)
Not Australia	53 (53.5%)
Marital status	
Married or de facto	54 (54.5%)
Single/ divorced/ widowed	45 (45.5%)
Living situation	
Alone	37 (37.4%)
With others	62 (62.6%)
Education level	
University/ TAFE	27 (27.3%)
Primary/ high school	72 (72.7%)
Number of chronic conditions	
None	3 (3.0%)
1-2	36 (36.4%)
3-4	41 (41.4%)
≥5	19 (19.2%)
Other minor eye conditions	
Yes	14 (14.1%)
No	85 (85.9%)

4.4 Cataract Treatment Characteristics

Cataract and cataract treatment characteristics are displayed in Table 4.2. All participants underwent first eye cataract surgery through one of three Western Australian hospitals, 55 at Sir Charles Gairdner Hospital (55.6%), 32 at Royal Perth Hospital (32.3%) and 12 at Fremantle Hospital (12.1%). The majority had the first eye surgery on their right eye (n=58, 58.6%). In terms of type of cataract, 72.7% had nuclear sclerotic cataract, 1.0% cortical, 4.0% posterior subcapsular and 22.2% had a combination of types in their first surgery eye.

Table 4.2 Cataract Treatment Characteristics (n=99)

Characteristic	n (%)
Treating hospital	
Sir Charles Gairdner	55 (55.6%)
Royal Perth	32 (32.3%)
Fremantle	12 (12.1%)
Surgery eye	
Right	58 (58.6%)
Left	41 (41.4%)
Type of cataract in surgery eye	
Nuclear sclerotic	72 (72.7%)
Cortical	1 (1.0%)
Posterior subcapsular	4 (4.0%)
Combination	22 (22.2%)
Complications	
None	94 (94.9%)
Mild	5 (5.1%)
New glasses received after surgery	
Yes	22 (22.2%)
No	77 (77.8%)

All cataract surgeries were performed using the phacoemulsification method of cataract extraction, under either local or general anaesthetic, immediately followed by the insertion of an intraocular lens. There were no serious intraoperative or postoperative cataract surgery complications, although five participants (5.1%) experienced minor complications including temporary inflammation and dislocated intraocular lens. By the second data collection (approximately 12 weeks after surgery) only 22 participants (22.2%) had received new glasses or lenses prescribed for their post surgery vision.

4.5 Cognitive Characteristics

Two cognitive tests, the MMSE and useful field of view UFOV® test were administered to participants before and after surgery. Table 4.3 presents the mean cognitive scores before and after first eye cataract surgery and the results of paired t-tests to determine whether there were significant changes in scores.

4.5.1 Mini Mental State Examination

The mean score on the MMSE before surgery was 27.36 (SD: 2.52) out of 30 and after surgery was 27.64 (SD: 2.43). A very low proportion of the sample had scores of 23 or lower, a cut point which represents the presence of some degree of cognitive impairment (8.1% before surgery, 4.0% after surgery). The paired t-test showed a statistically significant mean improvement in MMSE score of 0.27 points (SD: 1.05) following surgery. This change was not clinically meaningful.

4.5.2 Useful Field of View

The useful field of view tests measured visual attention, a form of cognition that may be associated with driving ability, with lower scores representing better visual attention (Clay et al. 2005; Owsley et al. 1998). For the first subtest examining visual processing, the mean score before surgery was 59.71 ms (SD: 82.09) and after surgery was 41.30 ms (SD: 55.76) representing a significant improvement (p=0.005). Scores for the divided attention and selective attention subtests were available for 98 participants before surgery and 98 after surgery. One participant could not complete the tests before surgery due to headache and a different participant could not complete after surgery due to shoulder pain. Mean scores on Subtests Two and Three also both significantly improved after surgery (Table 4.3).

Table 4.3 Cognitive Characteristics Before and After First Eye Cataract Surgery (n=99)

	Before surgery Mean (SD)	After surgery Mean (SD)	p value[1]
MMSE: score	27.36 (2.52)	27.64 (2.43)	0.011
Useful field of view (ms)			
Subtest 1: Processing speed	59.71 (82.09)	41.30 (55.76)	0.005
Subtest 2: Divided attention[2]	196.67 (143.13)	152.53 (117.66)	<0.001
Subtest 3: Selective attention[2]	335.86 (127.27)	289.62 (122.76)	<0.001

[1] p value obtained from paired t-tests
[2] Missing data=1, n=98

4.6 Objective Visual Characteristics

Table 4.4 presents the objective visual characteristics of the sample before and after first eye cataract surgery and the results of paired t-tests to determine whether changes in vision were significant. All visual tests were performed while participants wore their best lens correction. Lower values of visual acuity and stereopsis and higher values of contrast sensitivity represented better vision.

4.6.1 Visual Acuity

Before first eye cataract surgery, participants had a mean visual acuity in the eye scheduled for first cataract surgery (surgery eye visual acuity) of 0.57 logMAR units (SD: 0.31) (Table 4.4). This equated to a Snellen fraction of approximately 6/24. Surgery eye visual acuity ranged widely among participants from 0.06 to 1.3 logMAR units. After cataract surgery, mean visual acuity in the surgery eye was 0.11 logMAR units (approximately 6/7.5 Snellen fraction) representing a significant mean improvement of 0.46 logMAR units (SD: 0.32) (p<0.001). This equated to a clinically meaningful improvement of 23 letters or four and a half lines on the ETDRS chart. Clinicians often define a change of 0.1 logMAR units or one line on the chart as clinically meaningful. (Elliott & Sheridan 1988).

Table 4.4 Visual Characteristics Before and After First Eye Cataract Surgery (n=99)

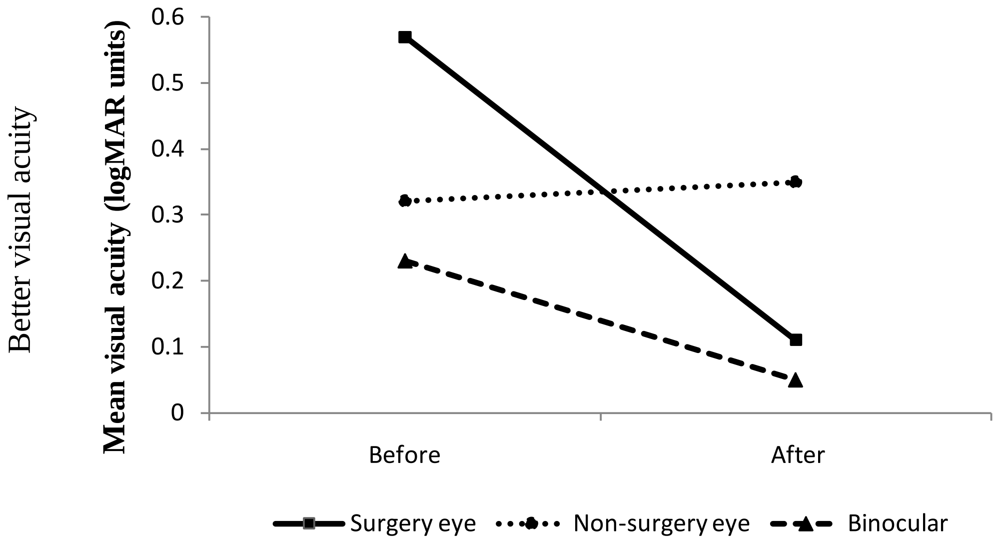
	Before surgery Mean (SD)	After surgery Mean (SD)	p value[1]
Visual acuity (logMAR units)			
Surgery eye	0.57 (0.31)	0.11 (0.16)	<0.001
Non-surgery eye	0.32 (0.19)	0.35 (0.23)	0.015
Binocular	0.23 (0.17)	0.05 (0.13)	<0.001
Contrast sensitivity (log units)			
Surgery eye	1.21 (0.42)	1.63 (0.17)	<0.001
Non-surgery eye	1.47 (0.25)	1.45 (0.26)	0.179
Binocular	1.55 (0.19)	1.70 (0.16)	<0.001
Stereopsis (log seconds of arc)	2.22 (0.61)	1.99 (0.46)	0.001

[1] p value obtained from paired t-tests

For the non-surgery eye, there was a small but statistically significant decline in visual acuity of 0.03 logMAR units from 0.32 before surgery to 0.35 logMAR after surgery (p=0.015) (Table 4.4). This represented a decline of only two letters on the ETDRS chart.

Mean binocular visual acuity (measured with both eyes) also significantly improved by 0.19 logMAR units after first eye surgery from 0.23 to 0.05 logMAR (p<0.001) (Table 4.4). This represented a clinically meaningful improvement of nearly two lines or 10 letters on the ETDRS chart. Figure 4.1 presents the change in surgery eye, non-surgery eye and binocular visual acuity from before to after first eye cataract surgery.

Figure 4.1 Mean Visual Acuity Before and After First Eye Cataract Surgery



In Western Australia, visual standards for driver licensing are based largely on the visual acuity measure. For unconditional licensing, drivers must be able to read the 0.30 logMAR line of a visual acuity chart with either their better eye or binocularly, making no more than two errors (Austroads 2006). Before surgery, the non-surgery eye provided the better eye visual acuity for the majority of study participants (89.9%). After surgery, the eye that had been operated on provided the better eye visual acuity for the majority of participants (87.9%). Table 4.5 displays the proportion of participants who met and did not meet visual standards for licensing before and after cataract surgery. Before first eye cataract surgery, 18 participants (18.2%) would have failed the vision test for licensing. After surgery, the proportion who would have failed significantly decreased to 4.0% ($p<0.001$).

Table 4.5 Proportion of Participants who would have Failed the Western Australian Visual Acuity Test for Licensing (n=99)

	Before surgery n (%)	**After surgery n (%)**	**p value[1]**
Pass	81 (81.8%)	95 (96.0%)	
Fail	18 (18.2%)	4 (4.0%)	0.001

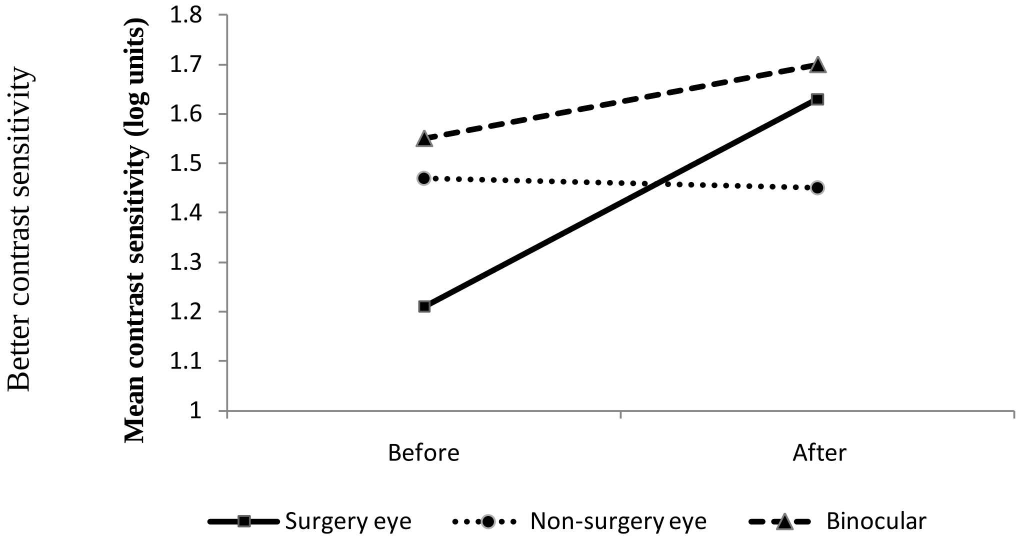
[1] p value obtained from McNemar's test

4.6.2 Contrast Sensitivity

Table 4.4 also presents the mean surgery eye, non-surgery eye and binocular contrast sensitivity before and after first eye cataract surgery, with higher values representing better contrast sensitivity. Before surgery, surgery eye contrast sensitivity ranged from 0.00 to 1.75 log units with a mean of 1.21 log units (SD: 0.42). After surgery, the mean surgery eye contrast sensitivity was 1.63 log units (SD: 0.17), representing a significant mean improvement of 0.42 log units (SD: 0.43) ($p<0.001$). This translated to a clinically significant improvement of approximately nine letters or one and a half lines on the Pelli-Robson chart. A change of 0.3 log units or one line is often considered to be clinically meaningful (Elliott, Sanderson & Conkey 1990).

Before surgery, mean contrast sensitivity in the non-surgery eye was 1.47 log units (SD: 0.25). After surgery, there was a decline to 1.45 log units (SD: 0.26) ($p=0.179$). Binocular contrast sensitivity also significantly improved from 1.55 (SD: 0.19) to 1.70 log units (SD: 0.16) after surgery ($p<0.001$). However, this mean improvement of 0.15 log units may not be of clinical meaning (Elliott, Sanderson & Conkey 1990). Figure 4.2 displays the change in contrast sensitivity from before to after first eye cataract surgery.

Figure 4.2 Mean Contrast Sensitivity Before and After First Eye Cataract Surgery



4.6.3 Stereopsis

Stereopsis was measured binocularly with lower scores representing better stereopsis. Before surgery, mean stereopsis was 2.22 log seconds of arc (SD: 0.61) or approximately 166 seconds of arc (Table 4.4). After surgery, stereopsis significantly improved by 0.22 log seconds to 1.99 log seconds of arc (SD: 0.46) ($p = 0.001$). However, some authors state that a change of 0.30 log seconds of arc is required to be clinically meaningful (Rubin et al. 2001).

4.6.4 Objective Visual Characteristics After Surgery by Receipt of New Glasses

Table 4.6 presents the visual scores after surgery for those who had received new glasses by the time of data collection and those who had not. Those who received new glasses had significantly better non-surgery eye visual acuity ($p=0.013$) and stereopsis (0.020) than those who did not receive new glasses. There was no significant difference between these groups for any of the other visual measures.

Table 4.6 Objective Visual Characteristics After First Eye Cataract Surgery by Receipt of New Glasses

	New glasses received Mean (SD)		p value[1]
	Yes (n=22)	No (n=77)	
Visual acuity (logMAR units)			
Surgery eye	0.08 (0.10)	0.11 (0.18)	0.462
Non-surgery eye	0.25 (0.15)	0.39 (0.24)	0.013
Binocular	0.02 (0.09)	0.06 (0.14)	0.201
Contrast sensitivity (log units)			
Surgery eye	1.63 (0.19)	1.63 (0.17)	0.900
Non-surgery eye	1.53 (0.18)	1.42 (0.28)	0.100
Binocular	1.75 (0.16)	1.69 (0.15)	0.094
Stereopsis (log seconds of arc)	1.79 (0.30)	2.05 (0.49)	0.020

[1] p value obtained from independent t-tests

4.6.5 Improvement in Visual Measures after Surgery

Table 4.7 presents the proportion of participants whose individual visual scores improved, remained the same or declined after first eye cataract surgery for surgery eye visual acuity, surgery eye contrast sensitivity and stereopsis measures. For surgery eye visual acuity, all but three participants (3.0%) experienced an improvement after surgery. Surgery eye contrast sensitivity also improved in 87.9% of participants with 6.1% declining and 6.1% remaining the same after surgery. For stereopsis however, only 54 participants (54.5%) experienced improved stereopsis after first eye cataract surgery. The stereopsis of 21 participants (21.2%) remained the same and 24 (24.2%) declined.

Table 4.7 Proportion of Participants whose Individual Visual Scores Improved, Remained the Same and Declined after Surgery (n=99)

	Improved: n (%)	Same: n (%)	Declined: n (%)
Surgery eye visual acuity (logMAR units)	96 (97.0%)	1 (1.0%)	2 (2.0%)
Surgery eye contrast sensitivity (log units)	87 (87.9%)	6 (6.1%)	6 (6.1%)
Stereopsis (log seconds of arc)	54 (54.5%)	21 (21.2%)	24 (24.2%)

4.7 Self-Reported Driving Difficulty

4.7.1 Driving Difficulty: Descriptive and Univariate Statistics

Self-reported driving difficulty was a major outcome of interest for this study and was collected using the Driving Habits Questionnaire developed by Owsley et al. (Owsley et al. 1999). The driving difficulty composite score and individual driving items were described for the sample before and after first eye cataract surgery. Paired t-tests and McNemar's tests were used to initially examine significant changes in driving difficulty. Information on driving exposure was also collected and described.

4.7.1.1 Driving Exposure

Table 4.8 shows the mean self-reported driving exposure before and after first eye cataract surgery. Before surgery, participants drove, on average five days per week (SD: 1.92) and there was no significant change following surgery. There was a significant increase however, in mean kilometres driven per week from 104.46 kilometres (SD: 88.41) before surgery to 127.66 kilometres (SD: 102.41) after surgery ($p<0.001$).

4.7.1.2 Composite Driving Difficulty Score

The composite self-reported driving difficulty score was a major outcome of interest for this study and its calculation was described in Chapter Three. Higher scores on the scale represented less driving difficulty. Before surgery, the composite driving difficulty score ranged from 15.63 to 100.00 points with a mean score of 80.49 (SD: 17.64) (Table 4.8). Before surgery, ten participants (10.1%) scored the maximum possible driving difficulty score of 100.00 points, representing no difficulty. After surgery, driving difficulty scores improved on average by 10.87 points (SD: 16.51) to a mean score of 91.36 (SD: 9.44). This change was statistically significant ($p<0.001$) and clinically meaningful (Table 4.8). After surgery, scores ranged from 62.50 to 100.00 points with 27 participants (27.3%) achieving the maximum score of 100.00. The 99 participants were also examined in terms of improvement in driving difficulty scores. After surgery, 72 (72.7%) had improved their composite scores (a better score than before), 16 (16.2%) of them remained the same but 11 patients (11.1%) got worse.

Table 4.8 Self-Reported Driving Exposure and Driving Difficulty Score Before and After First Eye Cataract Surgery (n=99)

	Before surgery Mean (SD)	After surgery Mean (SD)	p value[1]
Driving exposure			
Days per week	5.00 (1.92)	5.20 (1.95)	0.061
Kilometres per week	104.46 (88.41)	127.66 (102.41)	<0.001
Driving difficulty composite score	80.49 (17.64)	91.36 (9.44)	<0.001

[1] p values obtained from paired t-tests

For the 72 participants whose driving difficulty scores improved, paired t-tests revealed that they experienced significant mean improvements in surgery eye visual acuity ($p<0.001$), surgery eye contrast sensitivity ($p<0.001$) and stereopsis ($p<0.001$) following surgery (Table 4.9). The 19 participants whose driving difficulty scores got worse or remained the same after surgery (eight participants who scored 100 before and after surgery were removed) also experienced statistically significant improvements in surgery eye visual acuity ($p<0.001$) and surgery eye contrast sensitivity ($p<0.001$) after surgery but no significant change in stereopsis ($p=0.940$) (Table 4.9).

Table 4.9 Mean Change in Visual Variables by Improvement and Non-Improvement in Driving Difficulty[1] (n=91)

	Improved driving difficulty (n=72)		Not improved driving difficulty (n=19)	
	Mean change (SD)	**p value[3]**	**Mean change (SD)**	**p value[3]**
Surgery eye visual acuity (log MAR)[2]	-0.52 (0.34)	<0.001	-0.33 (0.18)	<0.001
Surgery eye contrast sensitivity (log units)	0.50 (0.48)	<0.001	0.18 (0.18)	<0.001
Stereopsis (log seconds of arc)[2]	-0.29 (0.68)	<0.001	0.01 (0.64)	0.940

[1] Eight participants who scored 100 on the driving difficulty scale before and after surgery were removed from analysis
[2] Negative changes in visual acuity and stereopsis represent improvement
[3] p values obtained from paired t-tests

4.7.1.3 Driving Difficulty Items

Each of the eight items on the driving difficulty scale and the three additional driving items were examined separately as binary variables. Table 4.10 details the proportion of participants who experienced “any difficulty” or “no difficulty” with each driving task before and after first eye surgery.

Table 4.10 Proportion of Participants Experiencing Specific Driving Difficulties Before and After First Eye Cataract Surgery (n=99)

Driving items	Before surgery n (%)	After surgery n (%)	p value[1]
In the rain			
Any difficulty	52 (52.5%)	21 (21.2%)	
No difficulty	47 (47.5%)	78 (78.8%)	<0.001
Alone			
Any difficulty	23 (23.2%)	8 (8.1%)	
No difficulty	76 (76.8%)	91 (91.9%)	0.001
Parallel parking			
Any difficulty	31 (31.3%)	23 (23.2%)	
No difficulty	68 (68.7%)	76 (76.8%)	0.134
Right hand turns			
Any difficulty	31 (31.3%)	16 (16.2%)	
No difficulty	68 (68.7%)	83 (83.8%)	0.004
On the freeway			
Any difficulty	18 (18.2%)	3 (3.0%)	
No difficulty	81 (81.8%)	96 (97%)	<0.001
On high traffic roads			
Any difficulty	23 (23.2%)	7 (7.1%)	
No difficulty	76 (76.8%)	92 (92.0%)	0.001
During peak hour traffic			
Any difficulty	17 (17.2%)	4 (4.0%)	
No difficulty	82 (82.8%)	95 (96.0%)	0.002
At night			
Any difficulty	85 (85.9%)	61 (61.6%)	
No difficulty	14 (14.1%)	38 (38.4%)	<0.001
Judging distances			
Any difficulty	40 (40.4%)	24 (24.2%)	
No difficulty	59 (59.6%)	75 (75.8%)	0.005
Positioning vehicle correctly			
Any difficulty	14 (14.1%)	7 (7.1%)	
No difficulty	85 (85.9%)	92 (92.9%)	0.092
Reading street signs			
Any difficulty	82 (82.8%)	42 (42.4%)	
No difficulty	17 (17.2%)	57 (57.6%)	<0.001

[1] p values obtained from McNemar's tests

Before surgery, the driving tasks that participants most commonly had difficulty with were; driving at night (89.5%), reading street signs (82.8%) and driving in the rain (52.5%). Following surgery there was a significant decrease in the proportion experiencing any difficulty with driving in the rain (p<0.001), driving alone (p<0.001), making right hand turns across traffic (p=0.004), driving on the freeway (p<0.001), driving on high traffic roads (p<0.001), in peak hour traffic (p=0.002), at night (p<0.001), judging the distance of other vehicles and objects (p=0.005) and reading street signs (p<0.001). However, there was no significant change for parallel parking or correctly positioning the vehicle in the lane while driving. Despite significant improvements after first eye surgery, a considerable proportion of participants still experienced difficulty driving at night (61.6%), reading street signs (42.4%), judging distances (24.2%), and driving in the rain (21.2%). In addition, 23.2% of participants still experienced difficulty with parallel parking. However, since there was no control group of "healthy" drivers, it was not possible to determine what proportion of drivers experiencing difficulties could be attributed to change in the parameters measured in the study.

4.7.2 Driving Difficulty: Generalised Linear Estimating Equation

A linear GEE model was constructed to analyse the effect of first eye cataract surgery on the major outcome of interest, the self-reported driving difficulty composite score. The Pearson correlation coefficient for mean driving difficulty scores before and after surgery was calculated because these were repeated measurements from the same participant and confirmed that the measures were correlated (r=0.38). Therefore, a linear GEE model was fitted for 98 participants for whom complete data were available with the driving difficulty score as the outcome variable and time (before or after surgery) was added as an explanatory variable. The logarithm of kilometres driven per week was entered as an offset variable to adjust for driving exposure. The change in driving difficulty from before to after surgery was then assessed while taking account of all potential confounding factors. Table 4.11 summarises the results of the linear GEE model.

Table 4.11 Generalised Linear Estimating Equation Model of Self-Reported Driving Difficulty (n=98)

Variable	Coefficient (SE)	95% CI	p value
Before/ after surgery: after	9.79 (1.55)	6.74 to 12.83	<0.001
Age (years)	0.41 (0.19)	0.05 to 0.78	0.027
Number of chronic health conditions	-1.70 (0.80)	-3.28 to -0.26	0.033
Gender: female	-1.05 (2.21)	-5.38 to 3.29	0.637
Country of birth: non-Australian	-0.15 (2.19)	-4.44 to 4.13	0.944
Other eye conditions: yes	-5.66 (3.70)	-12.93 to 1.60	0.126
New glasses after surgery: yes	-0.47 (3.22)	-6.78 to 5.84	0.885
MMSE (score)	0.20 (0.53)	-0.83 to 1.24	0.697
UFOV Visual Processing (ms)	0.02 (0.02)	-0.01 to 0.06	0.138
UFOV Divided Attention (ms)	9.72 (0.01)	-0.03 to 0.00	0.121
UFOV Selective Attention (ms)	0.00 (0.00)	-0.02 to 0.02	0.829

Working correlation coefficient: 0.28
Logarithm of kilometres driven per week entered as offset variable

The working correlation coefficient was estimated to be 0.28, indicating that the GEE approach was appropriate to use. Interactions between the main effects on driving difficulty in the linear GEE model were investigated. Two-way interaction terms were created for each combination of the significant main effect variables and entered into a full model. None of the interaction terms were found to be significant.

The results of the final linear GEE model showed a significant improvement in self-reported driving difficulty of nearly 10 points from before to after first eye cataract surgery ($p<0.001$), confirming the results of the univariate analysis. Advancing age was significantly associated with less driving difficulty ($p=0.027$) and a greater number of chronic health conditions was associated with more driving difficulty (p=0.033). Other factors including gender, country of birth, presence of other eye conditions, receipt of new glasses after surgery and cognitive measures were not significantly associated with driving difficulty in the linear GEE model.

4.7.3 Driving Difficulty: Multiple Linear Regression

To investigate whether changes in particular measures of vision were associated with changes in driving difficulty from before to after surgery, a multiple linear regression model was constructed, controlling for potential confounding factors. The driving difficulty score after surgery was modelled as the outcome variable with the driving difficulty score before surgery included as an explanatory variable in the model. Using this method, change was defined relative to the value of the driving difficulty score before surgery, correcting for regression to the mean (Twisk 2003).

For each visual measure including surgery eye visual acuity, non-surgery eye visual acuity, surgery eye contrast sensitivity, non-surgery eye contrast sensitivity and stereopsis, a new variable was calculated representing the change in each visual score from before to after surgery. Binocular measures of visual acuity and contrast sensitivity were highly correlated with the non-surgery eye measures so were not included in the model. The visual variables and all potential confounders including age, gender, country of birth, number of chronic health conditions, other eye conditions, receipt of new glasses after surgery, change in driving exposure, change in MMSE score and change in the three useful field of view sub-scores were then entered into the multiple linear regression model as explanatory variables. Complete data on all the baseline and change variables was available for 97 participants.

The significance of these variables were examined using two model fitting strategies; the full model and stepwise approaches. Explanatory variables with two sided p-values less than 0.05 were considered significant. These two methods produced consistent results with driving difficulty score before surgery, number of chronic health conditions, receipt of new glasses after surgery and change in surgery eye contrast sensitivity emerging as significant variables related to change in driving difficulty in both models. The stepwise multiple linear regression model provided the most parsimonious model that explained more of the variability in change in driving difficulty (defined as driving difficulty after surgery relative to driving difficulty before surgery) and results are detailed in Table 4.12.

Table 4.12 Stepwise Multiple Linear Regression Model for Change in Driving Difficulty[1] (n=97)

Variable [2]	Coefficient (SE)	95% CI	p value
Constant	67.55 (4.97)	57.69 to 77.41	<0.001
Driving difficulty before surgery (score)	0.29 (0.05)	0.19 to 0.38	<0.001
Surgery eye contrast sensitivity (change)	7.24 (1.94)	3.39 to 11.08	<0.001
New glasses after surgery: yes	7.29 (1.87)	3.58 to 10.99	<0.001
Number of chronic health conditions	-1.21 (0.50)	-2.20 to -2.23	0.016

[1] R squared = 0.40, adjusted R squared = 0.37, $F_{4,92} = 15.18$, $p < 0.001$
[2] Other variables tested in the model included age, gender, country of birth, other eye conditions, change in driving exposure, change in MMSE score, change in the three useful field of view sub-scores, change in surgery eye visual acuity, non-surgery eye visual acuity, non-surgery eye contrast sensitivity and stereopsis. Addition of these variables did not improve the fit of the model, so they were excluded.

Interactions between the significant main effects on change in driving difficulty in the model were investigated. Two-way interaction terms were created for each combination of the significant main effect variables. None of the interaction terms were found to be significant. The adjusted R squared value of the stepwise multiple linear regression model was 0.371. This indicated that 37.1% of the variance in the driving difficulty score after surgery was accounted for by the driving difficulty score before surgery, change in surgery eye contrast sensitivity, whether participants had received new glasses after surgery and number of chronic health conditions (after taking into account the number of variables in the model and the number of participants the model is based on). The overall F test ($F_{4,92} = 15.183$, $p < 0.001$) showed that the regression was significant. After controlling for confounding factors, change in surgery eye contrast sensitivity was the only visual measure associated with change in driving difficulty after first eye cataract surgery. Driving difficulty score significantly improved as surgery eye contrast sensitivity improved ($p<0.001$). In addition, having received new glasses by the time of the second data collection was significantly associated with improvement in driving difficulty score ($p<0.001$). Finally, a greater number of chronic health conditions was associated with less improvement in driving difficulty ($p=0.016$).

4.8 Vision-Related Quality of Life

4.8.1 Vision-Related Quality of Life: Descriptive and Univariate Statistics

VRQOL was the second major outcome of interest for this study and was measured using the NEI VFQ-25 (Mangione et al. 2001). The VRQOL composite score and subscale scores were described for the sample before and after first eye cataract surgery. Paired t-tests were used to initially examine significant changes in VRQOL.

4.8.1.1 Composite Vision-Related Quality of Life Score

The composite VRQOL score was obtained by averaging all the subscale scores except for general health, with higher scores representing better quality of life. Before surgery, composite quality of life scores ranged from 32.12 to 99.24 with a mean score of 80.69 points (SD: 13.12) (Table 4.13). No participant scored the maximum possible composite score of 100.00. After surgery, composite scores improved on average by 9.62 points (SD: 11.16) to a mean score of 90.30 (SD: 9.18). This change was statistically significant ($p<0.001$) and clinically meaningful (Table 4.13). After surgery, scores ranged from 45.80 to 100.00 points with five participants (5.1%) scoring the maximum of 100.00 points. Overall, the composite quality of life score of 85 participants improved after surgery (85.9%), one remained the same (1.0%) and 13 declined (13.1%).

Table 4.13 Vision-Related Quality of Life Before and After First Eye Cataract Surgery (n=99)

	Before surgery Mean (SD)	After surgery Mean (SD)	p value[1]
NEI VFQ-25 composite score	80.69 (13.12)	90.30 (9.18)	<0.001
Subscale scores			
General health	49.24 (27.07)	50.76 (27.77)	0.441
General vision	62.83 (16.91)	76.36 (13.51)	<0.001
Ocular pain	91.41 (15.43	92.55 (13.71)	0.438
Near activities	72.64 (20.34)	86.78 (15.61)	<0.001
Distance activities	74.49 (22.27)	88.51 (14.69)	<0.001
Vision Specific:			
Social functioning	93.69 (14.10)	97.85 (7.99)	0.001
Mental health	76.64 (25.39)	90.85 (15.16)	<0.001
Role difficulties	70.58 (28.92)	87.88 (19.92)	<0.001
Dependency	91.08 (17.99)	96.55 (11.10)	0.003
Driving	68.86 (20.54)	83.84 (16.67)	<0.001
Colour vision	96.72 (8.49)	98.23 (6.44)	0.057
Peripheral vision	88.64 (20.29)	93.94 (14.33)	0.014

[1] p value obtained from paired t-tests

For the 85 participants whose VRQOL composite scores improved, paired t-tests revealed that they experienced significant mean improvements in surgery eye visual acuity ($p<0.001$), surgery eye contrast sensitivity ($p<0.001$) and stereopsis ($p<0.001$) following surgery (Table 4.14). The 14 participants whose composite scores got worse or remained the same after surgery also experienced statistically significant improvements in surgery eye visual acuity ($p=0.002$) and surgery eye contrast sensitivity ($p=0.036$) after surgery but experienced a no significant change in stereopsis ($p=0.941$) (Table 4.14).

Table 4.14 Mean Change in Visual Variables by Improvement and Non-Improvement in Vision-Related Quality of Life (n=99)

	Improved (n=85)		**Not improved (n=14)**	
	Mean change (SD)	**p value [2]**	**Mean change (SD)**	**p value [2]**
Surgery eye visual acuity (log MAR)[1]	-0.48 (0.31)	<0.001	-0.32 (0.32)	0.002
Surgery eye contrast sensitivity (log units)	0.47 (0.44)	<0.001	0.11 (0.18)	0.036
Stereopsis (log seconds of arc)[1]	-0.26 (0.65)	<0.001	0.01 (0.69)	0.941

[1] Negative changes in visual acuity and stereopsis represent improvement
[2] p values obtained from paired t-tests

4.8.1.2 Vision-Related Quality of Life Subscale Scores

The NEI VFQ-25 consisted of 12 subscales each scored on a scale of zero to 100. Table 4.13 lists each subscale score before and after first eye cataract surgery. Before surgery subscale scores were low for general health with a mean score of 49.24, general vision with a score of 62.83 and driving with a score of 68.86 and high for colour vision, vision specific social functioning and vision specific dependency, all with mean scores over 90 points. Following surgery, there were statistically significant improvements in mean scores for the all the subscales except general health, ocular pain and colour vision. The lowest scoring subscales after surgery were the same subscales as before surgery.

4.8.2 Vision-Related Quality of Life: Generalised Linear Estimating Equation

Another linear GEE model was constructed to analyse the effect of first eye cataract surgery on the second major outcome of interest, the VRQOL composite score. The Pearson correlation coefficient for mean VRQOL scores before and after surgery was calculated because these were repeated measurements from the same participant and confirmed that these measures were correlated (r=0.55). Therefore, a linear GEE model was fitted with the composite VRQOL score as the outcome variable and time (before or after surgery) was added as an explanatory variable. The change in VRQOL from before to after surgery was then assessed while taking account of all potential confounding factors. Table 4.15 summarises the results of the linear GEE model.

Table 4.15 Generalised Linear Estimating Equation Model of Vision-Related Quality of Life (n=99)

Variable	Coefficient (SE)	95% CI	p value
Before/ after surgery: after	9.53 (1.10)	7.38 to 11.69	<0.001
Age (years)	0.26 (0.13)	0.01 to 0.52	0.048
Gender: female	-4.12 (2.16)	-8.36 to 0.12	0.057
Number of chronic health conditions	-0.97 (0.53)	-2.01 to -0.08	0.071
Country of birth: non-Australian	-0.81 (1.82)	-4.37 to 2.76	0.657
Other eye conditions: yes	-1.78 (2.75)	-7.16 to 3.61	0.518
New glasses after surgery: yes	2.95 (2.06)	-1.09 to 6.99	0.152
MMSE (score)	0.30 (0.48)	-0.65 to 1.24	0.537
Education level: university/ TAFE	0.13 (2.19)	-4.16 to 4.41	0.955
Marital status: single	2.03 (2.88)	-3.62 to 7.67	0.481
Living situation: live with others	1.49 (2.75)	-3.90 to 6.87	0.589

Working correlation coefficient: 0.48

The working correlation coefficient was estimated to be 0.48, indicating that the GEE approach was appropriate to use. The results of the final linear GEE model showed a significant improvement in VRQOL of nearly 10 points from before to after first eye cataract surgery (p<0.001). Age was the only variable significantly associated with VRQOL with advancing age marginally associated with better VRQOL (p=0.048). No other variables were associated with VRQOL in the linear GEE model once other variables were controlled for.

4.8.3 Vision-Related Quality of Life: Multiple Linear Regression

To investigate whether changes in particular measures of vision were associated with changes in VRQOL from before to after surgery, a multiple linear regression model was used, controlling for potential confounding factors. As for the previous multiple linear regression model, the composite VRQOL score after surgery was modelled as the outcome variable with the composite score before surgery being included as an explanatory variable in the model. Therefore, change was defined relative to the value of the composite score before surgery. (Twisk 2003).

Variables representing the change in each visual measure from before to after cataract surgery were calculated including surgery eye visual acuity, non-surgery eye visual acuity, surgery eye contrast sensitivity, non-surgery eye contrast sensitivity and stereopsis. All of these visual variables and potential confounders including age, gender, country of birth, education, marital status, living situation, number of chronic health conditions, other eye conditions, receipt of new glasses and change in MMSE score were then entered into the multiple linear regression model as explanatory variables. The significance of these variables was examined using two model fitting strategies; the full model and stepwise approaches. Explanatory variables with two sided p values less than 0.05 were considered significant. VRQOL before surgery, age, receipt of new glasses and change in surgery eye contrast sensitivity were significant in both models. Change in non-surgery eye visual acuity was significant only in the full model and country of birth significant only in the stepwise model.

Hierarchical linear regression analysis was subsequently undertaken to determine whether the addition of the change in non-surgery eye visual acuity or country of birth variables improved the fit of a model containing the VRQOL score before surgery, age, receipt of new glasses after surgery and change in surgery eye contrast sensitivity variables. Adding change in non-surgery eye visual acuity to the main effects model produced an F change statistic of 2.55 with 1 and 93 degrees of freedom (p=0.114), indicating that this addition did not significantly improve the model. The addition of country of birth to the main effects model produced an F change statistic of 4.52 with 1 and 93 degrees of freedom (p=0.036), indicating a significant improvement to the model. Therefore, country of birth was included in the final model of main effects but change in non-surgery eye visual acuity was excluded.

The stepwise multiple linear regression model provided the most parsimonious model that explained more of the variability in change in VRQOL (defined as quality of life after surgery relative to quality of life before surgery) and results are detailed in Table 4.16. Interactions between the significant main effects on change in VRQOL in the model were investigated and none of the interaction terms were found to be significant.

The adjusted R squared value of the stepwise multiple linear regression model was 0.50. This indicated that 50.0% of the variance in the VRQOL score after surgery was accounted for by the VRQOL score before surgery, change in surgery eye contrast sensitivity, age, country of birth and whether participants had received new glasses after surgery. The overall F test ($F_{5,93} = 20.57$, $p < 0.001$) showed that the regression was significant. After controlling for confounding factors, change in surgery eye contrast sensitivity was the only visual measure associated with change in VRQOL after first eye cataract surgery. The composite score significantly improved as surgery eye contrast sensitivity improved (p<0.001). In addition, having received new glasses by the time of the second data collection was significantly associated with improvement in VRQOL score (p<0.001). Advancing age (p=0.002) and being non-Australian born (p=0.036) were also significantly associated with less improvement in VRQOL score after surgery.

Table 4.16 Stepwise Multiple Linear Regression Model for Change in Vision-Related Quality of Life [1] (n=99)

Variable [2]	Coefficient (SE)	95% CI	p value
Constant	67.69 (7.07)	53.65 to 81.73	<0.001
VRQOL before surgery (score)	0.52 (0.06)	0.41 to 0.63	<0.001
Surgery eye contrast sensitivity (change)	5.99 (1.64)	2.74 to 9.24	<0.001
New glasses after surgery: yes	7.27 (1.61)	4.06 to 10.47	<0.001
Age (years)	-0.30 (0.09)	-0.49 to -0.12	0.002
Country of birth: non-Australian	-2.80 (1.32)	-5.42 to -0.18	0.036

[1] R squared = 0.53, adjusted R squared = 0.50, $F_{5,93} = 20.57$, $p < 0.001$
[2] Other variables tested in the model included gender, number of chronic health conditions, education, marital status, living situation, other eye conditions, change in MMSE score, change in surgery eye visual acuity, non-surgery eye visual acuity, non-surgery eye contrast sensitivity and stereopsis. Addition of these variables did not improve the fit of the model, so they were excluded.

4.9 Depressive Symptoms

4.9.1 Depressive Symptoms: Descriptive and Univariate Statistics

Depressive symptoms score was the third major outcome of interest for this study and data were collected using the CES-D (Radloff 1977). The depressive symptoms composite score was described for the sample before and after first eye cataract surgery and paired t-tests were used to examine significant changes.

4.9.1.1 Depressive Symptoms Score

The depressive symptoms score was obtained by totalling the scores for all 20 items on the CES-D scale as described in Chapter Three. Possible scores ranged from zero to 60 with higher scores representing more depressive symptoms. Before surgery, depressive symptoms scores ranged from zero to 33 with a mean score of 8.87 (SD: 7.96). Before surgery, six participants (6.1%) scored zero on the scale indicating no depressive symptoms. After surgery, the mean score was 7.52 (SD: 7.60) with 10 participants (10.1%) scoring zero on the scale. Mean scores significantly improved by 1.35 points (SD: 6.07) following surgery (p=0.029) However, this improvement was small and not considered to be clinically meaningful (Beekman et al. 2002). Overall the depressive symptoms score improved in 49 participants (49.5%), remained the same in 20 participants (20.2%) and got worse in 30 participants (30.3%).

For the 49 participants whose depressive symptom scores improved, paired t-tests revealed that they experienced significant mean improvements in surgery eye visual acuity (p<0.001), surgery eye contrast sensitivity (p<0.001) and stereopsis (p=0.001) following surgery (Table 4.17). The 47 participants whose depressive symptoms got worse or remained the same after surgery (three participants who scored zero before and after surgery were removed) also experienced statistically significant improvements in surgery eye visual acuity (p<0.001) and surgery eye contrast sensitivity (p<0.001) after surgery but experienced no significant change in stereopsis (p=0.186) (Table 4.17).

Table 4.17 Mean Changes in Visual Variables by Improvement and Non-Improvement in Depressive Symptoms[1] (n=96)

	Improved (n=49)		Not improved (n=47)	
	Mean change (SD)	**p value[3]**	**Mean change (SD)**	**p value[3]**
Surgery eye visual acuity (log MAR)[2]	-0.48 (0.36)	<0.001	-0.46 (0.28)	<0.001
Surgery eye contrast sensitivity (log units)	0.48 (0.51)	<0.001	0.37 (0.35)	<0.001
Stereopsis (log seconds of arc)[2]	-0.32 (0.65)	0.001	-0.13 (0.69)	0.186

[1] Three participants who scored zero on depressive symptoms scale before and after surgery were removed from analysis
[2] Negative changes in visual acuity and stereopsis represent improvement
[3] p values obtained from paired t-tests

4.9.2 Depressive Symptoms: Generalised Linear Estimating Equation

A third linear GEE model was constructed to analyse the effect of first eye cataract surgery on the final major outcome of interest, depressive symptoms score. The Pearson correlation coefficient for mean depressive symptom scores before and after surgery was calculated and confirmed that these measures were significantly correlated (r=0.70, p<0.001). Therefore, a linear GEE model was fitted with the depressive symptoms score as the outcome variable and time (before or after surgery) was added as an explanatory variable. The change in depressive symptoms from before to after surgery was then assessed while taking account for all potential confounding factors. Table 4.18 summarises the results of the linear GEE model.

Table 4.18 Generalised Linear Estimating Equation Model of Depressive Symptoms (n=99)

Variable	Coefficient (SE)	95% CI	p value
Before/ after surgery: after	-1.33 (0.59)	-2.48 to -0.17	0.024
Education level: university/TAFE	-3.70 (1.30)	-6.25 to -1.14	0.005
Number of chronic health conditions	1.10 (0.40)	0.30 to 1.89	0.007
Gender: female	2.78 (1.70)	-0.56 to 6.12	0.103
Age (years)	-0.07 (0.09)	-0.24 to 0.10	0.389
Country of birth: non-Australian	-0.53 (1.30)	-3.06 to 2.01	0.685
Marital status: single	0.35 (2.21)	-3.99 to 4.69	0.875
Living situation: live with others	1.02 (1.93)	-2.76 to 4.81	0.596
Other eye conditions: yes	1.74 (2.11)	-2.39 to 5.87	0.409
New glasses after surgery: yes	-0.63 (1.53)	-3.62 to 2.36	0.679
MMSE (score)	-0.10 (0.24)	-0.58 to 0.38	0.685

Working correlation coefficient: 0.68

The working correlation coefficient was estimated to be 0.68, indicating that the GEE approach was appropriate to use. Interactions between the significant main effects on depressive symptoms were investigated and none were found to be significant.

The results of the final linear GEE model showed significant improvement in depressive symptoms of just over one point from before to after first eye cataract surgery ($p<0.024$). When all potential confounding factors were controlled for in the linear GEE model, education level ($p=0.005$) and number of chronic health conditions ($p=0.007$) were the only variables significantly associated with depressive symptoms. Having a university or TAFE degree and less chronic conditions were associated with less depressive symptoms.

4.9.3 Depressive Symptoms: Multiple Linear Regression

To investigate whether changes in particular measures of vision were associated with changes in depressive symptoms from before to after surgery, a multiple linear regression model was used, controlling for potential confounding factors. As previously, the depressive symptoms score after surgery was modelled as the outcome variable with the depressive symptoms score before surgery being included as an explanatory variable in the model. Therefore, change was defined relative to the value of the depressive symptoms score before surgery (Twisk 2003).

Variables representing change in each visual score from before to after surgery were calculated including surgery eye visual acuity, non-surgery eye visual acuity, surgery eye contrast sensitivity, non-surgery eye contrast sensitivity and stereopsis. All of these visual variables and potential confounders including age, gender, country of birth, education, marital status, living situation, number of chronic health conditions, other eye conditions, receipt of new glasses and change in MMSE score were then entered into the multiple linear regression model as explanatory variables. The significance of these variables were examined using two model fitting strategies; the full model and stepwise approaches. Explanatory variables with two sided p-values less than 0.05 were considered significant. Depressive symptoms score before surgery, age, receipt of new glasses after surgery and number of chronic health conditions were significant in both models. Change in stereopsis was significant only in the stepwise model.

Hierarchical linear regression analysis was subsequently undertaken to determine whether addition of change in stereopsis improved the fit of a model containing depressive symptoms score before surgery, age, receipt of new glasses after surgery and number of chronic health conditions. Adding change in stereopsis to the main effects model produced an F change statistic of 4.73 with 1 and 93 degrees of freedom (p=0.032), indicating a significant improvement to the model. Therefore, change in stereopsis was included in the final model of main effects. The stepwise multiple linear regression model provided the most parsimonious model that explained more of the variability in change in depressive symptoms (defined as depressive symptoms after surgery relative to depressive symptoms before surgery) and results are detailed in Table 4.19.

Interactions between the significant main effects on change depressive symptoms in the model were investigated and none of the interaction terms were found to be significant. The adjusted R squared value of the stepwise multiple linear regression model was 0.60. This indicates that 60.0% of the variance in the depressive symptoms score after surgery was accounted for by the depressive symptoms score before surgery, change in stereopsis, number of chronic health conditions, receipt of new glasses after surgery and age. The overall F test ($F_{5,93} = 30.88$, $p < 0.001$) showed that the regression was significant.

Table 4.19 Stepwise Multiple Linear Regression Model for Change in Depressive Symptoms[1] (n=99)

Variable [2]	**Coefficient (SE)**	**95% CI**	**p value**
Constant	-13.08 (4.77)	-22.55 to -3.60	0.007
Depressive symptoms before surgery (score)	0.66 (0.06)	0.54 to 0.79	<0.001
Stereopsis (change)	1.64 (0.75)	0.14 to 3.14	0.032
Number of chronic health conditions	1.19 (0.32)	0.56 to 1.82	<0.001
New glasses after surgery: yes	-4.28 (1.22)	-6.71 to -1.85	0.001
Age: years	0.17 (0.06)	0.04 to 0.30	0.009

[1] R squared = 0.62, adjusted R squared = 0.60, $F_{5,93} = 30.88$, $p < 0.001$
[2] Other variables tested in the model included gender, country of birth, education, marital status, living situation, other eye conditions, change in MMSE score, change in surgery eye visual acuity, non-surgery eye visual acuity, surgery eye contrast sensitivity and non-surgery eye contrast sensitivity. Addition of these variables did not improve the fit of the model, so they were excluded.

After controlling for confounding factors, change in stereopsis was the only visual measure associated with change in depressive symptoms after first eye cataract surgery. Depressive symptoms significantly improved as stereopsis improved (p=0.032). Having more chronic health conditions (p<0.001) and advancing age (p=0.009) were both significantly associated with a poorer depressive symptoms score, while receiving new glasses after surgery (p=0.001) was associated with a better score.

CHAPTER 5

Discussion

5 DISCUSSION

Overall, our study aimed to gain a better understanding of the impact of first eye cataract surgery on self-reported driving difficulty, VRQOL and depressive symptoms. It also aimed to determine how changes in these outcomes were associated with changes in objective visual measures after surgery. The results found that there were significant improvements in vision, driving difficulty and VRQOL after first eye cataract surgery but no meaningful change in depressive symptoms. In addition, changes in the major outcomes after surgery were associated with changes in contrast sensitivity and/or stereopsis but not visual acuity.

5.1 Cataract Surgery and Objective Visual Outcomes

Our study found significant improvements in vision after first eye cataract surgery, for measures including surgery eye visual acuity, binocular visual acuity, surgery eye contrast sensitivity, binocular contrast sensitivity and stereopsis. These improvements were all considered to be clinically meaningful except for the change in binocular contrast sensitivity (Elliot 1988; Elliot 1990; Rubin 2001). Mean baseline vision of participants in our study was better than that of participants in studies from Spain, Denmark and India (Acosta-Rojas et al. 2006; Castells et al. 2006; Mamidipudi et al. 2003; Norregaard et al. 2003). This may be explained by the exclusion of patients who had better visual acuity in these studies. Vision was similar however, to two studies from the UK and USA (Elliott et al. 2000; McGwin et al. 2006). Observed changes in visual measures following first eye surgery were therefore of a smaller magnitude than previous investigations. Nevertheless, our study demonstrated meaningful improvements in visual acuity, contrast sensitivity and stereopsis after first eye cataract surgery, even for a group of bilateral cataract patients who had better baseline vision.

Our study also described the proportion of participants who improved, remained the same or declined on visual measures after first eye cataract surgery. While the majority of participants had improved surgery eye visual acuity (97%) and surgery eye contrast sensitivity (88%), only 55% had improved stereopsis after surgery. Stereopsis remained the same for 21% and declined for 24% of participants. This finding was consistent with two studies that reported that first eye surgery could sometimes result in considerable differences in vision between the operated and un-operated eyes, compromising binocular vision and consequently stereopsis (Comas et al. 2007; Castells et al. 2006). Furthermore, research has indicated that second eye cataract surgery could reduce these differences and bring about large improvements in stereopsis (Comas et al. 2007; Castells et al. 2006). It is therefore plausible that a proportion of patients do not improve after first eye cataract surgery and require the second surgery to achieve visual benefits. Further investigation into this issue is required.

Of concern, our study also found that 18% of participants were in fact, driving illegally before first eye surgery based on their visual acuity levels. Without surgery, at least 18% would have failed their next vision test for licensing. Past research has revealed a strong link between driving and independence, health and well-being for older adults (Oxley & Whelan 2008; Windsor et al. 2007). The large improvements in surgery eye and bilateral visual acuity after first eye cataract surgery, significantly reduced the proportion who did not meet visual criteria for licensing to 4%. This finding demonstrated the importance of first eye cataract surgery for keeping older drivers on the road and maintaining their independence.

5.2 Cataract Surgery and Driving Difficulty

5.2.1 Driving Difficulty Composite Score

Our study was the first to examine the separate impact of first eye cataract surgery on self-reported driving difficulty, using a detailed and validated questionnaire. Results found a significant 10 point improvement in driving difficulty score after surgery.

This positive result is strongly supported by past research with eight prospective studies suggesting an association between cataract surgery and decreased driving difficulty (Bevin, Derrett & Molteno 2004; Castells et al. 1999; Elliott et al. 2000; Mamidipudi et al. 2003; McGwin et al. 2003b; Monestam, Lundquist & Wachtmeister 2005; Monestam & Wachtmeister 1997; Owsley et al. 2002). However, most of these studies did not examine the separate effects of first or second eye surgery, combining those who underwent first, second or both eye surgeries in the analyses. In addition, most of these studies measured driving difficulty using general questionnaires containing only two items on day and night driving. Only Owsley et al. used the detailed Driving Habits Questionnaire (Owsley et al. 1999) to measure driving difficulty and reported an improvement of approximately eight points after surgery (Owsley et al. 2002). It should be noted that this study included those who underwent first or both eye surgeries in the analysis as well as unilateral and bilateral patients (Owsley et al. 2002). Another study of only 17 drivers reported significant improvements in day and night driving difficulty after first eye surgery (Elliott et al. 2000).

Our study also demonstrated that self-reported driving difficulty improved for 73% of participants after first eye surgery. Sixteen percent remained the same and 11% declined. The proportion who improved was lower than previously reported. One Spanish study found that 89% of participants improved in day driving and 79% in night driving after first eye surgery (Castells et al. 1999). The differences found in our study may be attributed to the use of a more comprehensive driving difficulty scale that encompassed more areas of difficulty for participants.

Of particular interest, these results found that there may be a proportion of drivers who do not improve or even decline in self-reported driving difficulty after first eye surgery. Interestingly, it was found that those who remained the same or declined, experienced significant improvements in surgery eye visual acuity and contrast sensitivity after surgery but no significant change in stereopsis. The role of stereopsis in driving has not been thoroughly investigated in the literature but early evidence has suggested that it plays a role in judging the distance of objects (Bauer et al. 2001) and affects onset of braking and stopping distances (Tijtgat et al. 2008). It is also possible that stereopsis served as a marker of increased differences in vision between the two eyes after surgery, which can interfere with binocular vision and cause binocular inhibition, as mentioned in Chapter 2 (Comas et al. 2007; Castells et al. 2006). The sample size of our study however, did not have sufficient power to further examine characteristics of non-improvers.

5.2.2 Driving Difficulty Tasks

Our study was the first to examine changes in the proportion of drivers who experienced difficulty on specific driving tasks after first eye surgery. Before surgery, the majority of participants reported some degree of difficulty with night driving (90%), reading street signs (83%) and driving in the rain (53%). One study did report on specific driving difficulties but the participants consisted of cataract patients about to undergo first eye surgery and normally sighted older drivers (McGwin, Chapman & Owsley 2000). Their findings were consistent with our study for proportions experiencing difficulty driving in the rain, on the freeway, driving alone and parallel parking. However, our study found higher rates of difficulty driving at night and making turns across traffic and lower rates of difficulty in high traffic or in peak hour traffic (McGwin, Chapman & Owsley 2000). These discrepancies may have resulted because participants in the study by McGwin et al. were younger, had better vision and some did not have cataract (McGwin, Chapman & Owsley 2000). Alternatively, the study by McGwin et al. was conducted in the USA, so differences in road environments between the two countries, including different road lighting and traffic volumes may have contributed to the discrepancies.

Our study also observed a significant decrease in the proportion of participants experiencing difficulty on each driving difficulty item after surgery, except for parallel parking and vehicle positioning in the lane. Improvements were not observed for these two tasks possibly because they rely on stereopsis, a visual measure that did not improve in a number of participants. Alternatively, only a small proportion of participants reported difficulty on these tasks before surgery and this may explain the results. Our study also added three separately scored driving difficulty items to the eight item Driving Habits Questionnaire scale. These items addressed reading street signs, judging the distance of objects and vehicles and positioning of the vehicle in the lane. The results also found a significant decrease in the proportion of participants experiencing difficulty reading street signs and judging distances after first eye surgery. Therefore, it may be important to include these two items in future assessments of driving difficulty for cataract patients.

Despite a wide range of improvements in driving difficulty after first eye surgery, results revealed that a considerable proportion of participants still experienced difficulty driving at night (62%), reading street signs (42%), judging distances (24%), parallel parking (23%) and driving in the rain (21%). This may be attributed to other areas of function including health and cognition which can influence driving difficulty. Further research is required to determine whether these difficulties are due to the presence of one remaining cataract or impaired stereopsis in bilateral patients and whether the second eye surgery can provide additional benefits for driving difficulty.

5.2.3 Visual Measures Associated with Change in Driving Difficulty

Study results found that change in surgery eye contrast sensitivity after first eye cataract surgery was the only visual measure associated with change in driving difficulty, after controlling for other visual measures and confounding factors. This confirmed recent investigations identifying contrast sensitivity as a potential predictor of driving-related outcomes (Freeman et al. 2006; Keay et al. 2009; van Rijn et al. 2011). Owsley et al. reported that contrast sensitivity worse than 1.25 log units was the only independent predictor of crash involvement for cataract patients in the previous five years (Owsley et al. 2001). They also found that the relationship was stronger for worse eye contrast sensitivity than better eye (Owsley et al. 2001). A small Australian study also confirmed that driving difficulty before surgery was strongly associated with contrast sensitivity (Walker, Anstey & Lord 2006). In contrast, a cross-sectional analysis reported that visual acuity was the only measure independently associated with driving difficulty as measured by the Driving Habits Questionnaire before surgery (McGwin, Chapman & Owsley 2000). Their study however, included only better eye values for each measure in the analysis, which may explain the conflicting results.

Another small Australian study reported that change in on-road driving performance after bilateral cataract surgery was associated with change in contrast sensitivity in the second operated eye but not with visual acuity (Wood & Carberry 2006). McGwin et al. also found that change in night driving difficulty was associated with changes in both visual acuity and contrast sensitivity in the first operated eye (McGwin et al. 2003b). Change in day driving difficulty was not associated with any visual measures. Their analysis however, used only two questions to measure driving difficulty and included patients who underwent first or both eye surgeries (McGwin et al. 2003b).

The findings of our study, together with previous research, suggest that contrast sensitivity, particularly in the worse or surgery eye, may be an important measure associated with driving outcomes in cataract patients. Results also suggest that while change in surgery eye contrast sensitivity is associated with the overall change observed in driving difficulty after first eye surgery, for the smaller proportion of participants who did not improve, stereopsis may have played a major role. Contrast sensitivity has been found to be associated with a wide range of driving tasks. It is plausible that contrast sensitivity may be more important than visual acuity for driving because the road environment presents objects mostly of low contrast (Wood 2002). Several reviews have concluded that evidence for an association between visual acuity and crash risk is weak, so these results call into question the reliance on visual acuity measures for licensing assessments (Bohensky et al. 2008; Desapriya et al. 2011).

5.2.4 Other Factors Associated with Change in Driving Difficulty

Having a greater number of chronic conditions was associated with less improvement in driving difficulty after surgery. The association between chronic conditions and poorer driving outcomes is well supported by the literature (Lyman, McGwin & Sims 2001; McGwin et al. 2000). Moreover, receiving new glasses after first eye surgery was significantly associated with improvement in driving difficulty. Three months after first eye surgery, only 22% of participants had purchased new prescription glasses. Due to the expense of prescription glasses, it is likely that most bilateral cataract patients requiring glasses hold their purchase until after their second surgery. A recent study from Thailand confirmed that provision of appropriate glasses after cataract surgery had a modest but significant impact on vision (Maki et al. 2008). Therefore, bilateral patients who do not receive new glasses after first eye surgery may function at less than optimal vision during the considerable waiting period for second eye surgery. In addition, they may experience less benefit from first eye surgery in terms of driving difficulty, which is a concern for road safety.

5.3 Cataract Surgery and Vision-Related Quality of Life

5.3.1 Vision-Related Quality of Life Composite Score

The study results revealed a significant improvement of nearly 10 points on the composite VRQOL score after first eye cataract surgery. Previous literature also reported significant improvements after first eye surgery (Castells et al. 1999; Castells et al. 2006; Elliott et al. 2000; Gray et al. 2006; Gutierrez et al. 2009; Harwood et al. 2005; Javitt et al. 1995; Mamidipudi et al. 2003; Norregaard et al. 2003; Walker et al. 2006). Almost all of the 10 studies however, used the VF-14 to measure VRQOL (Steinberg et al. 1994). This instrument addresses only visual symptoms and difficulty with visually demanding tasks. Meanwhile, studies examining the association between first eye cataract surgery and generic, non-vision related HRQOL outcomes have reported mixed results (Castells et al. 1999; Castells et al. 2006; Harwood et al. 2005; Elliott et al. 2000). Our study used the NEI VFQ-25 to measure VRQOL (Mangione et al. 2001). This instrument not only measures difficulty with visual tasks but also the influence of visual impairment on areas of

HRQOL including social functioning, mental health, role difficulties and dependency (Mangione et al. 2001). Our study was the first to demonstrate significant improvements after first eye cataract surgery in VRQOL as measured by the NEI VFQ-25.

Two studies conducted in Japan and one in the USA have demonstrated significant improvements on the NEI VFQ-25 composite score after both eye surgeries (Ishii, Kabata & Oshika 2008; Oshika et al. 2005; Zhang et al. 2011). Detailed information was available for one of the Japanese studies, which reported an improvement of 15 points on the composite score after both eye surgeries (Ishii, Kabata & Oshika 2008). Their greater improvement may have reflected additional effects of the second eye surgery on VRQOL or could have been due to the lower composite scores of participants at baseline.

Our study also found that 86% of participants improved on the composite VRQOL score after surgery. Only 1% remained the same and 13% declined. As reported for the driving difficulty outcome, those who did not improve after surgery experienced statistically significant improvements in surgery eye visual acuity and surgery eye contrast sensitivity, but no significant change in stereopsis after surgery. Incidentally, a UK-based study using the VF-14, found that while mean scores improved overall after first or second eye surgery, 25% of participants experienced no change or declined (Black et al. 2009). The higher percentage reported by Black et al. may be explained by their inclusion of second eye patients with high initial scores in the sample. Nevertheless, there appears to be a proportion of bilateral cataract patients who do not improve or even decline in VRQOL after first eye surgery. This implies that the performance of daily tasks as well as the social, emotional and mental health of these patients may be significantly impaired while waiting for second eye surgery. Further research is required to determine whether second eye surgery can bring about benefits for these patients.

5.3.2 Vision-Related Quality of Life Subscale Scores

Our study also examined changes in the 12 NEI VFQ-25 subscale scores after first eye cataract surgery. Before surgery, scores were lowest for the general health, general vision and driving subscales, with scores below 70 points. Scores were highest for the colour vision, vision-specific social functioning, vision-specific dependency and ocular pain subscales with mean scores above 90 points. Statistically significant improvements were observed in nine subscale scores after first eye surgery. No significant changes were demonstrated for the general health, ocular pain or colour vision subscales. Our results were generally consistent with those of previous studies. Three studies examining change in NEI VFQ-25 subscale scores after both eye surgeries reported significant improvements in all scores except for general health (Ishii, Kabata & Oshika 2008; Oshika et al. 2005; Zhang et al. 2011). It seems that self-rated general health is not influenced by vision for cataract patients. Few participants in the current study reported difficulty with colour vision or ocular pain before surgery, possibly explaining the non-significant findings.

Large improvements of more than 14 points were observed for subscales including general vision, near activities, distance activities and driving. Interestingly, large improvements were also found on two of the less task-related subscales namely, vision-specific role difficulties (17 points) and vision-specific mental health (14 points). Past research has reported that cataract can impact on emotional and social aspects of HRQOL that are not specifically related to task performance (Mangione et al. 1998). Our study reinforced this claim by demonstrating that first eye cataract surgery significantly improved these mental health-related subscales. Smaller improvements of four to five points were observed for the peripheral vision, vision-specific social functioning and vision-specific dependency subscales. It is not established whether these smaller changes have any clinical meaning (Clemons et al. 2003; Submacular Surgery Trials Research Group 2007). It should also be noted that after first eye surgery, six of the subscales had mean scores of over 90 points, suggesting potential ceiling effects of the NEI VFQ-25. Thus, the ability of this instrument to detect additional changes after second eye surgery warrants further research.

5.3.3 Visual Measures Associated with Change in Vision-Related Quality of Life

Change in surgery eye contrast sensitivity after first eye cataract surgery was the only visual measure associated with change in VRQOL composite score, after controlling for other visual measures and confounding factors. While a previous study reported that change in VRQOL after first eye surgery was associated with change in binocular contrast sensitivity, it was most strongly related to change in stereopsis (Datta et al. 2008). In contrast, McGwin et al. found that change in VRQOL was most strongly related to change in visual acuity in the first surgery eye and not contrast sensitivity (McGwin et al. 2003b). However, their study included patients who underwent first or both eye surgeries. It has also been reported that visual acuity is strongly associated with VRQOL before first eye cataract surgery (Acosta-Rojas et al. 2006; Datta et al. 2008), but stereopsis and contrast sensitivity have more influence after surgery (Acosta-Rojas et al. 2006). All existing studies used the VF-14 or ADVS to examine VRQOL which focus strongly on activities that require visual acuity (Datta et al. 2008). Consequently, this may have led to the positive findings for visual acuity.

The environment contains many low-contrast stimuli, meaning contrast sensitivity is necessary for the performance of a wide range of daily activities (Datta et al. 2008; McCulloch et al. 2011; West et al. 2002). It is therefore plausible that contrast sensitivity plays an important role in VRQOL. Although contrast sensitivity is usually correlated with visual acuity, some cataract patients can have very low contrast sensitivity and experience considerable visual impairment, even when their visual acuity is within normal limits (Bal et al. 2011). Consequently, the current focus on visual acuity in Ophthalmology practice, to determine visual disability and prioritise patients for cataract surgery, may overlook patients who are significantly impaired.

5.3.4 Other Factors Associated with Change in Vision-Related Quality of Life

Receiving new glasses after first eye surgery was significantly associated with improvement in VRQOL. Patients who wait until after second eye surgery to purchase appropriate glasses may experience less benefit from first eye surgery in terms of VRQOL as well as driving difficulty. Advancing age and not being born in Australia were also found to be significantly associated with less improvement in VRQOL score after surgery. Advancing age has been widely reported to be associated with poorer quality of life outcomes in the literature (Chia et al. 2003; Wu et al. 2008). There is also evidence linking immigrants to poorer quality of life outcomes (Wilmoth & Chen 2003).

5.4 Cataract Surgery and Depressive Symptoms

5.4.1 Depressive Symptoms Composite Score

Results found a statistically significant improvement of just over one point on the CES-D scale of depressive symptoms after first eye cataract surgery. However, the magnitude of this change did not have any clinical meaning for participants (Beekman et al. 2002). Theoretically, first eye cataract surgery could reduce depressive symptoms by improving visual functioning and allowing the older person to engage in valued activities, yet studies to date have provided little evidence of such an effect (Walker et al. 2006).

A UK-based RCT of 154 women aged over 70 years who underwent surgery and 152 who did not, reported a small improvement in depressive symptoms after first eye surgery, compared to the no surgery group who deteriorated over the follow up period (Harwood et al. 2005). It is therefore possible that our study underestimated the impact of first eye surgery on depressive symptoms due to the absence of a comparison group. However, other studies with comparison groups and similar sample sizes also reported no significant differences in depression after surgery (Foss et al. 2006; McGwin et al. 2006; McGwin et al. 2003a). Before surgery, participants exhibited a mean CES-D score of approximately nine points, indicating low depressive symptoms. This was similar to but slightly worse than the mean baseline CES-D score of cataract patients in the study by McGwin et al. (McGwin et al. 2006). They similarly reported no significant improvement after surgery (McGwin et al. 2006). The low prevalence of depressive symptoms before surgery, coupled with small sample sizes may have contributed to the inability to detect improvements in depressive symptoms. On the other hand, depression is a complex construct with multi-factorial causes and pathways (Cole & Dendukuri 2003). A single factor such as cataract surgery may not be sufficient to have a significant impact on depressive symptoms. (McGwin et al. 2003a).

Overall, approximately half of participants improved in CES-D score after surgery and half remained the same or deteriorated. The proportion of improvement was much lower than that for the driving difficulty or VRQOL outcomes. Again, those who did not improve in depressive symptoms experienced a significant improvement in surgery eye visual acuity and surgery eye contrast sensitivity but no significant change in stereopsis.

5.4.2 Visual Measures Associated with Change in Depressive Symptoms

Our study demonstrated that change in stereopsis after first eye cataract surgery was the only visual measure associated with change in depressive symptoms, after controlling for other visual measures and confounding factors. Datta et al. reported that change in depression after first eye surgery was not associated with any visual measures but that binocular visual acuity was associated with depression before surgery (Datta et al. 2008). The mechanism by which stereopsis may impact on depression is unclear. According to a study of 200 older people in Taiwan, while visual acuity is associated with performance of tasks, stereopsis is important for more generic quality of life and well-being outcomes (Kuang et al. 2005).

5.4.3 Other Factors Associated with Change in Depressive Symptoms

Receiving new glasses after first eye surgery was again found to be significantly associated with improvement in depressive symptoms. It is possible that receiving new glasses may result in a better visual outcome and increase satisfaction with surgery, thus reducing depression. However, it should be noted that updating glasses may be more prevalent among those with less depressive symptoms and those who are more proactive, meaning the relationship is not causal. In addition, having more chronic health conditions and advancing age were associated with less improvement in depressive symptoms. Both are well known risk factors for depression in the general community (Huang et al. 2010; Pirkis et al. 2009).

5.5 Study Strengths

The current study provided valuable information on the effects of first eye cataract surgery on self-reported driving difficulty, VRQOL and depressive symptoms. Previous studies have not analysed the separate effects of first, second or both eye cataract surgeries, and have combined unilateral and bilateral cataract patients in their samples. This study specifically examined the impact of first eye cataract surgery for bilateral cataract patients who drive. Past investigations have also included few drivers in their samples. A substantial proportion of bilateral cataract patients in Western Australia who drive, undergo cataract surgery through the public hospital system. These patients have to wait long periods of time before first eye surgery and again before the second eye surgery. Therefore, the information on the separate effects of first eye surgery provided by this study, is of great importance for the safety and well being of these particular patients.

Another strength of the study was the use of GEE modelling to examine the effects of first eye cataract surgery on the outcomes of interest. GEE models account for the within-subject correlation in repeated measures data, thereby providing more robust regression coefficients than alternative methods (Ballinger 2004).

Self-reported driving difficulty has frequently been measured using only two simple questions concerning day and night driving. A strength of this study was the use of the eight-item driving difficulty scale from the Driving Habits Questionnaire (Owsley et al. 1999). This allowed the impact of first eye surgery on specific driving tasks to be investigated. Similarly, previous research examining cataract surgery and VRQOL has used instruments that measure the impact of vision on the performance of daily activities only. The NEI VFQ-25 used in this study provided a multidimensional assessment of VRQOL and allowed the impact of first eye surgery on mental health and social functioning, as well as daily activities to be examined (Mangione et al. 2001).

An additional benefit of this study was the inclusion of three objective visual measures including visual acuity, contrast sensitivity and stereopsis. Previous studies examining outcomes of cataract surgery have seldom measured stereopsis. This provided new information on how changes in the major outcomes of interest were associated with changes in vision after first eye surgery. In terms of driving, these findings have important implications for the assessment of fitness to drive in cataract patients. Finally, the specific examination of patients who did not improve after first eye cataract surgery in terms of driving difficulty, VRQOL and depressive symptoms, was a particular strength of the study. Through this, stereopsis was identified as a potentially useful test for non-improvement and for recognising those who may be at risk of poor safety and well-being outcomes after first eye surgery.

5.6 Study Limitations

The before and after design used in this study has several limitations. Since all suitable public hospital patients are offered cataract surgery in Western Australia, it was not possible to recruit a group of drivers who did not undergo first eye surgery as a comparison group. It would also have been unethical to delay surgery. Limited resources also did not permit the inclusion of a normally-sighted comparison group. Therefore, changes in major outcomes of interest were compared within the individual before and after surgery. It is acknowledged that the absence of a comparison group makes it difficult to establish cause and effect in this study. The observed improvements may be attributed to factors other than cataract surgery, the Hawthorne effect or regression to the mean. However, no study to date has reported improvements in driving difficulty, VRQOL or depressive symptoms for cataract patients who did not undergo surgery. Several studies have reported declines in these outcomes for the non-surgery participants (Harwood et al. 2005; McGwin et al. 2003b; Owsley et al. 2002). Therefore, our study may have underestimated the effect of first eye cataract surgery on improvements in the major outcomes of interest.

Reporting bias also posed an intrinsic risk due to the nature of self-reported data. In particular, the self-reported driving difficulty measure was subject to under-reporting due to fear of losing his/her licence or poor awareness of driving deficits. Although self-reported driving difficulty, as measured by the Driving Habits Questionnaire, was a quick and inexpensive measure, whether it reflects actual on-road driving performance or crash risk is still unknown (Owsley et al. 1999). Nevertheless, studies have suggested that self-report measures of driving ability can be predictive of on-road driving performance for older Australians (Baker et al. 2003).

Another limitation concerns the lack of inclusion of other types of visual impairment measures including visual fields, disability glare and refractive error. This is because they are expensive and expertise is required to conduct these tests. It should also be noted that past studies have found no association between disability glare and driving outcomes (McGwin, Chapman & Owsley 2000; Owsley et al. 2001). This study instead measured three important objective visual measures namely visual acuity, contrast sensitivity and stereopsis. Stereopsis has seldom been included in studies examining driving difficulty, VRQOL and depressive symptom outcomes for cataract patients but our results showed that it should be included in future research. It would also be valuable to include a measure of ocular dominance in future research as it may affect how satisfied a person is with surgery.

Our study was not designed to evaluate long term outcomes of first eye cataract surgery because the majority of participants were also scheduled for second eye cataract surgery. The follow-up data were collected approximately twelve weeks after first eye cataract surgery. This is a sufficient time period for vision to stabilise after surgery and to provide patients the opportunity to undertake a wide range of visual tasks (Gray et al. 2006). It is plausible however, that twelve weeks may have been insufficient for changes in more complex outcomes such as depressive symptoms to become apparent (Walker et al. 2006). Examining the impact of second-eye cataract surgery on the three major outcomes was also beyond the scope of this study.

Although the sample size was adequate for investigating the major outcomes of interest, it did not allow sufficient power to detect differences in smaller subgroups within the sample. Finally, in spite of our high response and low drop-out rate among eligible cataract patients, the results can only be generalised to patients in the Australian public hospital system who drive. This group may be healthier and have better cognitive functioning than non-drivers. Also, the results cannot be extrapolated to non-English speaking patients, those with severe co-morbid eye disorders or patients in rural and remote areas.

5.7 Clinical Implications

The findings have implications for Ophthalmology practices, Government funding and visual standards for driver licensing. First eye cataract surgery was associated with significant benefits for driving difficulty and a range of VRQOL outcomes. This provides strong grounds for Ophthalmologists to recommend cataract surgery to all suitable drivers with bilateral cataract.

By the end of the waiting period for first eye cataract surgery, 18% of the participating drivers did not meet the visual standards for licensing in Western Australia. Cataract surgery reduced this proportion to 4%, highlighting its importance for keeping older drivers licensed. Driving cessation has been linked to poor physical and mental health outcomes for older adults (Oxley 2008) and the demand for cataract surgery is set to increase due to the ageing population of Australia (Rochtchina et al. 2003). Therefore, the study findings provide a compelling rationale for increasing funding to reduce the waiting period for cataract surgery for public patients in Western Australia.

There were a substantial proportion of bilateral cataract patients who did not improve or declined on driving difficulty, VRQOL or depressive symptom outcomes after first eye cataract surgery. It may be able to be possible to identify such patients through the objective visual measure of stereopsis. Ophthalmologists could use this simple measure to identify bilateral patients who did not benefit from first eye cataract surgery, allowing them to be advised and prioritised for second eye surgery.

For driving difficulty, VRQOL and depressive symptom outcomes, receiving new glasses after first eye surgery was significantly associated with greater improvements. Therefore, bilateral cataract patients who do not receive new glasses during the substantial waiting period for second eye surgery, may not enjoy the maximum benefits of first eye surgery. In light of this, encouraging up to date spectacle prescription is important and Ophthalmologists should consider issuing interim glasses for bilateral cataract patients in order to optimise their safety and well-being during the waiting period.

Finally, contrast sensitivity and stereopsis, but not visual acuity were associated with changes in the three major outcomes after cataract surgery. This calls into question the reliance on visual acuity measures in determining levels of visual impairment and prioritising cataract patients for surgery. Ophthalmologists should incorporate contrast sensitivity and stereopsis into their assessments to ensure cataract patients who have normal visual acuity but are significantly impaired on the former measures are not missed. Finally, this study confirmed previous findings that contrast sensitivity but not visual acuity was associated with driving difficulty for cataract patients. This has implications for driver licensing authorities worldwide that rely heavily on visual acuity measures for licensing. Using visual acuity alone may firstly, not identify all those who are at risk on the road due to visual impairment and secondly, lead to the restriction of older drivers who are not significantly impaired. While historically it has been difficult to identify tests predictive of crash risk, it is imperative for licensing authorities to further investigate the role of contrast sensitivity as a potential screening test for licensing.

5.8 Recommendations for Further Research

Future research should examine the separate effects of second eye cataract surgery on driving difficulty, VRQOL and depressive symptoms. It is important to determine whether second eye surgery provides any specific additional benefits and for which groups of patients it is effective. Information on the impact of second eye cataract surgery on driving outcomes is particularly lacking. In addition, new studies examining the impact of cataract surgery on depressive symptoms require larger sample sizes to enable sufficient power to detect any effect of surgery.

Some bilateral cataract patients did not improve in driving difficulty, VRQOL and depressive symptoms after first eye surgery. Further research is needed to identify factors associated with non-improvement and to understand whether these patients require second eye surgery to bring about benefits. In addition, stereopsis was identified as a possible predictor of non-improvement in the outcomes after first eye surgery. It is thus of interest to fully investigate the mechanisms by which stereopsis may impact on driving outcomes, VRQOL and depressive symptoms.

Finally, future research should examine the separate effects of first and second eye cataract surgery on objective driving outcomes including on-road performance, simulator performance and crash involvement for older drivers. Since contrast sensitivity has emerged as a potentially important visual measure associated with driving outcomes, investigations should attempt to establish cut-off points for crash risk so that the measure can be effectively used in driver licensing tests.

5.9 Conclusion

Past studies examining the impact of cataract surgery have combined patients who underwent first, second or both eye surgeries in the analyses. Our study provided important information on the impact of first eye cataract surgery on driving difficulty, VRQOL and depressive symptoms for older drivers. Findings are of particular relevance to bilateral cataract patients in the Western Australian public hospital system, who wait considerable periods of time between their first and second eye surgeries. This study demonstrated significant benefits from first eye cataract surgery in terms of driving difficulty, VRQOL and maintenance of levels of vision required for driver licensing, but not depressive symptoms. As the population ages, it is therefore essential for Australian public hospital systems to meet increasing demands for cataract surgery, in order to maximise the safety and well being of older Australians.

Despite overall benefits, some patients did not benefit from first eye surgery in terms of driving difficulty or VRQOL. This has implications for Ophthalmology practices in terms of identifying and possibly prioritising these patients for second eye surgery. Our results suggested that the stereopsis measure may be useful for identifying such patients. Finally, contrast sensitivity or stereopsis, but not visual acuity, were associated with changes in major outcomes. This challenges the current reliance on visual acuity for assessment and prioritisation of cataract patients for surgery, and in driver licensing. Further research is required to validate the results of this study with objective measures of driving performance and crash involvement. In addition, further investigation is needed to determine the additional effects of second eye cataract surgery for older drivers, to uncover factors associated with non-improvement of cataract patients after first eye surgery and to develop appropriate visual tests for driver licensing.

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APPENDIX A

Participant Information Sheets

Curtin University of Technology

Fremantle Hospital & Health Service

Participant Information Sheet

A study to measure the impact of first-eye cataract surgery on driving and quality of life for older drivers

Investigators: Prof. Andy Lee, Dr Lynn Meuleners (Curtin University), A/Prof. Nigel Morlet & Dr Jonathon Ng (Royal Perth Hospital)

Study summary

Cataract surgery is a very common procedure. However little is known about the specific effects of first-eye cataract surgery on driving and quality of life for older drivers. This study aims to follow 100 cataract patients through their surgery and monitor their vision, driving outcomes and quality of life. The study will include participants from Fremantle, Royal Perth and Sir Charles Gairdner Hospitals.

What participation in this study involves

If you agree to participate in this study, there will be no change to your cataract treatment or your waiting time for surgery. It involves attending two assessments during the course of your cataract treatment.

If you agree to participate we will ask you to do the following things:

- Participate in face-to-face questionnaires delivered by the researcher about your driving experience, driving difficulties, quality of life and depression
- Participate in short cognitive assessments
- Complete three simple vision tests. These are visual acuity, contrast sensitivity and stereopsis. These simple tests ask you to read letters or determine pictures and cause no discomfort or risk to yourself

Your participation will involve two assessments:

1. During the week before your 1st eye cataract surgery
2. Three months after your 1st eye surgery

Each visit will take 60-75 minutes and exactly the same questionnaire, cognitive test and vision tests will be performed each time. These visits will usually take place in your own home.

What are the benefits of the study?

We cannot promise any personal benefits to you from participating in this study. However, we believe the results of this study will allow future patients to be better informed about driving difficulties before and after cataract surgery. It will also allow doctors to better determine who will benefit from the surgery and who may experience difficulties following the surgery and should be prioritised for the second surgery.

What are the possible risks or burdens to participation?

The questionnaire, cognitive and visual tests involved in this study will not cause any form of discomfort or pose any risk to yourself.

What if I sustain an injury during the study?

In the event that you suffer an adverse event or a medical accident during this study that arises from your participation in the study, you will be offered all full and necessary treatment by Fremantle Hospital.

What are the costs to me?

Participation in this study will not result in any costs for you. Curtin University will reimburse you any reasonable expenses you incur due to travel.

How will your personal information be handled?

Special arrangements are in place to ensure that your data is handled in strict confidence and in compliance with all privacy laws (in Australia this is the Privacy Act 1988). Your name will not appear on study documents and you will be identified only by a participant ID number. Only the investigators on the study will have access to your data. Your name will not appear on any document or publication. The information you provide to the researchers will not be shared with or passed on to anyone including other medical practitioners or the Department of Transport in charge of driver licensing. However, if your vision (visual acuity) is found to be below the minimum criteria for a WA driver's license you may be asked by your Ophthalmologist not to drive until you have had your cataract surgery and your vision has been reassessed. If it is determined that your visual acuity will not improve in the near future it is your responsibility to inform the Department of Transport, WA. The researchers or Ophthalmologists will not inform the Department.

What are your rights?

Participation in this study is voluntary. You do not have to participate if you do not want to and can choose to withdraw from the study at any time without this affecting your cataract treatment. If you decide not to participate in the study you will receive your cataract treatment in the usual way and your decision will be respected by the doctors treating you and will not affect any future treatment you might need.

Further information

This is a Masters student research project conducted by Michelle Fraser from the School of Public Health, Curtin University of Technology. If you have questions about the study you may contact:

Michelle Fraser (Masters student): Ph: 0408 326 510

OR

Professor Andy Lee
(Supervisor): Ph: 9266 4180

This study has been approved by the South Metropolitan Area Health Service Human Research Ethics Committee. If you should have any complaints or concerns about the way in which the study is being conducted, you may contact the Chairman of the Committee on 9431 2929.

Appendix A2 Royal Perth Hospital Participant Information Sheet

Participant Information Sheet

A study to measure the impact of first-eye cataract surgery on driving and quality of life for older drivers

Investigators: Prof. Andy Lee, Ms Michelle Fraser, Dr Lynn Meuleners (Curtin University), A/Prof. Nigel Morlet & Dr Jonathon Ng (Royal Perth Hospital)

Study summary

Cataract surgery is a very common procedure. However little is known about the specific effects of first-eye cataract surgery on driving and quality of life for older drivers. This study aims to follow 100 cataract patients through their surgery and monitor their vision, driving outcomes and quality of life. The study will include participants from, Royal Perth, Sir Charles Gairdner and Fremantle Hospitals.

What participation in this study involves

If you agree to participate in this study, there will be no change to your cataract treatment or your waiting time for surgery. It involves attending two assessments during the course of your cataract treatment.

If you agree to participate we will ask you to do the following things:

- Participate in face-to-face questionnaires delivered by the researcher about your driving experience, driving difficulties, quality of life and depression
- Participate in short cognitive assessments
- Complete three simple vision tests. These are visual acuity, contrast sensitivity and stereopsis. These simple tests ask you to read letters or determine pictures and cause no discomfort or risk to yourself

Your participation will involve two assessments:

1. During the week before your 1^{st} eye cataract surgery
2. Three months after your 1^{st} eye surgery

Each visit will take 60-75 minutes and exactly the same questionnaire, cognitive test and vision tests will be performed each time. These visits will usually take place in your own home.

What are the benefits of the study?

We cannot promise any personal benefits to you from participating in this study. However, we believe the results of this study will allow future patients to be better informed about driving difficulties before and after cataract surgery. It will also allow doctors to better determine who will benefit from the surgery, who may experience difficulties following the surgery and who should be prioritised for the second surgery.

What are the possible risks or burdens to participation?

The questionnaire, cognitive and visual tests involved in this study will not cause any form of discomfort or pose any risk to yourself.

What if I sustain an injury during the study?

In the event that you suffer an adverse event or a medical accident during this study that arises from your participation in the study, you will be offered all full and necessary treatment by Royal Perth Hospital.

What are the costs to me?

Participation in this study will not result in any costs for you. Curtin University will reimburse you any reasonable expenses you incur due to travel.

How will your personal information be handled?

Special arrangements are in place to ensure that your data is handled in strict confidence and in compliance with all privacy laws (in Australia this is the Privacy Act 1988). Your name will not appear on study documents and you will be identified only by a participant ID number. Only the investigators on the study will have access to your data. Your name will not appear on any document or publication. The information you provide to the researchers will not be shared with or passed on to anyone including other medical practitioners or the Department of Transport in charge of driver licensing. However, if your vision (visual acuity) is found to be below the minimum criteria for a WA driver’s license you may be asked by your Ophthalmologist not to drive until you have had your cataract surgery and your vision has been reassessed. If it is determined that your visual acuity will not improve in the near future it is your responsibility to inform the Department of Transport, WA. The researchers or Ophthalmologists will not inform the Department.

What are your rights?

Participation in this study is voluntary. You do not have to participate if you do not want to and can choose to withdraw from the study at any time without this affecting your cataract treatment. If you decide not to participate in the study you will receive your cataract treatment in the usual way and your decision will be respected by the doctors treating you and will not affect any future treatment you might need.

Further information

This is a Masters student research project conducted by Michelle Fraser from the School of Public Health, Curtin University of Technology. If you have questions about the study you may contact:

Michelle Fraser (Masters student): Ph: 0408 326 510

OR

Professor Andy Lee
(Supervisor): Ph: 9266 4180

This study has been approved by the RPH Ethics Committee. If you have any concerns about the conduct of the study or your rights as a research participant, please contact Prof Frank van Bockxmeer, Chairman of the RPH Ethics Committee, telephone (08) 9224 2244.

Curtin University of Technology

Sir Charles Gairdner Hospital

Participant Information Sheet

A study to measure the impact of first-eye cataract surgery on driving and quality of life for older drivers

Investigators: Dr Graham Barrett (Sir Charles Gairdner Hospital), Ms Michelle Fraser, Prof. Andy Lee, Dr Lynn Meuleners, Prof. James Semmens (Curtin University), A/Prof. Nigel Morlet & Dr Jonathon Ng (Royal Perth Hospital)

Study summary

Cataract surgery is a very common procedure. However little is known about the specific effects of first-eye cataract surgery on driving and quality of life for older drivers. This study aims to follow 100 cataract patients through their surgery and monitor their vision, driving outcomes and quality of life. The study will include participants from Sir Charles Gairdner, Royal Perth and Fremantle Hospitals.

What participation in this study involves

If you agree to participate in this study, there will be no change to your cataract treatment or your waiting time for surgery. It involves attending two assessments during the course of your cataract treatment.

If you agree to participate we will ask you to do the following things:

- Participate in face-to-face questionnaires delivered by the researcher about your driving experience, driving difficulties, quality of life and depression
- Participate in short cognitive assessments
- Complete three simple vision tests. These are visual acuity, contrast sensitivity and stereopsis. These simple tests ask you to read letters or determine pictures and cause no discomfort or risk to yourself

Your participation will involve two assessments:

1. During the week before your 1st eye cataract surgery
2. Three months after your 1st eye surgery

Each visit will take 60-75 minutes and exactly the same questionnaire, cognitive tests and vision tests will be performed each time. These visits will usually take place in your own home.

What are the benefits of the study?

We cannot promise any personal benefits to you from participating in this study. However, we believe the results of this study will allow future patients to be better informed about driving difficulties before and after cataract surgery. It will also allow doctors to better determine who will benefit from the surgery, who may experience difficulties following the surgery and who should be prioritised for the second surgery.

What are the possible risks or burdens to participation?

The questionnaire, cognitive and visual tests involved in this study will not cause any form of discomfort or pose any risk to yourself.

What if I sustain an injury during the study?

Medical treatment will be provided at no cost to you for research-related harm. The term “research-related harm” means both physical and mental injury caused by the product or procedures required by the trial. This does not affect your right to pursue a legal remedy from any party involved with the study, in respect of injury alleged to have been suffered as a result of participation.

What are the costs to me?

Participation in this study will not result in any costs for you. Curtin University will reimburse you any reasonable expenses you incur due to travel.

How will your personal information be handled?

Special arrangements are in place to ensure that your data is handled in strict confidence and in compliance with all privacy laws (in Australia this is the Privacy Act 1988). Your name will not appear on study documents and you will be identified only by a participant ID number. All project data will be securely stored in a locked filing cabinet at Curtin University or on password protected computer files for a period of seven years. Only the investigators on the study will have access to your data. Your name will not appear on any document or publication. The information you provide to the researchers will not be shared with or passed on to anyone including other medical practitioners or the Department of Planning and Infrastructure in charge of driver licensing. However, if your vision (visual acuity) is found to be below the minimum criteria for a WA driver’s license you may be asked by your Ophthalmologist not to drive until you have had your cataract surgery and your vision has been reassessed. If it is determined that your visual acuity will not improve in the near future it is your responsibility to inform the Department of Transport, WA. The researchers or Ophthalmologists will not inform the Department.

What are your rights?

Participation in this study is voluntary. You do not have to participate if you do not want to and can choose to withdraw from the study at any time without this affecting your cataract treatment. If you decide not to participate in the study you will receive your cataract treatment in the usual way and your decision will be respected by the doctors treating you and will not affect any future treatment you might need.

Further information

This is a Masters student research project conducted by Michelle Fraser from the School of Public Health, Curtin University of Technology. If you have questions about the study you may contact:

Michelle Fraser (Masters student): Ph: 0408 326 510

OR

Professor Andy Lee
(Supervisor): Ph: 9266 4180

This study has been approved by the Sir Charles Gairdner Group Human Research Ethics Committee. If you have any concerns about the conduct of the study or your rights as a research participant, please contact the Executive Officer of the Committee, telephone: (08) 9346 2999

APPENDIX B

Consent Forms

Curtin University of Technology

Fremantle Hospital & Health Service

CONSENT FORM

A study to measure the impact of first-eye cataract surgery on driving and quality of life for older drivers

Investigators: Prof. Andy Lee, Ms Michelle Fraser, Dr Lynn Meuleners (Curtin University), A/Prof. Nigel Morlet & Dr Jonathon Ng (Royal Perth Hospital)

I,.. agree entirely voluntarily to participate in the above study and I am over 18 years of age. I have read and understood the participant information sheet and I have been given a copy of it. I have been given the opportunity to ask questions about the study. I understand that I may withdraw from the study at any time without affecting my future medical treatment, or the treatment of my cataract which is the subject of the trial. I understand that the investigator and sponsor of the trial will adhere to usual standards of confidentiality in the collection and handling of my personal information and that the standards of the Privacy Act 1988 will apply to the way my information is handled.

Signed …………………………….............. Date ………………….

Signature of Investigator ……….................. Date ………………….

Appendix B2 Royal Perth Hospital Participant Information Sheet

CONSENT FORM

A study to measure the impact of first-eye cataract surgery on driving and quality of life for older drivers

Investigators: Prof. Andy Lee, Ms Michelle Fraser, Dr Lynn Meuleners (Curtin University), A/Prof. Nigel Morlet & Dr Jonathon Ng (Royal Perth Hospital)

I,... agree entirely voluntarily to participate in the above study and I am over 18 years of age. I have read and understood the participant information sheet and I have been given a copy of it. I have been given the opportunity to ask questions about the study. I understand that I may withdraw from the study at any time without affecting my future medical treatment, or the treatment of my cataract which is the subject of the trial. I understand that the investigator and sponsor of the trial will adhere to usual standards of confidentiality in the collection and handling of my personal information and that the standards of the Privacy Act 1988 will apply to the way my information is handled.

Signed ………………………………………. Date ………………….

Signature of Investigator …………………. Date …………………

Curtin University of Technology

Sir Charles Gairdner Hospital

CONSENT FORM

A study to measure the impact of first-eye cataract surgery on driving and quality of life for older drivers

Investigators: Dr Graham Barrett (Sir Charles Gairdner Hospital), Prof. Andy Lee, Ms Michelle Fraser, Dr Lynn Meuleners, (Curtin University), A/Prof. Nigel Morlet & Dr Jonathon Ng (Royal Perth Hospital)

Participant Name: ....

Date of Birth: ....

1. I have been given clear information (verbal and written) about this study and have been given time to consider whether I want to take part.
2. I have been told about the possible advantages and risks of taking part in the study and I understand what I am being asked to do.
3. I have been able to ask questions and all questions have been answered satisfactorily.
4. I know that I do not have to take part in the study and that I can withdraw at any time during the study without affecting my future medical care. My participation in the study does not affect any right to compensation, which I may have under statute or common law.
5. I agree to take part in this research study and for the data obtained to be published provided my name or other identifying information is not used.
6. I will be provided with a copy of the Information Sheet for my personal records.

If you are unclear about anything you have read in the Participant Information Sheet or this Consent Form, please speak to the researcher before signing this Consent Form.

Signed …………………………………….....   Date ……………

Signature of Investigator ……………………......   Date ……………

The Sir Charles Gairdner Group Human Research Ethics Committee has given ethics approval for the conduct of this project. If you have any ethical concerns regarding the study you can contact the Executive Officer of the Committee on telephone: (08) 9346 2999.

APPENDIX C

Ethics Approvals

Appendix C1 Curtin University Ethics Approval

memorandum

Curtin University of Technology

Office of Research and Development

Human Research Ethics Committee

TELEPHONE	9266 2784
FACSIMILE	9266 3793
EMAIL	hrec@curtin.edu.au

To	Professor James Semmens, Population Health Research, CHIRI
From	A/Professor Stephan Millett, Chair, Human Research Ethics Committee
Subject	Protocol Approval **HR 91/2009**
Date	05 August 2009
Copy	Dr Lynn Meuleners, Public Health Professor Andy Lee, Public Health Michelle Fraser c/- Centre for Population Health Research Graduate Studies Officer, Faculty of Health Sciences

Thank you for your application submitted to the Human Research Ethics Committee (HREC) for the project titled "*Impact Of Second-Eye Cataract Surgery On Driving Difficulty And Quality Of Life For Older Drivers*". Your application has been reviewed by the HREC and is **approved**.

- You have ethics clearance to undertake the research as stated in your proposal.
- The approval number for your project is **HR 91/2009.** *Please quote this number in any future correspondence.*
- Approval of this project is for a period of twelve months **04-08-2009** to **04-08-2010**. To renew this approval a completed Form B (attached) must be submitted before the expiry date **04-08-2010**.
- If you are a Higher Degree by Research student, data collection must not begin before your Application for Candidacy is approved by your Faculty Graduate Studies Committee.
- The following standard statement **must be** included in the information sheet to participants:
  This study has been approved by the Curtin University Human Research Ethics Committee (Approval Number HR 91/2009). The Committee is comprised of members of the public, academics, lawyers, doctors and pastoral carers. Its main role is to protect participants. If needed, verification of approval can be obtained either by writing to the Curtin University Human Research Ethics Committee, c/- Office of Research and Development, Curtin University of Technology, GPO Box U1987, Perth, 6845 or by telephoning 9266 2784 or by emailing hrec@curtin.edu.au.

Applicants should note the following:

It is the policy of the HREC to conduct random audits on a percentage of approved projects. These audits may be conducted at any time after the project starts. In cases where the HREC considers that there may be a risk of adverse events, or where participants may be especially vulnerable, the HREC may request the chief investigator to provide an outcomes report, including information on follow-up of participants.

The attached **FORM B** should be completed and returned to the Secretary, HREC, C/- Office of Research & Development:

When the project has finished, or

- If at any time during the twelve months changes/amendments occur, or
- If a serious or unexpected adverse event occurs, or
- 14 days prior to the expiry date if renewal is required.
- An application for renewal may be made with a Form B three years running, after which a new application form (Form A), providing comprehensive details, must be submitted.

Regards,

A/Professor Stephan Millett
Chair Human Research Ethics Committee

Appendix C2 Fremantle Hospital Ethics Approval

Government of **Western Australia**
Department of **Health**
South Metropolitan Area Health Service

Human Research Ethics Committee

wk
21 October 2009

Professor James Semmens
Centre for Population Health
Curtin University of Technology
Building 405
GPO Box 1987
Perth WA 6845

Dear Professor Semmens,

Re: A Study to Measure the Impact of First and Second-eye Cataract Surgery on Driving Difficulty and Quality of Life for Older Drivers.

Thank you for your correspondence dated 21 September 2009, enclosing a research application form and relevant documents relating to the above study and seeking approval from the South Metropolitan Area Health Service (SMAHS) Human Research Ethics Committee (HREC), under the reciprocal agreement, to undertake the research in the Eye Clinic at Fremantle Hospital.

I have perused the documentation that you have provided and I do not consider that the study raises any specific ethical issues for Fremantle Hospital and I have, therefore, recommended to the Chief Executive that the study be approved at Fremantle, on the basis that the study protocol has been reviewed and approved by the HREC at Royal Perth Hospital and also at Curtin University.

I can confirm that the Chief Executive's delegate, on 20 October 2009 and under delegated authority from the Minister for Health, endorsed my recommendation to approve the study. You may, therefore, commence the study at Fremantle Hospital.

Under the reciprocal agreement, approval of protocol amendments and reporting of events is the responsibility of the primary committee, in this instance Royal Perth Hospital HREC. However, the SMAHS HREC requires annual progress reports and would like to be informed of any locally occurring events as they arise.

A progress report is due on this study in October 2010.

A reference number for this study will be forwarded to you by the HREC Office following the next SMAHS HREC meeting (10 November), which you will be required to quote on future correspondence with the Committee.

Yours sincerely

DR DAVID BLYTHE
ACTING CHAIR
HUMAN RESEARCH ETHICS COMMITTEE

cc: Dr Dimitri Yellachich, Head of Ophthalmology, FH
Chairman, RPH HREC (Registration No. EC 2009/077)
Chair, Curtin HREC (HR 91/2009)

Human Research Ethics Committee
c/- Fremantle Hospital and Health Service
Alma Street Fremantle Western Australia 6160
Postal Address: PO Box 480 Fremantle Western Australia 6959
Telephone: (08) 9431 2929 Fax: (08) 9431 3930

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Appendix C3 Royal Perth Hospital Ethics Approval

Department of Health
Government of Western Australia
South Metropolitan Area Health Service

Royal Perth Hospital

ETHICS COMMITTEE

Prof F M van Bockxmeer PhD MHGSA, ARCPA, FAHA
PathWest Laboratory Medicine
Tel: 9224 2322 Fax: 9224 2491
Email Frank.VB@health.wa.gov.au

Room 4112 Level 4, Kirkman House
Tel: 9224 2292

Ref: EC 2009/077
(This number must be quoted on all correspondence)

17th September 2009

Dr Nigel Morlet
Opthalmology
Royal Perth Hospital

Dear Nigel

2009/077 Impact of second-eye cataract surgery on driving difficulty and quality of life for older drivers

Thank you for your responses to the Committee's queries about the above study which I am pleased to advise is now **APPROVED**.

The following general conditions apply to all approvals by this Committee, and starting a trial or research project following the issue of ethics approval will be deemed to be an acceptance of them by all investigators:

1. The submission of an application for Ethics Committee approval will be deemed to indicate that the investigator and any sponsor recognises the Committee as a registered (with AHEC) Health Research Ethics Committee and that it complies in all respects with the National Statement on Ethical Conduct Research Involving Humans and all other national and international ethical requirements. **The Committee will not enter into further correspondence on this point.**

2. All income arising from the study must be lodged in a hospital special purposes account. Performance of a clinical trial for a sponsor is a service for tax purposes and all GST obligations must be met.

3. The investigator will report adverse events accompanied by a statement as to whether or not the trial should continue. The Committee reserves the right to not receive reports whose complexity or level of detail requires the expenditure of unreasonable time and effort. The Committee receives voluminous paperwork relating to adverse event reporting. From time to time the Committee chairman may require these reports to be summarised and approval is granted subject to the agreement of the investigator that he or she will prepare such a summary on request.

4. The Committee has decided that, as the responsibility for the conduct of trials lies with the investigator, all correspondence should be signed by the investigator.

5. All trial drugs must be dispensed by the Pharmacy Department. A fee is levied for this service and investigators must regard this fee as an item requiring a budget allocation. Alternatively, if a sponsor agrees, separate direct funding of pharmacy services may be undertaken. There are provisions for this fee to be waived for locally-inspired unfunded studies not having an external sponsor.

6. Though state institutions are outside the jurisdiction of the Privacy Act and related legislation, the Committee will assume that the privacy provisions of that Act will be the minimum standards applying during the conduct of a trial at Royal Perth Hospital. Traditional standards of patient confidentiality will apply.

7. The Committee will not acknowledge trial communications as a matter of course, unless they relate to a matter requiring Committee approval. Evidence of dispatch of a letter will be deemed to be evidence of receipt. This rule may be waived at the Committee's discretion on provision of a *pro forma* receipt by the investigator for the Chairman's signature and return. However, trivial correspondence (as judged by the Committee) will not be acknowledged even if a *pro forma* receipt is provided. Where an investigator requests written approval or written record of a matter for special purposes (say at the request of a sponsor), the investigator should prepare the required letter for the chairman's signature rather than expect the Committee secretary to prepare it. This mechanism increases the probability that the trial details in the letter are correct.

8. The Committee will provide the names and representative affiliation of members on request, but will not provide personal details or voting records.

9. A brief annual report on each project approved will be required at the end of each fiscal year, in default of which approval for the study may be suspended. Ethics approvals at RPH do not carry an expiry date so the annual report is an important part of Ethics Committee procedure.

10. The Committee has the authority to audit the conduct of any trial without notice. Exercise of this authority will only be considered if there are grounds to believe that some irregularity has occurred or if a complaint is received from a third party, or the Committee wishes to undertake an audit for QA purposes.

11. Complaints relating to the conduct of a clinical trial should be directed to the Chairman and will be promptly investigated. Complaints about the Ethics Committee decisions or policies that cannot be resolved by discussion with the Chairman or about any actions of a particular member including the Chairman, should be directed to the Director of Clinical Services. Only written complaints (not e-mail) will be accepted for investigation.

Investigators of sponsored studies are advised to draw the above conditions to the attention of the sponsor. Investigators are reminded that records of consent or authorisation for participation in special studies (including clinical trials) form part of the Acute Hospital Patient Record and should be stored with that record in accordance with the WA *Health Patient Information Retention and Disposal Schedule (Version 2) 2000.* A copy of the 'Patient Information Sheet' should also be included in the medical records as part of informed consent documentation.

Yours sincerely

Prof Frank M van Bockxmeer
Chairman, Royal Perth Hospital Ethics Committee

The Royal Perth Hospital Ethics Committee is constituted and operates in accordance with NH&MRC Guidelines.

Copies: Michelle Fraser & Prof James Semmens (Centre for Population Health Research, Curtin University)

Appendix C4 Sir Charles Gairdner Hospital Ethics Approval

Government of **Western Australia**
Department of **Health**
Ethics Ref: 2009-150
Ext 2999

Sir Charles
Gairdner Hospital

17 December 2009

Professor Graham Barrett
Ophthalmology
Ground Floor E Block
Sir Charles Gairdner Hospital
Hospital Ave
NEDLANDS WA 6009

Dear Professor Barrett

APPLICATION TO CONDUCT HUMAN RESEARCH AT SCGH:
TRIAL No: 2009-150
TRIAL TITLE: Impact of second-eye cataract surgery on driving difficulty and quality of life for older drivers

On behalf of the Sir Charles Gairdner Group Executive I give approval to conduct your research project at Sir Charles Gairdner Hospital based on the favourable reviews provided to me by the Research Governance Unit and the Sir Charles Gairdner Group Human Research Ethics Committee. This approval is granted until 31 December 2011, and on the basis of compliance with all requirements laid out in your application and with the provision of reports as required by the RGU and approving HREC in giving their favourable opinion (attached).

The responsibility for the conduct of this study remains with you as the Principal Investigator. You must notify the Research Governance Unit of any relevant issues arising during the conduct of the study that may affect continued favourable opinions by the hospital or by an HREC.

Please quote Study number 2009-150 on all correspondence associated with this study.

Yours sincerely

S.Davis

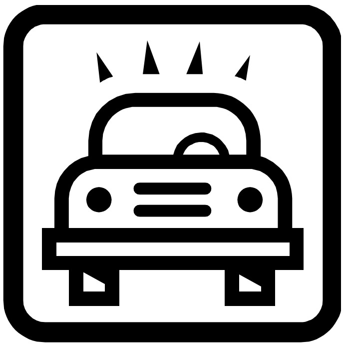
SUE DAVIS
Acting Executive Director of Nursing Services
Sir Charles Gairdner Group
North Metropolitan Health Service

APPENDIX D

Study Questionnaire

Questionnaire:
Impact of cataract surgery on driving difficulty and quality of life for older drivers study

(Researcher - Administered)



Questionnaire Information

“The following is a survey containing some general questions, questions about your driving, statements about problems which involve your vision and depressive symptoms. After each question please choose the response that best describes your situation. Please take as much time as you need to answer each question. If you wear glasses or contact lenses, please answer all of the following questions as though you were wearing them”

Statement of Confidentiality

“Any information that would permit identification of any person who completed this questionnaire will be regarded as strictly confidential. Such information will be used only for the purposes of this study and will not be disclosed or released for any other purposes without prior consent, except as required by law.”

Section 1: General Questions

"First, we will ask you some general questions"

DATE: ____/ ______/ _______ **Participant Identification Number:** ____________

1. Sex: Male
Female

2. What is your date of birth? ________/_________/__________

3. What country were you born in? _____________________

4a. Are you: Married
Single
Widowed
De facto

4b. Do you live alone? Yes
No

5. What is the highest level of education you have completed?
Primary school
Secondary school
TAFE/ other certificate
University degree
University postgraduate degree

6. Do you wear glasses or contact lenses when you drive?
Yes
No

7. Please tell me if you currently have a diagnosis of any of the following medical conditions:

	Medical Condition	**Tick box**
a)	Cancer	
b)	Heart disease	
c)	Angina	
d)	Stroke	
e)	Diabetes	
f)	Rheumatoid arthritis	
g)	Osteoarthritis	
h)	Kidney disease	
i)	Epilepsy	
j)	Hearing impairment	
k)	Sleep apnoea	
l)	Depression	
m)	Anxiety disorder	
n)	Schizophrenia	
o)	Alcohol abuse or dependence	

Are there any other medical conditions you have been diagnosed with?

____

____

____

Section 2: Driving Habits Questionnaire (Owsley et al. 1999)
"Next, I'm going to ask you about when, where and with whom you drive"

Section 2a: Driving Exposure

8. In an average **week**, how many days per week do you normally drive?

Number of days per week

9. Please consider all the places you drive in a typical week (Pause). Now tell me those places (prompt)

Place	How many times a week	Estimated kilometres from home (one way)
Shop		
Church		
Work		
Relative's house		
Friend's house		
Out to eat		
Appointment (doctor, hair)		

Now, are there any other places you drive in a typical week?

Place	How many times a week	Estimated kilometres from home (one way)

Total number of places travelled to *Total trips* *Total kilometres driven*

Section 2b: Dependence

10a. Are you **always** the driver when you go out in a car with friends and/ or family members?

- Yes (If yes, go to question 11)
- No

10b. Please list your friends and/ or family members that you regularly travel with in a car since your last cataract surgery

	Relationship	When travelling with this individual, who usually drives? (prompt)	Score
a)		I am usually the driver	1
		This person is usually the driver	3
		About half and half	2
b)		I am usually the driver	1
		This person is usually the driver	3
		About half and half	2
c)		I am usually the driver	1
		This person is usually the driver	3
		About half and half	2
d)		I am usually the driver	1
		This person is usually the driver	3
		About half and half	2
e)		I am usually the driver	1
		This person is usually the driver	3
		About half and half	2
f)		I am usually the driver	1
		This person is usually the driver	3
		About half and half	2

Total number of individuals(0 if the person always drives self)

Total dependency score = Average score of 3a-f (1 if the person always drives self)

Section 2c: Driving difficulty and avoidance

"Now I am going to ask you some more questions about your driving"

11. During the last 3 months, have you driven when it is raining?

Yes ____ (go to question 11b)

11b. Would you say that you drive when it is raining with:

5 5 No difficulty at all
4 A little difficulty
3 Moderate difficulty
2 Extreme difficulty

No ____ (go to question 11c)

11c. Is it mostly because of your visual problems that you do not drive when it is raining?

1 Yes
No

12a. During the last 3 months, have you driven alone?

Yes ____ (go to question 12b)

12b. Would you say that you drive alone with:

5 No difficulty at all
4 A little difficulty
3 Moderate difficulty
2 Extreme difficulty

No ____ (go to question 12c)

12c. Is it mostly because of your visual problems that you do not drive alone?

1 Yes
No

13a. During the last 3 months, have you parallel parked?

Yes ____ (go to question 13b)

13b. Would you say that you parallel park with:

5 No difficulty at all
4 A little difficulty
3 Moderate difficulty
2 Extreme difficulty

No ____ (go to question 13c)

13c. Is it mostly because of your visual problems that you do not parallel park?

1 Yes
No

14a. During the last 3 months, have you made right hand turns across oncoming traffic?

Yes ____ (go to question 14b)

14b. Would you say that you make right hand turns across oncoming traffic with:

5 No difficulty at all
4 A little difficulty
3 Moderate difficulty
2 Extreme difficulty

No ____ (go to question 14c)

14c. Is it mostly because of your visual problems that you do not make right hand turns across oncoming traffic?

1 Yes
No

15a. During the last 3 months, have you driven on the freeway?

Yes ____ (go to question 15b)

15b. Would you say that you drive on the freeway with:

5 No difficulty at all
4 A little difficulty
3 Moderate difficulty
2 Extreme difficulty

No ____ (go to question 15c)

15c. Is it mostly because of your visual problems that you do not drive on the freeway?

1 Yes
No

16a. During the last 3 months, have you driven on high traffic roads?

Yes ____ (go to question 16b)

16b. Would you say that you drive on high traffic roads with:

5 No difficulty at all
4 A little difficulty
3 Moderate difficulty
2 Extreme difficulty

No ____ (go to question 16c)

16c. Is it mostly because of your visual problems that you do not drive on high traffic roads?

1 Yes
No

17a. During the last 3 months, have you driven in peak hour traffic?

Yes ____ (go to question 17b)

17b. Would you say that you drive in peak hour traffic with:

5 No difficulty at all
4 A little difficulty
3 Moderate difficulty
2 Extreme difficulty

No ____ (go to question 17c)

17c. Is it mostly because of your visual problems that you do not drive in peak hour traffic?

1 Yes
No

18a. During the last 3 months, have you driven at night?

Yes ____ (go to question 18b)

18b. Would you say that you drive at night with:

5 No difficulty at all
4 A little difficulty
3 Moderate difficulty
2 Extreme difficulty

No ____ (go to question 18c)

18c. Is it mostly because of your visual problems that you do not drive at night?

1 Yes
No

Difficulty score: (mean score on questions '11 to 18' – 1) x 25 =

Section 2d: Extra Questions

19. During the last 3 months, would you say you can judge the distance of other vehicles and objects while driving with:

5 No difficulty at all
4 A little difficulty
3 Moderate difficulty
2 Extreme difficulty

20. During the last 3 months, would you say you position your vehicle correctly in the lane while driving with:

5 No difficulty at all
4 A little difficulty
3 Moderate difficulty
2 Extreme difficulty

21. During the last 3 months, would you say you read street signs while driving with:

5 No difficulty at all
4 A little difficulty
3 Moderate difficulty
2 Extreme difficulty

Section 3: NEI VFQ-25 (Mangione et al. 2001)

Section 3a: General Health and Vision

"Next I am going to read you some statements about problems which involve your vision or feelings that you have about your vision. If you wear glasses or contact lenses remember to answer as though you are wearing them"

22. In general, would you say your overall health is:

General health

(Circle one)

Excellent	100
Very Good	75
Good	50
Fair	25
Poor	0

23. At the present time, would you say your eyesight using both eyes (with glasses or contact lenses, if you wear them) is excellent, good, fair, poor, or very poor or are you completely blind?

General vision

(Circle one)

Excellent	100
Good	80
Fair	60
Poor	40
Very poor	20
Completely blind	0

24. How much of the time do you worry about your eyesight?

Vision specific:

Mental health

(Circle one)

None of the time	100
A little of the time	75
Some of the time	50
Most of the time	25
All of the time	0

25. How much pain or discomfort have you had in and around your eyes (for example, burning, itching, or aching)? Would you say it is:

Ocular pain

(Circle one)

None	100
Mild	75
Moderate	50
Severe	25
Very severe	0

Section 3b: Difficulty with Activities

"The next questions are about how much difficulty, if any, you have doing certain activities wearing your glasses or contact lenses if you use them for that activity"

26. How much difficulty do you have reading ordinary print in newspapers? Would you say you have:

Near activities

(Circle one)

No difficulty at all	100
A little difficulty	75
Moderate difficulty	50
Extreme difficulty	25
Stopped doing this because of your eyesight...	0
Stopped doing this for other reasons or not interested in doing this	M

27. How much difficulty do you have doing work or hobbies that require you to see well up close, such as cooking, sewing, fixing things around the house, or using hand tools? Would you say:

Near activities

(Circle one)

No difficulty at all	100
A little difficulty	75
Moderate difficulty	50
Extreme difficulty	25
Stopped doing this because of your eyesight...	0
Stopped doing this for other reasons or not interested in doing this	M

28. Because of your eyesight, how much difficulty do you have finding something on a crowded shelf?

Near activities

(Circle one)

No difficulty at all	100
A little difficulty	75
Moderate difficulty	50
Extreme difficulty	25
Stopped doing this because of your eyesight...	0
Stopped doing this for other reasons or not interested in doing this	M

29. How much difficulty do you have reading street signs or the names of shops?

Distance activities

(Circle one)

No difficulty at all	100
A little difficulty	75
Moderate difficulty	50
Extreme difficulty	25
Stopped doing this because of your eyesight...	0
Stopped doing this for other reasons or not interested in doing this	M

30. Because of your eyesight, how much difficulty do you have going down steps, stairs, or curbs in dim light or at night?

Distance activities

(Circle one)

No difficulty at all	100
A little difficulty	75
Moderate difficulty	50
Extreme difficulty	25
Stopped doing this because of your eyesight...	0
Stopped doing this for other reasons or not interested in doing this	M

31. Because of your eyesight, how much difficulty do you have noticing objects off to the side while you are walking along?

Peripheral vision

(Circle one)

No difficulty at all	100
A little difficulty	75
Moderate difficulty	50
Extreme difficulty	25
Stopped doing this because of your eyesight...	0
Stopped doing this for other reasons or not interested in doing this	M

32. Because of your eyesight, how much difficulty do you have seeing how people react to things you say?

(Circle one)

Vision specific:

Social functioning

No difficulty at all	100
A little difficulty	75
Moderate difficulty	50
Extreme difficulty	25
Stopped doing this because of your eyesight..	0
Stopped doing this for other reasons or not interested in doing this	M

33. Because of your eyesight, how much difficulty do you have picking out and matching your own clothes?

Colour vision

(Circle one)

No difficulty at all	100
A little difficulty	75
Moderate difficulty	50
Extreme difficulty	25
Stopped doing this because of your eyesight..	0
Stopped doing this for other reasons or not interested in doing this	M

34. Because of your eyesight, how much difficulty do you have visiting with people in their homes, at parties, or in restaurants ?

(Circle one)

Vision specific:

Social functioning

No difficulty at all	100
A little difficulty	75
Moderate difficulty	50
Extreme difficulty	25
Stopped doing this because of your eyesight..	0
Stopped doing this for other reasons or not interested in doing this	M

35. Because of your eyesight, how much difficulty do you have going out to see movies, plays, or sports events?

(Circle one)

Distance activities

No difficulty at all	100
A little difficulty	75
Moderate difficulty	50
Extreme difficulty	25
Stopped doing this because of your eyesight..	0
Stopped doing this for other reasons or not interested in doing this	M

36a. Are you currently driving, at least once in a while?

(Circle one)

Yes	1	*Skip to Q 36d*
No	2	

36b. IF NO: Have you never driven a car or have you given up driving?

(Circle one)

Never drove	1	*Skip to Q 39*
Gave up	2	

36c. IF YOU GAVE UP DRIVING: Was that mainly because of your eyesight, mainly for some other reason, or because of both your eyesight and other reasons?

(Circle one)

Mainly eyesight	1	*Skip to Q 39*
Mainly other reasons	2	*Skip to Q 39*
Both eyesight and other reasons	3	*Skip to Q 39*

36d. IF CURRENTLY DRIVING: How much difficulty do you have driving during the daytime in familiar places? Would you say you have:

(Circle one)

Driving

No difficulty at all	100
A little difficulty	75
Moderate difficulty	50
Extreme difficulty	25
If 15b = 1 ………………………………..	0
If 15b = 2 or 3 …………………………..	M

37. How much difficulty do you have driving at night? Would you say you have:

(Circle one)

Driving

No difficulty at all	100
A little difficulty	75
Moderate difficulty	50
Extreme difficulty	25
Have you stopped doing this because of your eyesight.......................................	0
Have you stopped doing this for other reasons or are you not interested in	

38. How much difficulty do you have driving in difficult conditions, such as in bad weather, during rush hour, on the freeway, or in city traffic? Would you say you have:

Driving

(Circle one)

No difficulty at all	100
A little difficulty	75
Moderate difficulty	50
Extreme difficulty	25
Have you stopped doing this because of your eyesight.......................................	0
Have you stopped doing this for other reasons or are you not interested in	

Section 3c: Responses to Vision Problems

"The next questions are about how things you do may be affected by your vision. For each one, I'd like you to tell me if this is true for you all, most, some, a little, or none of the time"

		All of the time	Most of the time	Some of the time	A little of the time	None of the time
39.	Do you accomplish less than you would like because of your vision? *Vision specific: Role diffs*	**0**	**25**	**50**	**75**	**100**
40.	Are you limited in how long you can work or do other activities because of your vision? *Vision specific: Role diffs*	**0**	**25**	**50**	**75**	**100**
41.	How much does pain or discomfort in or around your eyes, for example, burning, itching, or aching, keep you from doing what you'd like to be doing? Would you say: *Ocular pain*	**0**	**25**	**50**	**75**	**100**

"For each of the following statements, please indicate whether for you the statement is definitely true, mostly true, mostly false, or definitely false for you or you are not sure"

		Definitely true	Mostly true	Not sure	Mostly false	Definitely false
42.	I stay home most of the time because of my eyesight. *Vision specific: Dependency*	**0**	**25**	**50**	**75**	**100**
43.	I feel frustrated a lot of the time because of my eyesight. *Vision specific: Mental health*	**0**	**25**	**50**	**75**	**100**

44.	I have much less control over what I do, because of my eyesight.: *Vision specific: Mental health*	**0**	**25**	**50**	**75**	**100**
45.	Because of my eyesight, I have to rely too much on what other people tell me... *Vision specific: Dependency*	**0**	**25**	**50**	**75**	**100**
46.	I need a lot of help from others because of my eyesight. *Vision specific: Dependency*	**0**	**25**	**50**	**75**	**100**
47.	I worry about doing things that will embarrass myself or others, because of my eyesight. *Vision specific: Mental health*	**0**	**25**	**50**	**75**	**100**

Section 3d: Depressive Symptoms (CES-D) (Radloff 1977)

" Next is a list of some of the ways you may have felt or behaved. Please indicate how often you have felt this way during the past week"

	During the past week:	**Rarely or none of the time (less than 1 day)**	**Some or a little of the time (1 or 2 days)**	**Occasionally or a moderate amount of time (3 to 4 days)**	**All of the time (5 to 7 days)**
48.	I was bothered by things that usually don't bother me	0	1	2	3
49.	I did not feel like eating; my appetite was poor	0	1	2	3
50.	I felt that I could not shake off the blues even with help from my family	0	1	2	3
51.	I felt that I was just as good as other people	3	2	1	0
52.	I had trouble keeping my mind on what I was doing	0	1	2	3
53.	I felt depressed	0	1	2	3
54.	I felt that everything I did was an effort	0	1	2	3
55.	I felt hopeful about the future	3	2	1	0
56.	I thought my life had been a failure	0	1	2	3
57.	I felt fearful	0	1	2	3
58.	My sleep was restless	0	1	2	3
59.	I was happy	3	2	1	0
60.	I talked less than usual	0	1	2	3

61.	I felt lonely	0	1	2	3
62.	People were unfriendly	0	1	2	3
63.	I enjoyed life	3	2	1	0
64.	I had crying spells	0	1	2	3
65.	I felt sad	0	1	2	3
66.	I felt that people disliked me	0	1	2	3
67.	I could not “get going”	0	1	2	3

“You have reached the end of the questionnaire

Thank you kindly for your participation”