# Visual Functioning and Quality of Life After Pars Plana Vitrectomy for Diabetic Eye Disease at Groote Schuur Hospital, Cape Town, South Africa

by

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Submitted to the University of Cape Town in Partial Fulfilment of the Requirements for the Degree MMED (Ophthalmology)

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**July 2009**

# DECLARATION

I, Bvumbi Azwihangwisi, hereby declare that the work on which this dissertation is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

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## DEDICATION

**This research report is dedicated to my wife, Humbulani,**

**and my children, Mufunwa, Onea, Warine and Wavhudi,**

**for their tireless support, patience and understanding**

**throughout the duration of the MMED.**

## ACKNOWLEDGEMENTS

The author wishes to acknowledge the following people:

- My supervisor, Dr Karin Lecuona, for her guidance and for making available her considerable experience;
- The respondents, who willingly allocated time out of their very emotional time;
- The University of Cape Town Ethics Committee, for assistance in approval of this study;
- Dr Nemavhandu, my brother, for the independent review and his assistance with the graphics and statistical analysis.
- Robin Elsegood, for her unveiling patience and assistance in typing and formatting;
- Professor Colin Cook, for his guidance;
- Dr London Myer for his guidance in formatting this research; and
- My wife, Humbulani, and children, Mufunwa and Onea, for their unflagging moral support.

Without the assistance of those mentioned above, this clinical report would not have been possible.

# ABSTRACT

## Purpose

The purpose of this study was to determine the visual function and quality of life of patients 6 months after undergoing *pars plana vitrectomy* for diabetic retinopathy complications at the Groote Schuur Hospital. The study also investigated the association between quality of life and the indications for surgery, the type of procedure performed, pan-retinal photocoagulation before surgery, the duration of complications, age, gender, the presence systemic disease and best-corrected visual acuity (BCVA).

## Method

The study was a prospective, consecutive, non-comparative case series. This observational study evaluated the visual functioning and quality of life using the SHORT FORM HEALTH SURVEY (SF-36) and National Eye Institute Visual Function Questionnaire (NEI VFQ-39). The SF-36 and NEI VFQ-39 questionnaires were administered as an interview to all patients undergoing pars plana vitrectomy for diabetic retinopathy. Two interviews were conducted, the first one, a day before surgery, and the second, six months after surgery.

The mean SF-36 and NEI VFQ-39 subscale scores were compared before surgery and after surgery to see if there was an improvement. Patient demographics, such as age, gender, previous pan-retinal photocoagulation (PRP), indications for surgery, LogMAR visual acuity and the type of procedures done were also recorded to see if they had any impact on visual functioning and the quality of life scores.

## Results

43 patients were interviewed using the SF-36 and NEI VFQ-39 questionnaires. The mean age of the study population was 55 years of age. 73% of the respondents reported having had PRP before surgery.

The Wilcoxon Signed Rank Test was used to compare pre-operative and post-operative measurements. Significant improvement was found in the post-operative values in three of twelve VFQ-39 subscales, namely general vision, near activities, and peripheral vision. The SF-36 questionnaire showed significant improvement in emotional well-being and significant worsening in fatigue. A statistically significant improvement in post-operative visual acuity LogMAR values was found. The mean

LogMAR value improvement was from 2.1 to 1.0. No significant differences were noted in the NEI VFQ-39 subscale between the group that had prior PRP and the group that did not have prior PRP, nor with different waiting times for surgery, indications for surgery or the type of surgery performed. There was a significant correlation between the LogMAR visual acuity of the operated eye and the vision-related quality of life score.

## Conclusion

Significantly, the study showed a marked improvement in visual acuity.

Although there was significant improvement in patient's perception of their general vision, near activities and peripheral vision, this study showed that vitrectomy for diabetic retinopathy, does not improve the overall vision-related quality of life.

Patients presented with an advanced stage of retinopathy resulting in severe impairment in their quality of life and very low baseline quality of life scores associated with decreased visual acuity in both eyes. In this study, vision-related quality of life was dependent on both operated and non-operated eye. There was a correlation between visual acuity and the NEI VFQ-39 scores in both operated on and non-operated on eyes. The study showed that patients undergoing vitrectomy for diabetic retinopathy had much lower NEI VFQ-39 scores than patients who did not need vitrectomy, as compared to the Okomoto study that compared vitrectomy for PDR vs. a control [(1)]. The study showed that patients with poor vision before vitrectomy tended to continue to have poor vision after vitrectomy, whereas those with good vision pre-operatively tended to continue to have good vision post-operatively.

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# CHAPTER 1

# INTRODUCTION AND BACKGROUND

## 1.1 Research Problem

The most commonly used conventional measure of visual function, distance acuity, does not adequately reflect visual functioning and the ability to perform vision dependent tasks ([21]).

Distance acuity is measured on a high contrast letter chart containing letters of progressively smaller sizes, which subtend progressively smaller angles at the focal point on the retina. These letters serve as a marker for the ability of the eye to resolve objects. Distance acuity is easily and quickly determined, hence its popularity in the clinical setting. However, traditional measures of visual acuity (VA) may be insufficient to provide necessary information regarding aspects of visual function that may be vital for patients' daily routine activities.

Ophthalmologists increasingly emphasise the importance of outcomes, such as physical function, social function and overall health, in addition to standard clinical outcome, when evaluating treatment for eye disease [22, 9]. However, measures of visual functioning and quality of life have rarely been incorporated into clinical studies of vitrectomy for diabetic retinopathy.

## 1.2 Purpose of Study

The purpose of this study was to determine both the visual functioning and the quality of life of patients with diabetic retinopathy undergoing pars plana vitrectomy (PPV) at Groote Schuur Hospital.

## 1.3 Research Questions

- Is there an improvement in quality of life in patients after vitrectomy for diabetic retinopathy?
- Do the indications for vitrectomy affect the patient's post-operative quality of life?
- Do gender or age or both have an effect on post-operative quality of life for patients with diabetic retinopathy?

- Is there a difference in quality of life for different surgical procedures done?
- Is there a correlation between quality of life and other diabetic complications, e.g., cardiovascular accident, cardiac disease and renal disease?
- Does waiting time for surgery affect patient quality of life after PPV?
- Does having pan-retinal photocoagulation (PRP) before the operation have an effect on quality of life after PPV?

## 1.4 Research Hypothesis

Vitrectomy resulted in significant changes in post-operative visual acuity (BCVA) in the operated eye.

Vitrectomy did not result in any changes in visual acuity (BCVA) of the non-operated eye.

Vitrectomy resulted in significant changes in post-operative vision and general health related quality of life for patients as measured by the NEI VFQ-39 and SF-36.

## 1.5 Variables

The research aimed to find out what the predictor variables for visual outcome and quality of life were after pars plana vitrectomy for diabetic eye disease. The following outcome variables were evaluated:

- Age
- Gender
- Visual outcome
- Pan retinal photocoagulation treatment before operation
- Indications for pars plana vitrectomy
- Surgical procedure performed in theatre
- Waiting time for surgery
- Presence of systemic disease such as renal disease, cardiac disease and cerebral vascular accident.

## 1.6 Background

Diabetes mellitus results in considerable morbidity and mortality affecting about 180 million people worldwide [13]. The disease is divided into, Type I DM (previously insulin dependent DM) and Type II DM (previously non-insulin dependent DM). The total number of people with diabetes is expected to rise to an estimated 300 million cases by the year 2025 [34].

People with diabetes are at risk for developing a number of irreversible complications that can be largely divided into micro-vascular and macro-vascular complications. The macro-vascular complications include cerebrovascular disease, coronary heart disease and peripheral vascular disease. The micro-vascular complications include diabetic retinopathy, diabetic neuropathy and diabetic nephropathy.

Diabetic retinopathy is the most common complication in Type I DM and nearly all patients will have some degree of retinopathy 15–20 years after diagnosis. Similarly, more than 60% of Type II diabetic patients will show evidence of diabetic retinopathy after having had the disease for 20 years [46].

Approximately 4.1 million American adults, 40 years and older, have diabetic retinopathy; one in every 12 individuals with DM in this age group has advanced, vision-threatening retinopathy [26].

Diabetic retinopathy is a progressive and inevitable complication of diabetic mellitus, in which retinal capillaries are damaged. The damaged capillaries become leaky and occluded, which is the stage termed 'non-proliferative diabetic retinopathy'. The retina attempts to compensate for damaged capillaries by Neovascularisation, a stage termed 'proliferative diabetic retinopathy'. However, the proliferating vessels are weak and prone to damage. Once the vessels rupture and haemorrhage, fibrosis may occur, which in turn damages other retinal cells so that peripheral vision may be impaired.

Central vision is affected when the damage occurs at or near the macula. Ultimately, blindness results from macular non-perfusion, retinal detachment or vitreous haemorrhage [33].

Diabetic retinopathy is one of the most common causes of blindness in developed countries affecting mostly patients in their working years (age 20–65). People with

diabetic mellitus are 25 times more likely than the general population to become blind [26]. In 2002, diabetic retinopathy accounted for about 5% of world blindness [25].

By incorporating the self-reporting of visual functioning and health-related quality of life into clinical studies, it may be possible to demonstrate the positive impact of pars plana vitrectomy in patients with advanced diabetic retinopathy, which may not be demonstrated by clinical measurements such as visual acuity. Diminished visual acuity has been associated with decreased performance in activities of daily living, poorer cognitive abilities, an increased risk of falls and ultimately poorer health related quality of life [19, 24]). Loss of vision carries significant economic and psychological costs for both individuals and society ([23]).

## 1.7 Proliferative Diabetic Retinopathy

Proliferative diabetic retinopathy (PDR) represents the most severe manifestation of diabetes in the eye. It is the result of the loss of normal retinal perfusion and the subsequent development of neovascular proliferative tissue in the fundus. The development of this neovascular tissue reflects an alteration in the balance between angiogenesis inhibitors and stimulators in the retina and the vitreous. Multiple local chemical mediators (cytokines) are believed to be at work. It is associated with bleeding, resulting in vitreous haemorrhage. The new vessels may undergo fibrosis and contraction; this and other fibrous proliferation may result in epiretinal membrane formation, vitreoretinal traction bands, retinal tears, and tractional or rhegmatogenous retinal detachments.

## 1.8 Clinical Signs

Neovascularisation of the disc (NVD) is neovascularisation that develops on the surface of the optic nerve or within one disc diameter of the optic nerve.

The term Neovascularisation Elsewhere (NVE) refers to retinal neovascularisation anywhere in the fundus that is not at the disc. Neovascularisation elsewhere in retina tends to occur in the posterior pole or midperiphery. Neovascularisation of the Iris (NVI) is an ominous sign because it can cause neovascular glaucoma (NVG), leading to a blind and painful eye.

Vitreous haemorrhage from NVD or NVE may occur and produce preretinal or vitreous haemorrhage. Vitreous haemorrhage is more likely when NVD and NVE are more extensive. Haemorrhages are usually spontaneous and produce a sudden development of floaters. Preretinal haemorrhage reflects sequestration of blood

between the inner retinal surface and an intact posterior hyaloid face. Therefore, this will generally occur in younger patients. This may produce a dense, well-circumscribed scotoma. Preretinal haemorrhage may break into the vitreous and produce more diffuse floaters characteristic of vitreous haemorrhage. Vitreous haemorrhage is often recurrent and can lead to profound visual loss.

## 1.9 Diabetic Macular Edema (DME)

DME is retinal thickening within one disc diameter (DD) of the centre of the macula. It is defined as the collection of intraretinal fluid in the macular area of the retina, with or without lipid exudates or cystoid changes. When DME causes retinal thickening or hard exudates with adjacent retinal thickening that threatens the centre of the macula, it is considered "clinically significant"; whether present in NPDR or PDR, DME results from micro aneurysms or other focal or diffuse vascular leakage within or near the macula. Visual acuity is generally compromised when DME affects the fovea. DME can occur at any stage of diabetic retinopathy; approximately 15% of patients with diabetic retinopathy have DME. The incidence of DME increases as diabetic retinopathy progresses from non-proliferative diabetic retinopathy to proliferative diabetic retinopathy.

## 1.10 Pars Plana Vitrectomy

Vitrectomy is the treatment of choice in proliferative diabetic retinopathy with vitreo-retinal traction, vitreous haemorrhage and maculopathy [(38)]. It can frequently restore useful vision in diabetic patients and reduce the risk of irreversible visual loss due to retinal detachments.

At least 51% of diabetics receiving optimal medical treatment will still develop progressive retinopathy requiring laser treatment and pars plana vitrectomy ([46]).

The outcome for vitreous surgery for proliferative diabetic retinopathy has improved over the past decade because both instrumentation and surgical techniques have been refined. Despite the success of pars plana vitrectomy in managing the severe complication of diabetic retinopathy, operative and post-operative complications still occur, leading to anatomical failure and blindness. Such complications include recurrence of retinal detachments, development of neovascular glaucoma (NVG), hypotony with subsequent ptysis bulbi, and lens opacities [(44)].

Since pars plana vitrectomy can improve anatomic features and functional visual acuity (VA), even for patients with advanced diabetic retinopathy, it has become the mainstay of therapy for complications of proliferative diabetic retinopathy (PDR).

## 1.11 Summary of Chapters

**Chapter One** indicates the importance of the study. It also highlights the purpose and objectives of the study and links the study to the current situation in diabetic retinopathy. It introduces the indications of vitrectomy in diabetic retinopathy and the significance of vision-related quality of life study.

**Chapter Two** links the objectives and purpose of the study to the published literature. It gives an overview of what has already been done in this field of research.

**Chapter Three** gives the detailed methodology used to undertake the study.

**Chapter Four** records the results of the research and contextualises the applicability of the findings as a basis for the discussion and recommendations in Chapter Five.

**Chapter Five** interprets the results recorded in Chapter Four and highlights further research opportunities.

# CHAPTER 2

# LITERATURE REVIEW

## 2.1 Prevalence of Diabetic Retinopathy

The prevalence of diabetic retinopathy in the United States was found to be 33.2% and macular oedema 9.0% [26]. Retinopathy and macular oedema were found to be significantly higher in Blacks, 36.7% and 11.1%, compared to whites, 24.8% and 2.7%[26]. In Maseru, Lesotho, diabetic retinopathy was found in 47.8% of 153 consecutive diabetic clinic patients, background retinopathy was present in 78% of patients with retinopathy and 22% had proliferative changes [65].

## 2.2 Impact of Diabetic Retinopathy on Economy

Visual disorders result in a substantial economic burden on the economy. The cost of diabetic retinopathy in the United States is estimated to exceed US$ 500 million, per year ([33]).

## 2.3 Impact of Diabetic Retinopathy on Patients

Visual loss can affect every aspect of a patient's life. In a Lions Club survey, visual loss was reported to be one of the most feared complications of diabetes, more than amputation or heart attack ([36]). Visual loss is associated with a higher than normal risk of depression and it can hinder daily activities associated with independence [37]. Everyday visual loss has a significant impact on patients' lives, affecting the way they experience and interact with the world [37].

## 2.4 Quality of Life Questionnaires

A number of questionnaires have been developed to measure health-related quality of life. The best known and most widely validated is the medical outcome study, 36-item short form (SF-36) questionnaire [35].

The SF-36 has been used in numerous outcomes studies of general medical diseases (e.g., diabetes and hypertension) and ophthalmic conditions such as uveitis, cataract, glaucoma, and age-related macular degeneration diabetic retinopathy, corneal transplantation, keratoconus, optic neuritis and ocular melanoma [1,3,4,7,8,927,28,16,18]. The SF-36 measures health status across eight

dimensions, namely physical functioning, role limitation caused by physical disability, bodily pain, general health, vitality, social functioning, role limitation caused by emotional disability and mental health ([29]).

The National Eye Institute sponsored the development of a vision-related quality of life (VR-QOL) questionnaire (NEI VFQ-39) that could be used for individuals with diverse eye diseases ([2, 30]). The 39-item NEI VFQ-39 contains 12 subscales and is both reliable and valid [(2)]. A composite score can also be computed from each of the vision-related scales (i.e., the average of all 11 subscales excluding the general health subscale).

The NEI VFQ-39 is a reliable and valid 39-item version of the 51-item National Eye Institute Visual Function Questionnaire (NEI VFQ). It is especially useful in settings such as clinical trials, where short interview duration is a critical consideration ([2]).

## 2.5 Previous Quality of Life Studies

The National Eye Institute Visual Function Questionnaire (NEI VFQ) was developed to test the psychometric impact of diseases that cause vision loss. Patients with age-related eye disease were found to have a decreased quality of life as measured by the Short Form Health Survey-36 (SF-36) and National Eye Institute Visual Function Questionnaire (NEI VFQ). In this regard, every ophthalmologist is a quality of life expert. Most of us devote our days not to adding years to life, but rather adding life to years.

Previous studies reported that vision-related quality of life (VR-QOL) significantly improved following vitrectomy. In patients with epiretinal membrane (ERM), vitrectomy improved two of the 12 National Eye Institute Visual Function questionnaire subscales (NEI VFQ-39), (general vision and distance activities) [(6)]. In patients with ERM, vitrectomy improved subjective perception of visual function as indicated by higher composite scores in the NEI VFQ-39 [(6)]. Central retinal vein occlusion was associated with a decreased vision-related quality of life [(9)].

A number of studies have assessed the quality of life in patients with vitreoretinal diseases, such as age-related macula degeneration. It was found that patients with vitroretinal disease had reduced visual-related quality of life that was often better correlated with self-reported visual impairment than with visual acuity [(1, 6, 9)].

## 2.6 Management Diabetic Retinopathy

The primary goal of current therapies for diabetic retinopathy is to reduce the risk of vision loss. In general, prompt treatment is advised for patients with high-risk proliferative diabetic retinopathy and clinically significant diabetic macular oedema.

Current treatments for proliferative diabetic retinopathy and diabetic macular oedema are **pan-retinal (scatter) laser photocoagulation** and **focal laser photocoagulation**, respectively [49]. Laser photocoagulation is the standard, most widely used technique for treating diabetic retinopathy. A **vitrectomy** is a surgery commonly used for patients who has developed vitreous haemorrhage. While these procedures are generally effective in stabilising or reducing vision loss, they do have limitations. They do not cure underlying diabetes, so patients are always at risk for additional retinopathy. Surgery does not reverse micro vascular damage associated with diabetic retinopathy. In addition, laser therapy, as an invasive procedure, damages the retina.

### *2.6.1 Laser treatment for diabetic retinopathy*

An early treatment diabetic retinopathy study (ETDRS) showed that immediate focal photocoagulation reduced the likelihood of patient losing ≥ 15 ETDRS letters by 50% for up to 3 years [46].

Full scatter photocoagulation reduces the rate of developing high-risk proliferative diabetic retinopathy by approximately 50% [46]. Timely application of laser photocoagulation is the mainstay of treatment to reduce visual loss and to avoid the need for vitrectomy in patients with more advanced forms of diabetic retinopathy. Even in eyes with severe retinopathy, only pan-retinal photocoagulation (PRP) may improve the subsequent surgical outcome [46].

### *2.6.2 Medical management of diabetic retinopathy*

#### Systemic glycaemic control

The diabetic control complication trial (DCCT) showed that intensive control of glucose at a level of HBA1C of 7.2% substantially reduced the risk of the onset and progression of diabetic retinopathy [48].

The United Kingdom Prospective Diabetes Study (UKPDS) showed a 25% risk reduction in micro vascular complications if glucose was controlled at an HBA1C of 7.0%.

The UKPDS also showed that controlling blood pressure (BP) 144/82 reduced the risk of micro vascular disease by 37% and the risk of retinal photocoagulation by 35%. Therefore, the control of blood pressure should have a high priority in the treatment of Type II DM [45].

## 2.7 New Pharmacotherapy

### Protein kinase C (PKC) inhibitors

PKC inhibitors are being developed to reduce micro vascular complications in patients with diabetes. One of these is ruboxistaurin, which is a specific inhibitor of PKC and has been found to block vascular complications of diabetes, including abnormalities in retinal blood flow; neovascularisation and VEGF mediated effects on permeability [49].

### Antivascular endothelial growth factors (anti VEGF)

#### Macugen (pegaptanib), Lucentis (ranibizumab) and Avastin (bavisizumab)

These have been demonstrated to inhibit vascular endothelial growth factors (VEGF) [118]. A preliminary analysis suggests that these agents are effective against DME and proliferative diabetic retinopathy [59].

### Corticosteroid

Triamcinilone reduced macular oedema and improved visual acuity for 6 months [58].

### Posardex

Biodegradable, implantable, extended release that delivers dexamethazone directly to posterior segment for a period of 35 days. This is under investigation [49].

### *2.7.1 Vitrectomy surgery for diabetic retinopathy*

Vitrectomy is an intraocular surgery used for patients with proliferative diabetic retinopathy who develop vitreous haemorrhaging that does not resolve spontaneously and/or develops a tractional retinal detachment [38]. With a vitrectomy, blood and vitreous is removed from the eye and replaced with intraocular tamponading agent, e.g., silicone oil, SF6 gas or C3F8. Vitreous attached to the retina is also removed if it is causing traction that could lead to retinal detachment or tears. The complications of surgery include recurring vitreous haemorrhaging and

retinal detachment, which can result in severe vision loss. There are reports in the literature suggesting that vitrectomy surgery may be helpful in eyes with refractory macular oedema [57]. Some eyes with tangential vitro macular traction may not be responsive to laser photocoagulation.

Machemer *et al.* performed the earliest successful vitrectomy, in 1970, in an eye with diabetic vitreous haemorrhage ([38]).

## 2.8 Indications for Surgery

The major indications for vitrectomy in a patient with diabetic retinopathy are [38]:

### Media opacities

- Non-clearing vitreous haemorrhage
- Subhyaloid, sub macular haemorrhage
- Anterior segment neovascularisation with posterior segment opacity

### Vitreoretinal tractions

- Progressive fibro vascular proliferation
- Tractional retinal detachment involving macula
- Combined tractional and rhegmatogenous retinal detachment

### Maculopathy

Macula oedema associated with a taut, persistently attached posterior hyaloid [54].

### Other

- Vitreous Hemorrhage/ghost cell glaucoma
- Retinal detachment – traction or rhegmatogenous
- Anterior hyaloid fibro vascular proliferation
- Epiretinal membrane

Currently, surgical intervention for non-clearing diabetic vitreous haemorrhage is usually considered at an earlier time. Since patients with Type II DM have a higher rate of spontaneous resolution of haemorrhage and slower progression of fibro vascular proliferation, the usual approach for patients with Type II DM is to defer surgical intervention longer than for patients with Type I diabetes. Vitrectomy is often

considered within a few weeks for Type I diabetic patients, especially if severe vitreous haemorrhage has shown no sign of spontaneous clearing [38].

A second indication for pars plana vitrectomy includes preretinal tractional defect. Tractional retinal detachment is the single most common indication for vitrectomy. Because peripheral and mid peripheral tractional retinal detachment progress to involve the macula in only 15% of cases per year, vitrectomy is only recommended for localised detachment that involves or clearly threatens the macula [46]. This class now constitutes the majority of patients undergoing vitrectomy for complications due to diabetic retinopathy.

The spectrum of this includes macular heterotopia, progressive fibro vascular proliferation (FVP) without retinal detachment, and tractional retinal detachment and rhegmatogenous retinal detachment with a break caused by progressive traction.

Frequently, FVP with traction coexists with vitreous haemorrhage. Progressive fibro vascular proliferation occurs despite appropriate panretinal photocoagulation, especially in Type I diabetics.

## 2.9 Surgical Objectives and Techniques

The objective of pars plana vitrectomy for advanced diabetic retinopathy is to remove axial opacities, relieve tangential and anteroposterior tractions, treat all retinal breaks and deliver laser treatment.

### Media opacities

The removal of axial opacities involves the vitreous cutter and in some cases the Lensectomy instrument. Vitrectomy instruments now offer a wide choice of cutting rates and suction pressure for removal of entire posterior cortical vitreous.

### Vitreoretinaltraction

The release of traction involves removal of anteroposterior and tangential traction. Several techniques have been developed to achieve this goal.

### Segmentation technique

This is sequential dissection of anterior-to-posterior vitreous traction, scissors dissection of bridging epiretinal membranes and, finally, removal of residual islands of surface traction (epiretinal membrane).

### Delaminating technique

The anterior to posterior traction is removed. Horizontal scissors and multifunction instruments (such as lighted picks or lighted forceps) are used to remove the preretinal tissue at the retinal plane in one or more large pieces.

### Enbloc technique

The surface traction is removed with scissors as a large, confluent piece, with the anteroposterior traction used for counter traction.

## 2.10 Visual Outcome after Vitrectomy

Macular ischemia has been found to be the most significant predictor of a poor visual outcome following pars plana vitrectomy (PPV) for diabetic retinopathy [(44)].

Other risk factors for poor visual outcome include pre-operative and post-operative iris neovascularisation (NVI) and postoperative vitreous haemorrhage [(44)].

Only a small proportion of patients who require PPV present with vitreous haemorrhaging as the sole cause of visual loss. The majority of patients present with varying degrees of pre-operative vitreoretinal traction, retinal detachment, capillary nonperfusion and macular oedema, which may influence the final visual acuity outcome in patients with diabetic retinopathy [(44)].

Mason et al., found that 16% of patients had worsening but functional vision, defined as worse but still less than 20/40: 4% had worsened, but had ambulatory vision, defined as count fingers (CF) or hand motion (HM); and 7% had poor visual outcome light perception (LP) or no light perception (NLP) [(44).]

## 2.11 Lens Extraction at the Time of Vitrectomy

Before endolaser photocoagulation was available, aphakic eyes often developed post-operative rubeosis iridis. Improved techniques for lens removal have improved outcomes [(52)]. Combining vitrectomy with phacoemulsification, an intraocular lens implant is often necessary as the phakic diabetic patient needing vitrectomy will often develop lens changes after surgery [(51)]. Combined surgery offers the advantages of a single intervention compared with multiple trips to the operating room, shorter recovery time and good post-operative visualisation if additional laser is needed and earlier ability to surgically treat the unoperated eye [(52)].

## 2.12 Summary

There have been many advances in the treatment of diabetes and diabetic retinopathy and its complications over the past 25 years. There is a better understanding of the importance of optimising glycaemic control and hypertension control, both of which directly reduce the micro vascular complications of diabetes. The major advances in treating macular oedema with a focal laser have been a result of clinical trials over the past 25 years. The surgical management of proliferative diabetic retinopathy, vitreous haemorrhage and tractional retinal detachment has been greatly facilitated by the development of the endolaser probe, indirect laser and improved vitrectomy machines and instrumentation. Pharmacotherapy is making an impact on the treatment of diabetic retinopathy and many treatments are currently under investigation. The future holds promise with improved pharmacotherapy that may decrease the progression of diabetic retinopathy and diabetic macular oedema and help with the treatment of the many complications that can occur due to proliferative diabetic retinopathy, including vitreous haemorrhage and tractional retinal detachment.

# CHAPTER 3

# RESEARCH METHODOLOGY

## 3.1 Introduction

Quantitative research was employed in this study as a mechanism to understand the perception of quality of life of respondents both before and after vitrectomy.

## 3.2 Population and Sample

The study was conducted at the Groote Schuur Hospital Ophthalmology Department. All patients that underwent pars plana vitrectomy for diabetic retinopathy complications were included in the study.

Forty-three patients were recruited for the study. There were no refusals. Patients that were undergoing a repeated vitrectomy for any reason were excluded from the study.

The study was conducted from June 2007 to December 2008.

The following pre-operative information was obtained from each patient: age, gender, duration of diabetic mellitus, other systemic complications of diabetes, the indication for surgery, the waiting time for surgery, the type of procedures performed and whether pre-treatment with panretinal photocoagulation was performed or not. The Snellen best-corrected visual acuity (BCVA) was obtained preoperatively and 6 months postoperatively.

## 3.3 Surgical Procedures

Six different vitreo-retinal surgeons, one full time and five part time, performed all the surgeries. All surgeries were performed under general anaesthesia. The crystalline lens was removed and an intraocular lens implanted when required, this was followed by a 20 gauge, 3-port pars plana vitrectomy, posterior hyaloid separation and removal of the posterior vitreous membrane. Membrane dissection and segmentation was performed when necessary. Peripheral vitrectomy and panretinal endophotocoagulation were routinely performed, as well as air fluid exchange and SF6 gas or silicone oil fill.

## 3.4 Instruments and Data Collection

In this study, we used the Short Form Health Survey (SF-36) and National Eye Institute Visual Function Questionnaires (NEI VFQ-39) to measure visual functioning and quality of life in patients with diabetic retinopathy complications who underwent pars plana vitrectomy at Groote Schuur Hospital.

A trained interviewer administered questionnaires to 43 patients, both one day before surgery and 6 months following surgery. The study was conducted between June 2007 and December 2008.

The NEI VFQ comprised 39 items. Patients were expected to assess their level of difficulty with particular visual symptoms or day-to-day activities; each item was assigned to one of the following twelve subscales.

- General health
- General vision
- Ocular pain
- Near activities
- Distance activities
- Vision specific social functioning
- Vision specific role difficulties
- Vision specific mental health
- Vision specific dependency
- Driving
- Colour vision
- Peripheral vision

The subscales were scored on a 0–100-point scale, where 100 indicated the highest possible function or the least impairment. The NEI VFQ-39 composite score was calculated as the un-weighted average response to all items, excluding the question regarding general health.

SF-36 comprised 36 items for which patients were expected to assess their level of difficulty with a particular aspect of day-to-day activities; each item was assigned to one of the following eight subscales:

- Physical functioning
- Role limitation due to physical health
- Role limitation due to emotional problems
- Energy/fatigue
- Emotional well-being
- Social functioning
- Pain
- General health

All the questions were scored on a scale from 0–100, with 100 representing the highest level of functioning possible. The scores from the questions that addressed

each specific area of functional health status were then averaged for a final score within each of the eight dimensions measured.

## 3.5 Validity and Reliability

**Reliability** refers to the extent to which the same or similar results can be obtained using the research methodology under different circumstances, at different times and using different respondents or interviewers.

**Validity** is the extent to which a research design measures what it purports to measure [42].

The NEI VFQ-39 and SF-36 questionnaires used in this study have been validated, as they have been used on people with common eye conditions ([31]) and they have appeared in publications [1, 6, 7, 9, 39]. The original questionnaires were used in this study without alterations.

## 3.6 Research Design and Strategy

This was a quantitative, prospective, non-comparative case series. The eligibility of participants to answer the questionnaires was assessed using nine structured questions (see Appendix 8). Patients had to have a score of 80% in order to be included; this was to exclude those patients who were unreliable from answering questionnaires. All participants were eligible for the study. The mini-mental status exam was not used because it was thought to take too long.

## 3.7 Ethics

Ethics refers to the moral principles or values that generally govern the conduct of an individual or group. In research, researchers have a responsibility to the sponsor and the respondents. The respondents have the right to privacy, safety, know the true purpose of the research, the research results and decide which questions to answer [43].

The University of Cape Town Ethics Committee and UCT's Department of Surgery Research Unit both approved the study. The ethical protocol was maintained at all stages of the study and each participant gave consent before conducting the interview.

### Permission to use questionnaires

RAND granted permission to use "RAND 36-Item Short Form Health Survey". The 36-Item Health Survey was developed at RAND as part of the medical outcomes study. No written permission was needed for use of this Health Survey [35]. The National Eye Institute allowed the use of the NEI VFQ-39 as long as there was an acknowledgement of the developers of this questionnaire.

## 3.8 Data Analysis

All data collected was captured into an Excel programme and coded. The SF-36 and the NEI VFQ-39 summary and subscale scores from one day before the operation, were computed according to published algorithms ([29, 33]) and compared with the mean scores, 6 months after the operation.

The mean scores and standard deviations were calculated for each NEI VFQ-39 and SF-36 subscale result as well as the composite score. A One Sample Kolmogorov-Smirnov test was performed to compare each subscale score and composite score before and after surgery. The Wilcoxon signed-ranks test was used for variables that were present both pre-operatively and post-operatively. The relationship of the questionnaire scores with visual acuity, gender, age, indications for surgery, pre-operative panretinal photocoagulation, systemic disease, waiting time for surgery and type of procedure performed were examined by the Spearman rank correlation test. To correlate the visual acuity with the questionnaire score, the Snellen visual acuity was converted to its LogMAR: equivalent approximation. The VA of counting fingers was converted to 20/2000; hand motion was converted to 20/4000 and light perception was converted to 20/8000 [9].

All tests of association were considered statistically significant if $p<0.05$.

Due to the sample size being only 43 in total, the statistical methods used were non-parametric in nature. In the non-parametric statistics range, the data is ranked and these ranks are compared and a z-statistic is computed to indicate the significance of the difference between the rankings. Mean scores are not used as the basis of analysis in non-parametric analysis.

A One-Sample Kolmogorov-Smirnov Test was used initially to determine if the sample was normally distributed. The Mann-Whitney U test was used for cases where groups were compared such as gender groups. The variables, in such cases,

were categorical in nature and this warranted the use of this test. The Spearman Rho test was used to establish differences between continuous variables.

The procedure followed was as given below:

1 Initially, the data file was split into data for the left eye (cases where the procedure was performed on the left eye) and data for the right eye (cases where the procedure was performed on the right eye). This was done to ensure that any changes to the procedure would be clearly observable and would not be contaminated by the other eye.

2 For further analysis, the data file was combined into one data file and the same analysis was performed on the data for both eyes. This was done to obtain statistics regarding changes in overall functioning.

3 The raw data was used in most cases except in the case of the NEI VFQ-39 and SF-36. In these cases, the raw data was used as the basis for compiling scale scores, utilising the appropriate scoring formula for each instrument. A separate spreadsheet was used to compile subscale scores. The transformed scores were imported back into the main data set.

4 The SPSS (Statistical Package for the Personal computer) version 16.0 was used for analysing the data.

The following hypotheses were tested:

- Vitrectomy resulted in significant changes in post-operative visual acuity (BCVA) in the operated eye.
- Vitrectomy did not result in any changes in visual acuity (BCVA) of the non-operated eye.
- Vitrectomy resulted in significant changes in post-operative vision and general health related quality of life of patients as measured by the NEI VFQ-39 and SF-36.

# CHAPTER 4

# FINDINGS

## 4.1 Introduction

This chapter is descriptive rather than interpretive; it records the results of the survey and contextualises the findings together with the purpose and rationale behind the construction of the survey instrument.

## 4.2 Demographic

### *4.2.1 Gender*

Table 1 indicates the gender distribution of the sample.

**Table 1: Gender distribution of the sample**

| | Frequency | % | Valid % | Cumulative % |
|---|---|---|---|---|
| Male | 22 | 51.2 | 51.2 | 51.2 |
| Female | 21 | 48.8 | 48.8 | 100.0 |
| **Total** | **43** | **100.0** | **100.0** | |

51% of all respondents were male. The rationale for this was to evaluate whether gender affected the quality of life after vitrectomy.

### *4.2.2 Age*

The youngest respondent was 25 years old and the oldest 77. On average, the respondents were 55 years old, with the standard deviation at 10.83. The age distribution of the sample is provided in the Figure 1.

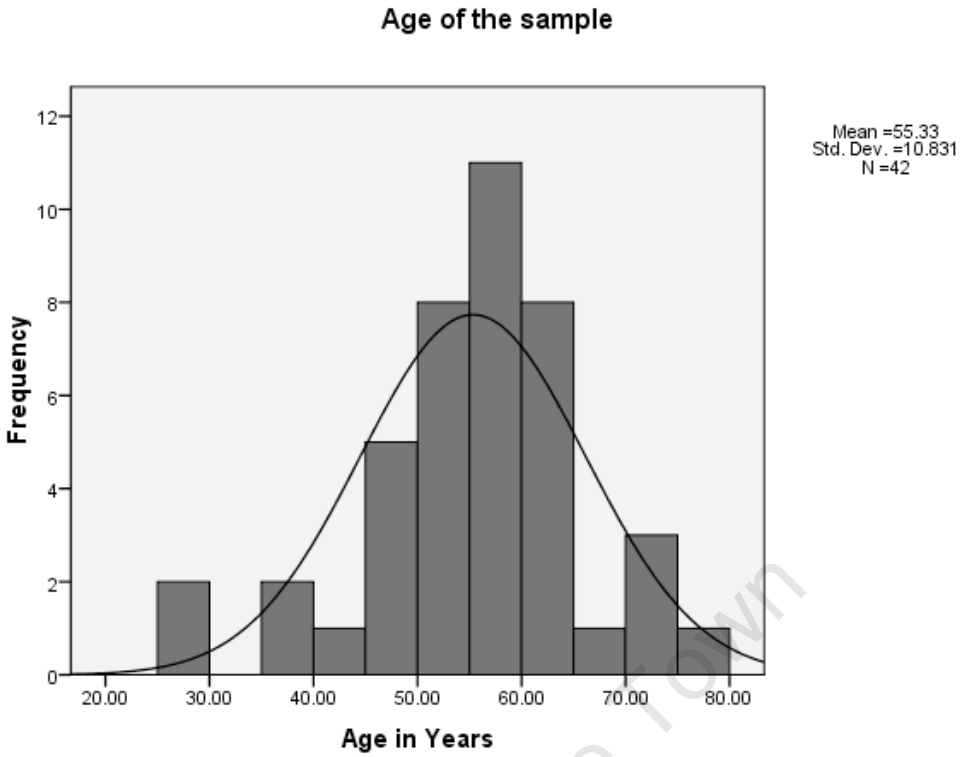


**Figure 1: Age distribution of the sample**

The age distribution across gender groups is displayed in the Figure 2.

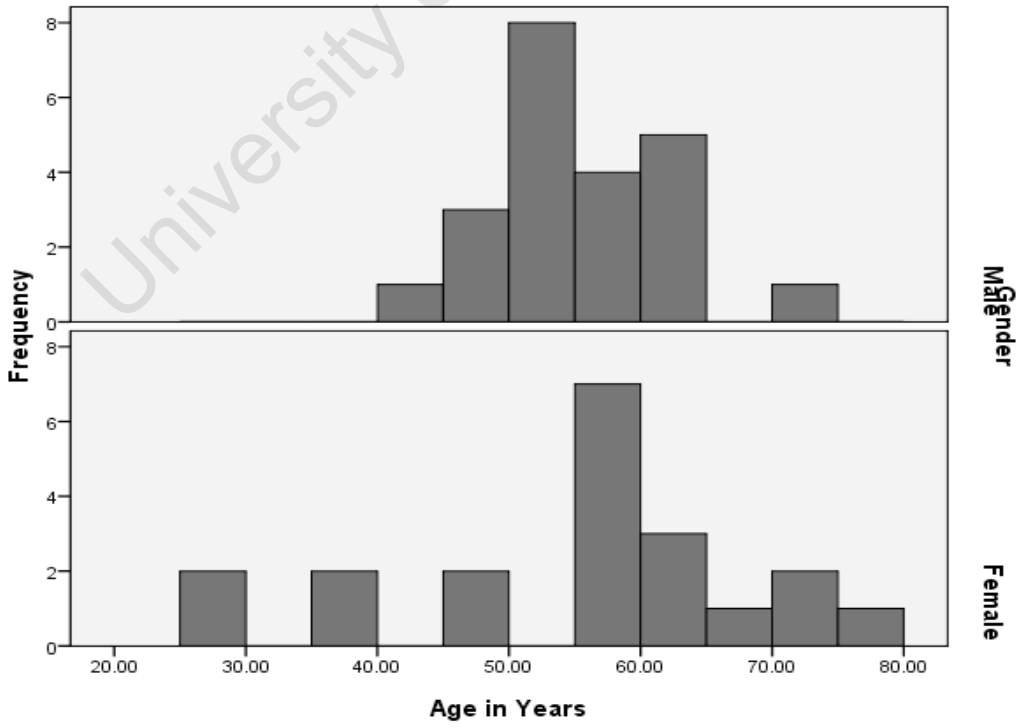


**Figure 2: Age distribution across gender groups**

The rationale was to evaluate whether age affects health-related quality of life.

## 4.3 Previous PRP

Table 2 below illustrates, as a percentage, the number of patients who had panretinal photocoagulation before vitrectomy:

**Table 2: Percentage of patients who had PRP before vitrectomy**

| | | Frequency | % | Valid % | Cumulative % |
|---|---|---|---|---|---|
| | Yes | 28 | 65.1 | 73.7 | 73.7 |
| | No | 10 | 23.3 | 26.3 | 100.0 |
| | **Total** | **38** | **88.4** | **100.0** | |
| Missing | | 5 | 11.6 | | |
| **Total** | | **43** | **100.0** | | |

73.7% of the respondents had PRP before vitrectomy. The rationale for including PRP was to assess whether panretinal photocoagulation before vitrectomy improved visual-related quality of life.

## 4.4 Waiting Time for Surgery

Figure 3 indicates the duration patients waited for their surgery from the time of diagnosis of indication requiring surgery to the time they actually had surgery. The rationale for including this was to evaluate whether delaying vitrectomy had an impact on the overall results of vitrectomy.

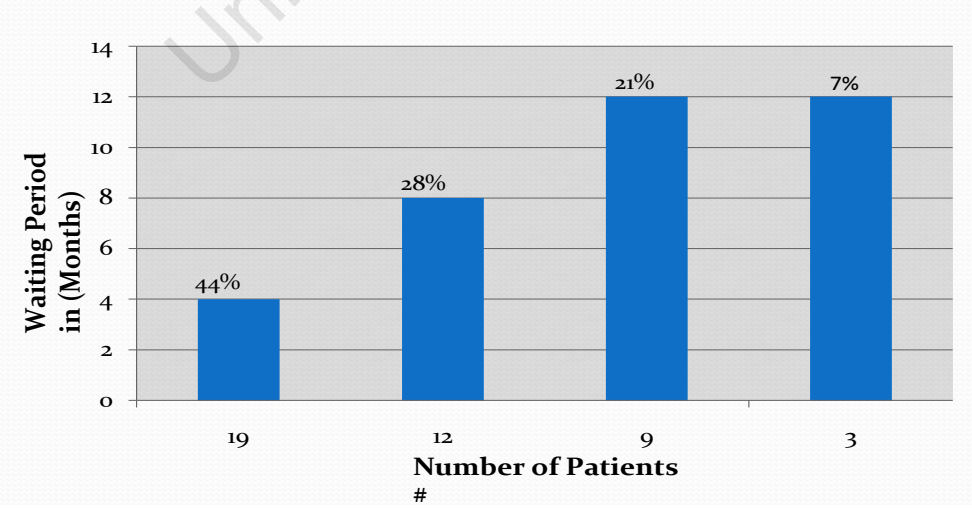


**Figure 3: Waiting time for surgery**

- 44% had surgery within four months of the diagnosis indicating a need for vitrectomy.
- 56% of patients waited for more than four months for their vitrectomy.
- 7% waited twelve months for their vitrectomy.

## 4.5 Type of Surgery Performed

- 62% of patients had pars plana vitrectomy and epiretinal membrane peeling.
- 14% had PPV and retinal detachment repair.
- 24% had PPV and lens extraction.

## 4.6 Indications for Vitrectomy

The rationale for evaluating indications for vitrectomy was to find out whether vision-related quality of life differed for different indications.

**Table 3: Indications for vitrectomy**

| | Frequency | % |
|---|---|---|
| Vitreous hemorrhage | 20 | 46.5 |
| Tractional retinal detachment | 17 | 39.5 |
| Combined tractional and rhegmatogenous retinal detachment | 5 | 11.6 |
| Macula oedema | 1 | 2.3 |
| **Total** | **43** | **100.0** |



## 4.7 Visual Outcome after Vitrectomy

There was significant improvement in LogMAR BCVA from mean 2.0 pre-operative to 1.0 post-operative (p=0.0001). Pre-operative LOGMAR ranged from 0.00 to 3, with 82% ranging from 0.8 to 3 and 9% 0.3 or better, and post-operative LogMAR ranged from 0.00 to NPL. 60% had LogMAR ranging from 0.8 to 3; 4% had NPL and 10% LogMAR 0.3 or better.

There was no significant difference in LogMAR values for non-operated eye pre- and post-vitrectomy (mean 1.4 pre- and 1.2 post-vitrectomy).

The following graphs indicate LogMAR visual acuity for both operated and non-operated eyes.

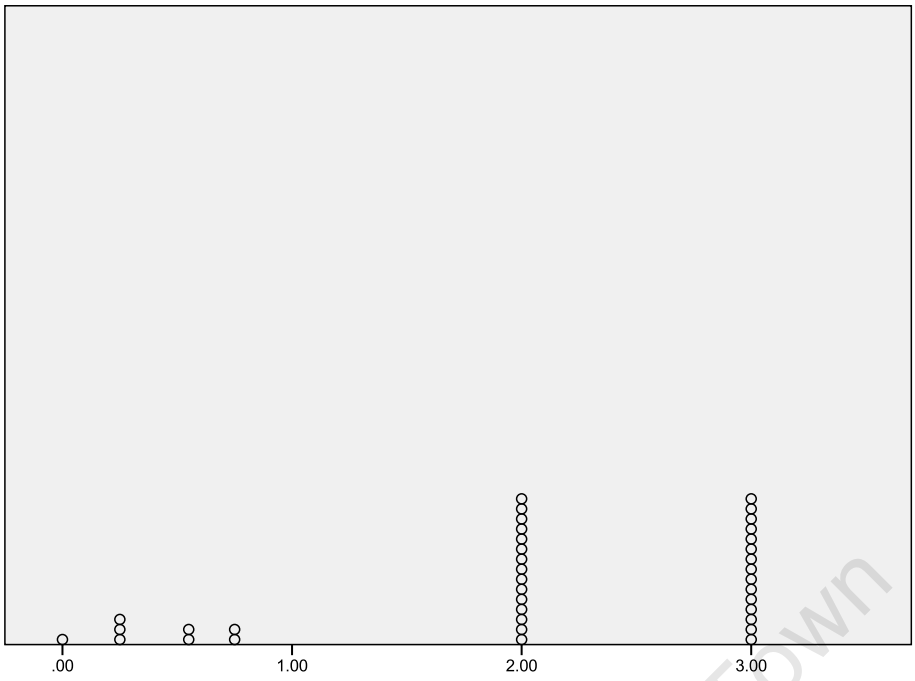


**Figure 4(a)**

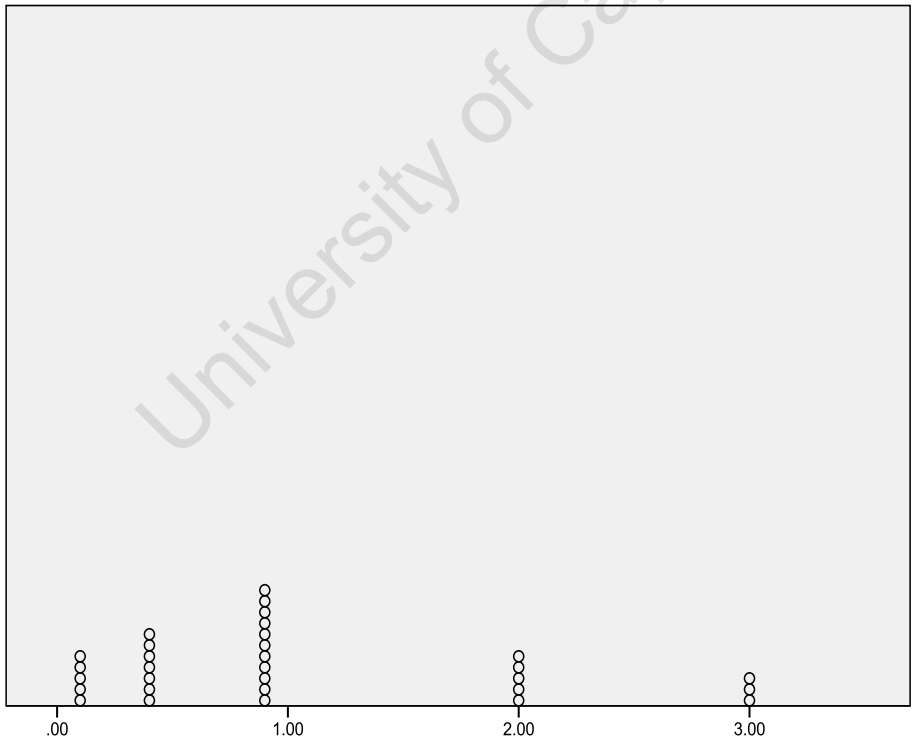


**Figure 4(b)**

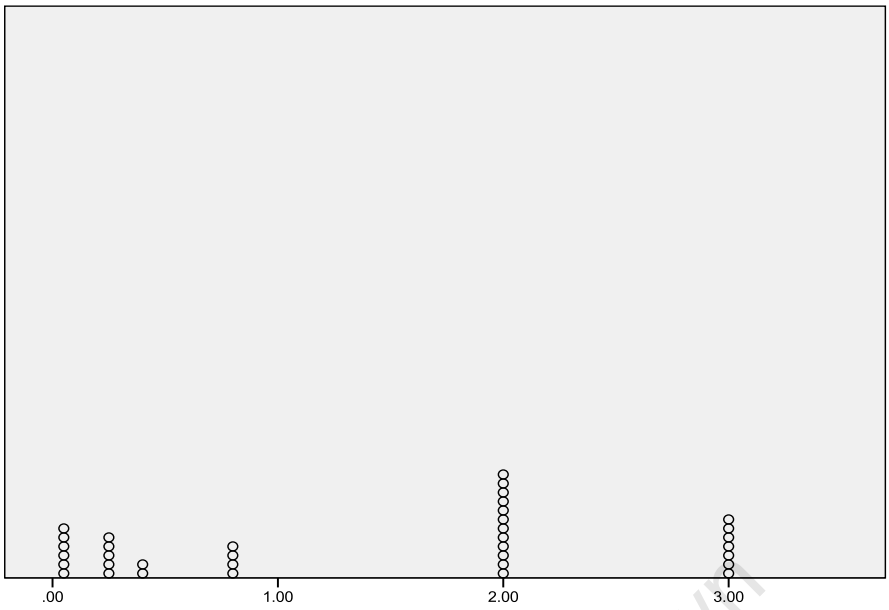


**Figure 4(c)**

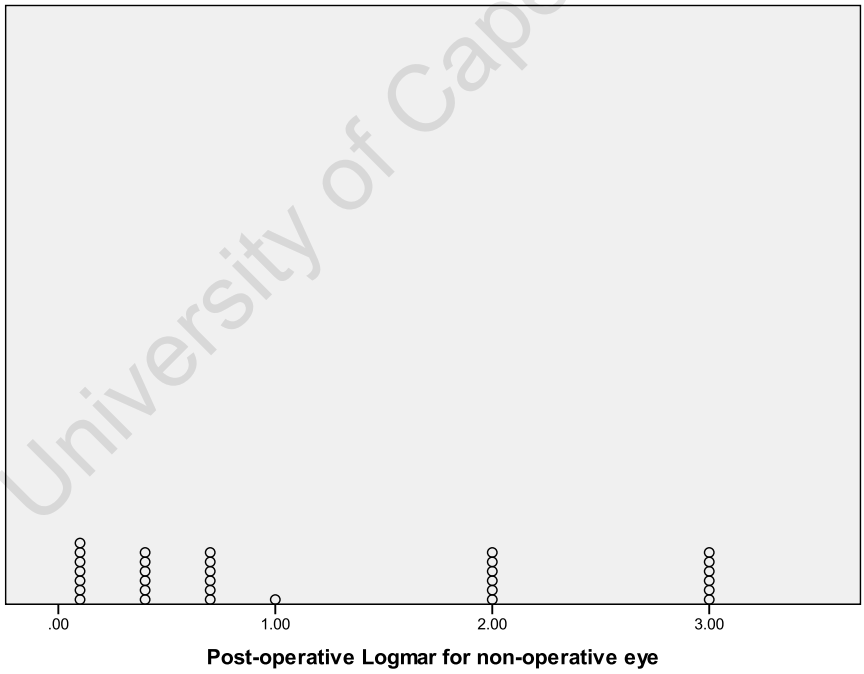


**Figure 4(d)**

**Figure 4(a)–(d): LogMAR visual acuity for both operated and non-operated eyes**

Scatter plots are visual representations of the comparison between two variables. It is basically a cross tabulation between the two variables.

Figure 5 below shows:

- a scatter plot for the pre- and post operative- visual acuity
- a scatter plot for the pre- and post vitrectomy visual acuity

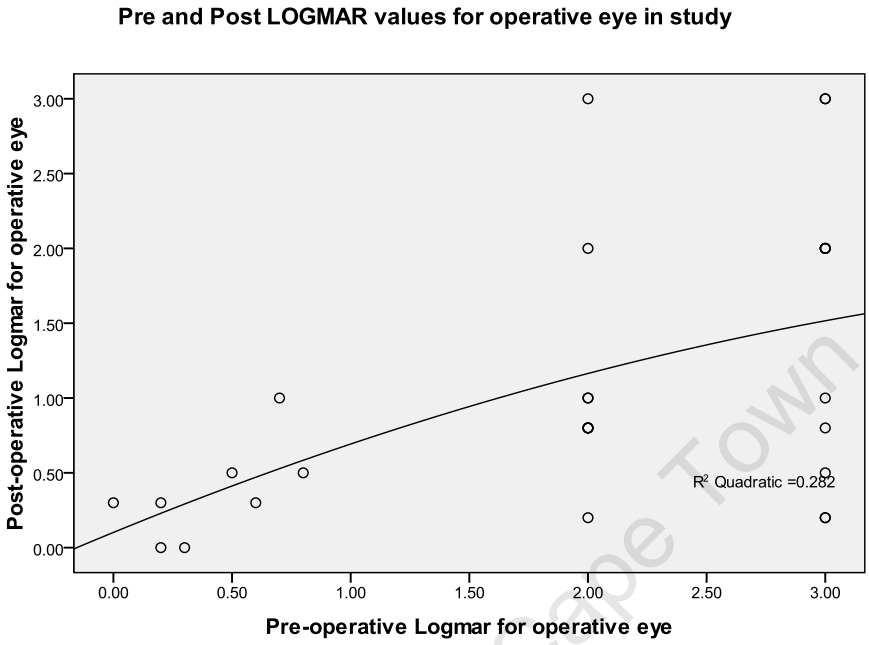


**Figure 5(a)**

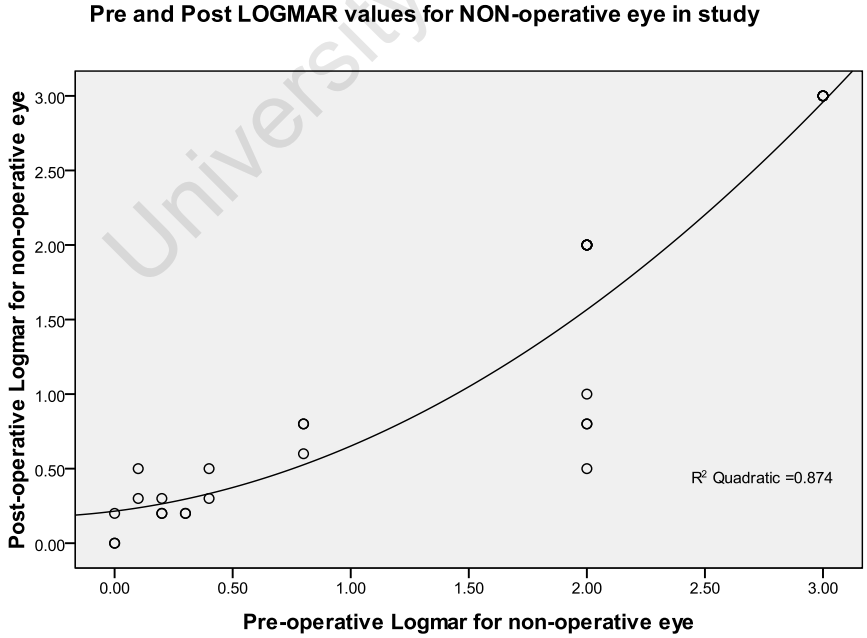


**Figure 5(b)**

**Figure 5(a)–(b): Visual acuity pre- and post-vitrectomy**

The rationale for this was to find out if there was significant improvement in visual acuity after vitrectomy and using the non-operated eye as a control.

## 4.8 Scatter Plot for the Visual Acuity Trend Pre and Post Operative

The following graph indicates a scatter plot for pre- and post-LogMAR values for the operative and non-operative group, as well as a plot for the difference between pre and post values.

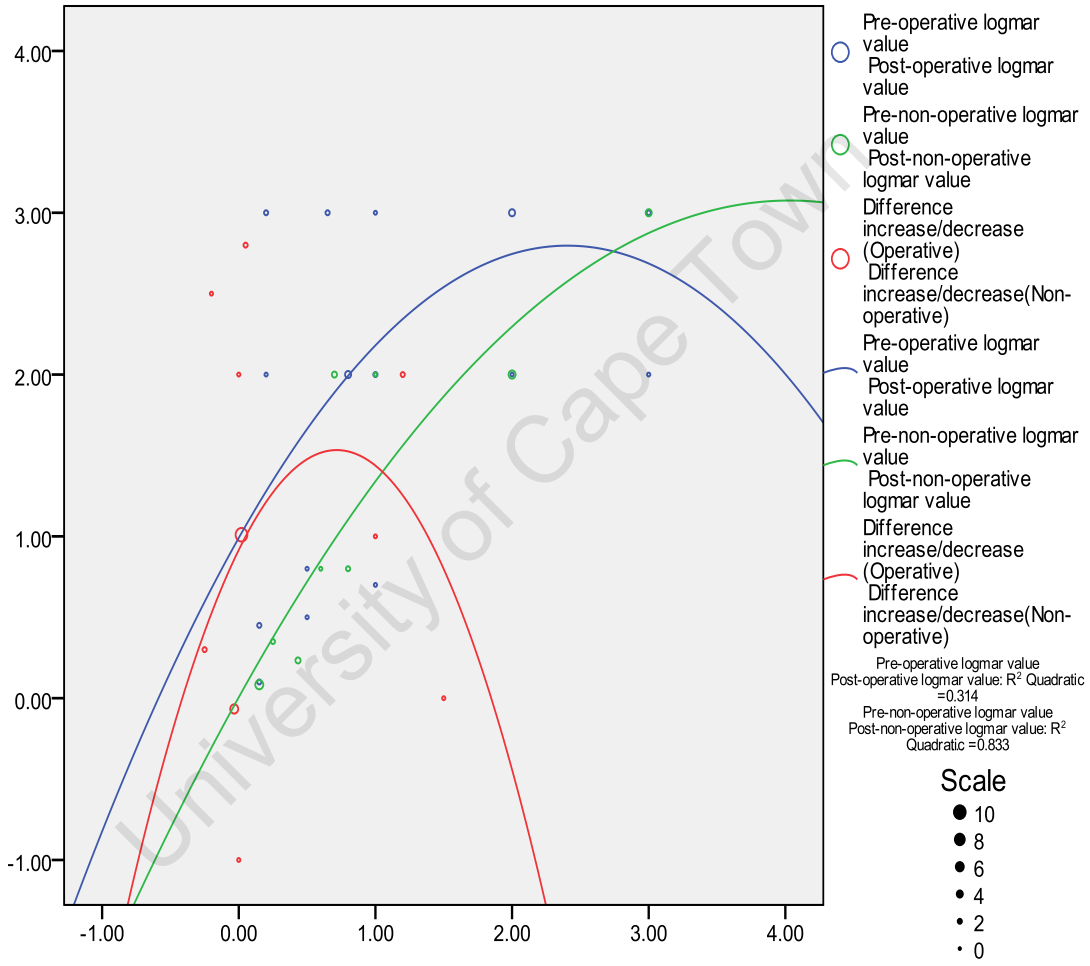


**Figure 6: Scatter plot for pre- and post-LogMAR values for the operative and non-operative group**

- The Y axis represents pre-operative values and the X axis represents post-operative values.
- Fit-lines were added to the plot to show trends in the data. These fit lines show the trend of the relationship between pre- and post-vitrectomy.
- The green line (representing the relationship between pre- and post non-operative LogMAR values) indicates that LogMAR values pre- and post are

more or less the same. The green line is almost diagonal (gradient = 0.815) in the graph, so for LogMAR 0 on Y, the corresponding X value would be 0 as well.

- The blue fit line indicates the relationship between pre- and post-operative LogMAR values. This line is less diagonal than the green line (gradient = 0.26). This shows an improvement due to the operation. For LogMAR 2.00 in the Y, there is corresponding improvement in LogMAR to 1.00 in X axis, which shows that this is the trend in the relationship.
- The red fit line indicates the relationship between calculated pre- and post-*difference* in LogMAR value. This line is even less diagonal (gradient not shown) than either of the other two and this shows the improvement in the difference values. In general, it shows an improvement in LogMAR values from pre-operative to post-operative.

## 4.9 Results for Visual Related Quality of Life Scores

**Table 4: NEI VFQ-39 questionnaire subscale scores**

| NEI VFQ-39 Questionnaire subscales | Mean Pre operative | Std. Deviation Pre operative | Mean Post operative | Std. Deviation Post Operative | P value as compared with pre-operative value |
|---|---|---|---|---|---|
| General health | 45.8 | 19.3 | 37.8 | 24.0 | **0.093** |
| General vision | 43.0 | 19.4 | 53.6 | 31.9 | **0.032** |
| Ocular pain | 69.9 | 26.7 | 47.8 | 37.0 | **0.005** |
| Near activities | 27.2 | 28.8 | 37.6 | 36.9 | **0.012** |
| Distance activities | 30.4 | 28.9 | 36.8 | 31.9 | 0.173 |
| Vision specific social functioning | 37.6 | 35.7 | 24.9 | 22.8 | **0.042** |
| Vision specific mental health | 27.3 | 27.9 | 33.8 | 39.7 | 0.523 |
| Vision specific role difficulties | 29.8 | 29.9 | 39.2 | 36.2 | 0.257 |
| Vision specific dependency | 33.8 | 38.5 | 38.3 | 44.9 | 0.618 |
| Driving | 8.6 | 22.5 | 2.4 | 9.3 | **0.038** |
| Colour vision | 48.8 | 38.9 | 36.0 | 44.4 | **0.051** |
| Peripheral vision | 29.0 | 33.6 | 51.2 | 44.6 | **0.002** |
| Composite score | 35.0 | 23.1 | 32.2 | 27.9 | 0.346 |

The NEI VFQ-39 subscale scores that were markedly reduced and worse were for driving, near activities, peripheral vision, vision specific mental health, vision specific role difficulties, distance activities, vision specific dependency and the composite score.

There was statistically significant difference six months post vitrectomy in seven of 12 VFQ subscales, with improvement in three of the 12 subscales, namely general vision (p=0.032), near activities (p=0.012), peripheral vision (p=0.002).

There was worsening in colour vision (p=0.051), vision specific social functioning (p=0.042) and driving (P=0.038) and ocular pain .There was no statistically significant difference in the composite score 6 months (p=0.005) post vitrectomy

## 4.10 Gender Groups

There were no significant differences in vision-related quality of life between gender groups. This is in itself indicated that both male and female perceptions of their vision-related daily activities were equally affected.

## 4.11 Previous PRP and the VFQ-39 Subscales

### *4.11.1 Post-operative*

No significant differences were observed in the subscale scores between those who had undergone previous PRP and those who had not.

### *4.11.2 Pre-operative*

A significant difference was observed for pre-operative driving; those who had undergone PRP ranked higher on this dimension.

### *4.11.3 Cardiac Disease*

Patients with cardiac disease had lower post-operative NEI VFQ-39 subscale scores than those without cardiac disease. Patients with cardiac disease showed significant worsening of six of 12 subscales, namely vision specific mental health (p=0.020), colour vision (p=0.049), peripheral vision (p=0.056), general vision (p=0.42), ocular pain (p=0.027), distance activities (p=0.030) and the composite score (p=0.042).

There was significant worsening of the composite score (p=0.042). Patients with cardiac disease had significant worsening of vision-related quality of life 6 months after vitrectomy for diabetic retinopathy.

### *4.11.4 Renal Disease*

There was no statistically significant difference in vision-related quality of life 6 months after vitrectomy, if patient had renal disease. 43% of patients with renal disease died within 6 months of vitrectomy.

### *4.11.5 CVA Post Operative*

A significant improvement was noted in one subscale of the NEI VFQ-39 subscale, namely, colour vision (p=0.051).

### *4.11.6 Type of Surgery Performed*

There was no significant difference in quality of life in different type of surgery performed.

## 4.14 Indications for Surgery

There was no significant difference in the quality of life in different indications for surgery.

## 4.15 Results for the Health-Related Quality of Life Scores

Table 5 below indicates the mean scores for the SF-36 questionnaire both before and after vitrectomy.

The health-related quality of life scores showed severe impairment in role limitation due to emotional problems, role limitation due to physical health and general health.

There was no statistically significant difference in the health-related quality of life (HRQoL) 6 months after vitrectomy for diabetic retinopathy. A significant general improvement was noted in role limitation due to emotional problem (p=0.055), although patients had less energy after vitrectomy (p=0.032).

**Table 5: SF-36 subscale scores pre- and post-operative**

| | Mean Pre-op | Std. Deviation Pre-op | Mean Post-op | Std. Deviation Post-op | Asymp. Sig. (2-tailed) |
|---|---|---|---|---|---|
| Physical functioning | 62.3 | 31.3 | 62.6 | 30.2 | 0.118 |
| Role limitations due to physical health | 18.2 | 21.8 | 22.1 | 26.7 | 0.472 |
| Role limitations due to emotional problems | 15.9 | 19.9 | 28.9 | 27.6 | 0.055* |
| Energy/fatigue | 62.7 | 25.1 | 56.1 | 27.8 | 0.032 |
| Emotional well being | 62.8 | 26.6 | 65.3 | 28.0 | 0.96 |
| Social functioning | 45.5 | 21.9 | 46.4 | 22.4 | 0.94 |
| Pain | 73.5 | 33.1 | 66.0 | 39.9 | 0.414 |
| General health | 35.9 | 22.3 | 32.7 | 23.1 | 0.262 |

## 4.16 Correlations between the Visual Acuity and the Visual Function Scores

The Spearman's RHO test showed significant correlations between the operated and non-operated eye LogMAR values and the NEI VFQ-39 subscales and the composite score (p=0.04).

# CHAPTER 5

# DISCUSSION

## 5.1 Demographics

There were equal numbers of male and female patients enrolled in the study, which indicated that there was no gender bias with regard to access to the health services. A risk factor for diabetic retinopathy is the duration of disease and retinopathy is expected to occur 5 to 20 years after diagnosis of diabetes [46].

The mean age in the study was 55, (range 25–77); this was similar to that of the Early Treatment Diabetic Retinopathy Study (ETDRS) study group. Nearly 50% of patients in the ETDRS were younger than 50 years [49]. Okomoto also found that the mean age of patients with proliferative diabetic retinopathy was 55 [1].

Although the visual function scores may decrease with age, the patient age did not correlate well with the patients' responses in this study.

## 5.2 Factors that Could Influence the Outcome of Vitrectomy

### *5.2.1 Panretinal photocoagulation (PRP)*

26% of patients did not have PRP prior to vitrectomy. This indicated that patients presented late in their disease. One would expect people requiring vitrectomy to have had panretinal photocoagulation according to the diabetic retinopathy study (DRS) [46]. One of the reasons for late presentation may have been that diabetic retinopathy screening and referral for laser treatment was inadequate. Currently, there is no diabetic retinopathy screening programme in South Africa.

The lack of a diabetic screening programme results in more patients presenting in the advanced stage of their disease. Theoretically, laser treatment reduces complications during vitrectomy, such as intra and postoperative vitreous haemorrhage, which affects the visual outcome of vitrectomy [44]. However, in this study, there was no statistical difference in quality of life in patients that had or had not had PRP before vitrectomy.

### *5.2.2 Waiting time for surgery*

Due to a shortage of vitreoretinal specialists, significant waiting lists for vitreous surgery had developed, and 56% of patients had to wait for more than 5 months for vitrectomy. We expected patients who had waited longer for surgery to have less improvement in their quality of life and visual outcome; however, in this study, there was no statistically significant difference in the outcome with respect to different waiting times.

### *5.2.3 Type of surgery performed*

Patients with vitreous haemorrhage who did not have traction or macular ischemia or oedema have a good prognosis for good visual outcome [38]. The majority of patients in this study had some form of traction of the macula, which required membrane peeling and this had an impact on their visual prognosis. This resulted in the poor visual acuity and low quality of life scores before and after vitrectomy. There was no statistically significant difference in their quality of life scores when comparing the different surgical procedures performed.

### *5.2.4 The indications for vitrectomy*

Vitreous haemorrhage and tractional retinal detachment was the commonest indication for vitrectomy, as was also found in other studies [38, 44, 52, 53, 54]. There was no statistical difference in quality of life for the different indications for vitrectomy. One would expect patients with vitreous haemorrhage to have better quality of life scores after vitrectomy; however, this was not demonstrated in this study. This was probably because patients presented late in their disease and the majority had some form of traction of the macula. In the Okomoto study, patients with vitreous haemorrhage had higher vision-related quality of life subscale scores 3 months after vitrectomy [1].

## 5.3 No Difference in Quality of Life in Different Factors that May Affect the Outcome of Vitrectomy

A possible explanation for there being no difference in quality of life in different factors that may affect the outcome of vitrectomy was that most of patients already had ischemic macula at the time of surgery. The perfusion of the macula is the main determinant of the post-operative visual outcome [38].

Smidy reported that some patients who had vitreous haemorrhage also had some elements of traction and macular ischemia [49], which resulted in poor visual functioning post vitrectomy.

## 5.4 Visual Outcomes

There was a statistically significant improvement in visual acuity after vitrectomy from mean LogMAR of 2.06 to mean 1.04 in the operated eye, whereas there was no statistical difference in the pre-operative and post-operative LogMAR values of the non-operated eye. The Okamoto study showed an improvement in vision from LogMAR 1.4 to LogMAR of 0.46 three months after vitrectomy for proliferative diabetic retinopathy. The visual acuity in this study was much lower than in other published series. This is largely because our patients presented in an advanced stage of retinopathy and patients had severely impaired visual acuity in both eyes.

Although there was a statistical improvement in visual acuity, this was improvement from counting fingers to 6/60.

Six months after vitrectomy, 56% of patients had visual acuity from 6/60 to hand motion and 26% had visual acuity better than 6/12, in the operated eye. Mason showed >6/12 in 38% of patients, 6/60 to hand motion in 21%, similar to other studies [38, 44, 61, 62, 63]. This showed that our patients had a lower visual acuity level as compared to other studies; however, the other studies were carried out in developed countries with better resources.

## 5.5 Vision-Related Quality of Life after Vitrectomy

In this study, the quality of life after vitrectomy depended on the visual acuity of the operated eye, which is contrary to other published studies that showed that quality of life after vitrectomy depended on the visual acuity of the non-operated eye. The non-operated eye had good vision in their series [1, 5, 6].

In this series, both eyes were similarly involved; hence, the operated eye had an impact on the quality of life. The vision in the non-operated eye was considerably impaired (LogMAR 1.2) and the difference between the operated and non-operated eyes was small (1.0 vs. 1.2). The visual function score correlated with the visual acuity not only in the non-operated eye but also in the operated eye.

These results are inconsistent with other studies that found that changes in visual functioning scores were linearly related to changes in visual acuity of the better-seeing eye, but were not associated with changes in the worse seeing eye [5, 9, 1].

Previous studies reported that quality of life significantly improved following vitrectomy for AMD, macular hole, ERM peeling and proliferative diabetic retinopathy. ([1, 5, 9]. However, in this study, patients had better baseline vision-related quality of life scores before vitrectomy because it was a unilateral disease. In patients with macular hole, four of the 12 subscales (general vision, near activities, mental health and role difficulties) improved significantly after vitrectomy. In several studies investigating quality of life outcomes following vitrectomy, weak or absent correlation between increased quality of life and improvement of visual acuity was found. This was because in these studies the non-operated eye had a good vision. [10, 64]

Vitrectomy for ERM significantly improved two of the 12 subscales (general vision and distance activities). Vitrectomy for PDR significantly improved eight of the 12 subscales (general vision, near activities, distance activities, social functioning, mental health, role difficulties, driving and peripheral vision) [1].

In this study, vitrectomy for diabetic retinopathy improved in three of the 12 subscales of the NEI VFQ-39 (general vision, near activities and peripheral vision). Other studies all showed better improvement in visual functioning scores than in this study, where there was no significant change in the vision-related quality of life 6 months after vitrectomy. These patients had severely impaired vision-related quality of life before vitrectomy, with a composite score of 35, because they presented with very advanced diabetic retinopathy. The pre operative NEI VFQ-39 scores were much lower in this study than in Okamoto study and other published studies [1, 5, 6, 9, 64]. There are limited resources in South Africa's health care facilities as compared to developed countries with excellent health facilities, where most of the studies have been done; this is a major contributor to the difference in these results.

Although there was no significant improvement in vision-related quality of life 6 months after vitrectomy, the patients' perception of peripheral vision significantly improved. Our findings suggest that, as Snellen acuity does not measure peripheral vision, self-reported measures of visual functioning and quality of life (activities of daily vision) may augment the clinical findings and it may be useful to compare and follow up patients with advanced diabetic retinopathy.

## 5.6 General Health Related Quality of Life

The SF-36 scores for the vitality domain were significantly reduced post-operatively, with patients reporting feeling tired. This may be the result of other systemic pathologies, e.g., cardiac disease and renal disease. It is also possible that vitreoretinal surgery and the associated postoperative recovery are tiring for the elderly and could result in reduced vitality, even 6 months post-operatively. This is of importance when counselling patients for such vitreous surgery.

## 5.7 Limitations of the Study

**Sample size:** The sample size was small and there was no comparison control group.

**Short-term follow-up:** In the macular hole study, vision-related quality of life was better at one-year than at 3-months postoperatively [5]Long-term follow-up of patients after pars plana vitrectomy for diabetic retinopathy might give different results regarding VR-QOL, therefore, future research with longer follow-up and larger sample size is needed.

**Advanced diabetic retinopathy:** The advanced levels of diabetic retinopathy in this sample mean that generalisations from our findings can only be made about patients with the same health care service. Also, the study was performed at a single tertiary care specialty hospital and therefore may not represent the patients who are seen in other tertiary hospital centres. Notwithstanding these limitations, this study's strengths include its prospective design and the use of validated instruments. It was done in Africa, in a public sector where 80% of the patients are treated, and other studies in similar settings have not been published.



## 5.8 Conclusion and Recommendations

Significantly, the study showed a marked improvement in visual acuity.

Although there was significant improvement in patient's perception of their general vision, near activities and peripheral vision, this study showed that vitrectomy for diabetic retinopathy, did not improve the overall vision-related quality of life.

Patients presented with an advanced stage of retinopathy resulting in severe impairment in their quality of life and very low baseline quality of life scores associated with the decreased visual acuity in both eyes. In this study, vision-related quality of life was dependent on both the operated and the non-operated eye. There

was correlation between visual acuity and NEI VFQ-39 scores in both operated and non-operated eyes. The study showed that patients undergoing vitrectomy for diabetic retinopathy had much lower NEI VFQ-39 scores compared to patients who did not need vitrectomy, when compared to the Okomoto study, which compared vitrectomy for PDR vs. control [1]. This study showed that patients with poor vision before vitrectomy tended to continue to have poor vision after vitrectomy, whereas those with good vision pre-operatively tend to continue to have good vision post-operatively.

A better understanding of the positive impact of vision-preserving therapies on quality of life and, specifically, on a patient's capacity for independent living may preserve resource allocation for therapies designed to treat diabetic retinopathy.

There is a need to develop a diabetic screening programme in order to prevent patients presenting in such an advanced stage of the disease. Patients must also be aware of the need for early detection of diabetic retinopathy by a thorough examination through a dilated pupil to assess whether treatment is needed to prevent visual loss. Early referral to eye care facilities is necessary.

There should be a national eye health education programme responsible for education about diabetes and the need for diabetic retinopathy screening to patients and family members.

Secondary prevention in diabetic retinopathy needs to be improved with more patients getting laser treatment. The government needs to evaluate the need for vitreoretinal surgeons and employ such surgeons according to the burden of disease, so that patients do not have to wait for more than 5 months for vitrectomy.

Patients' macular perfusion status should be assessed prior to vitrectomy by means of a fluorescein angiogram. Patients should have extensive pre-operative counselling on what to expect from the surgery, based on the study results.

Patients will benefit from the introduction of supportive rehabilitation centres and low-vision clinics, where teams of social workers, orientation and mobility instructors and rehabilitation teachers can help patients develop coping strategies.

Although diabetic retinopathy is an inevitable sequel of diabetic mellitus, it can be influenced by glycaemic control, timely diagnosis and treatment through vitrectomy. Vision-related quality of life questionnaires are useful for assessing the outcome of vitrectomy in patients with very advanced diabetic retinopathy.

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**Note 1:** This bibliography reflects all references and sources both direct and indirect used in this dissertation.

**Note 2:** Wherever unpublished information has been quoted or used for the purposes of this dissertation, the respective organisations and/or individuals have given their permission to quote such information, on the basis that it will not be reprinted or quoted for any other purpose without their express, written permission.

# APPENDICES

## Appendix 1: Letter of Consent

This serves to assure you as a respondent that this interview is solely for research purposes.

### Your name will remain anonymous.

The information you supply will not be used for anything other than for the purpose of this research. The results of this study will be made available to every respondent. The study intends to enrol 200 participants.

The study will be conducted by means of two questionnaires before surgery and 4 months and 6 months after surgery. Each interview will last for 15 minutes. Questions will be related to quality of life and visual functioning. Overall duration of the study will be 24 months.

### Your participation is voluntary.

You may choose not to be included in this research. If you choose not to participate in this study, it will not, by anyhow, affect the quality of service to be rendered to you, either by the person under taking the research or any person rendering service to you. If in the middle of the study you choose to withdraw from participating in the study, there will be no prejudice to quality of clinical management and care rendered to you.

### The information to be given will remain confidential.



Thank you for choosing to participate in this research.

The aim of this research is to evaluate the quality of life and visual functioning after parsplana vitrectomy for patients with diabetic eye disease complications.

The researcher will contact you on the days of interviews. The follow-up interview will be conducted on the day of your follow-up visits to the retinal clinic. Therefore, no reimbursement will be made to participants.

A research report will be submitted to the University of Cape Town (UCT), Western Cape, South Africa, in partial fulfilment of the requirement for the Masters degree in ophthalmology (MMED).

The researcher is Dr BVUMBI AZWIHANGWISI, the Registrar in Ophthalmology Department (UCT) GROOTESCHUUR HOSPITAL. Contact details are 021 404 3525 (phone) and/or 082 3385 538 (mobile).

The Health Science Research Ethics Committee of the University of Cape Town, which reviews research on human subjects, will answer any question about your rights and welfare as a research subjects. You may contact Professor MARC BLOCKMAN at 021 406 6496 or 021 406 6338.

## Appendix 2: Patient Information Sheet

**Thank you for choosing to be included in this research.**

The study topic of this research is to evaluate the quality of life and visual functioning after parsplana vitrectomy for patients with diabetic eye disease complications in Groote Schuur Hospital Western Province.

The results of the study will help the ophthalmology fraternity in future recommendations of treatment. Results will help in assessing the overall impact of surgery on patients' quality of life.

The study will be conducted by means of two questionnaires, one before surgery and the other 4 months and 6 months after surgery. Each interview will last for 15 minutes. Questions will be related to quality of life and visual functioning. The overall duration of the study will be 24 months.

There are no benefits or disadvantages attached with being included or not being included in the study. The study intends to enrol 200 participants.

The researcher will contact you on the days of interviews. A follow-up interview will be conducted on the day of your follow-up visits to the retinal clinic. Therefore, no reimbursement will be made to participants.

The researcher is Dr BVUMBI AZWIHANGWISI, the Registrar in the Ophthalmology Department (UCT) GROOTESCHUUR HOSPITAL. Contact details are 021 404 3525 (phone) and/or 082 3385 538 (mobile).

The Health Science Research Ethics Committee of the University of Cape Town, which reviews research on human subjects, will answer any question about your rights and welfare as a research subjects. You may contact Professor MARC BLOCKMAN at 021 406 6496 or 021 406 6338.

## Appendix 3: Demographic Form

<table>
<tr><td colspan="2">Name</td><td colspan="4"></td></tr>
<tr><td colspan="2">Hospital</td><td colspan="2"></td><td>Hospital number</td><td></td></tr>
<tr><td></td><td></td><td colspan="4">Title</td></tr>
<tr><td colspan="2">(Office Use only)</td><td>Date</td><td>Time</td><td>Venue</td><td>Interviewer</td></tr>
<tr><td colspan="6">Interviewer’s comment</td></tr>
</table>

## Appendix 4: SF-36 Questionnaire

**Instructions:** These questions ask for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Answer every question by marking the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

---

**1** **In general, would you say your health is:** (Please tick **one** box)

| | |
|---|---|
| Excellent | ❑ |
| Very Good | ❑ |
| Good | ❑ |
| Fair | ❑ |
| Poor | ❑ |

**2** **Compared to one year ago, how would you rate your health in general now?** (Please tick **one** box)

| | |
|---|---|
| Much better than one year ago | ❑ |
| Somewhat better now than one year ago | ❑ |
| About the same as one year ago | ❑ |
| Somewhat worse now than one year ago | ❑ |
| Much worse now than one year ago | ❑ |

**3** **The following questions are about activities you might do during a typical day. Does <u>your health</u> now limit you in these activities? If so, how much?**

(Please circle **one** number on each line)

| | **Activities** | **Yes, limited a lot** | **Yes, limited a little** | **Not limited at all** |
|---|---|---|---|---|
| 3(a) | **Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports | 1 | 2 | 3 |
| 3(b) | **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf | 1 | 2 | 3 |
| 3(c) | Lifting or carrying groceries | 1 | 2 | 3 |
| 3(d) | Climbing **several** flights of stairs | 1 | 2 | 3 |
| 3(e) | Climbing **one** flight of stairs | 1 | 2 | 3 |
| 3(f) | Bending, kneeling, or stooping | 1 | 2 | 3 |
| 3(g) | Walking **more than a mile** | 1 | 2 | 3 |
| 3(h) | Walking **several blocks** | 1 | 2 | 3 |
| 3(i) | Walking **one block** | 1 | 2 | 3 |
| 3(j) | Bathing or dressing yourself | 1 | 2 | 3 |

**4 During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?**

| | (Please circle **one** number on each line) | **Yes** | **No** |
|---|---|---|---|
| 4(a) | Cut down on the **amount of time** you spent on work or other activities | 1 | 2 |
| 4(b) | Accomplished less than you would like | 1 | 2 |
| 4(c) | Were **limited** in the **kind** of work or other activities | 1 | 2 |
| 4(d) | Had **difficulty** performing the work or other activities (for example, it took extra effort) | 1 | 2 |

**5 During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (eg feeling depressed or anxious)?**

| | (Please circle **one** number on each line) | **Yes** | **No** |
|---|---|---|---|
| 5(a) | Cut down on the amount of time you spent on work or other activities | 1 | 2 |
| 5(b) | Accomplished less than you would like | 1 | 2 |
| 5(c) | Didn't do work or other activities as carefully as usual | 1 | 2 |

**6 During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours, or groups?** (Please tick **one** box)

- Not at all ❑
- Slightly ❑
- Moderately ❑
- Quite a bit ❑
- Extremely ❑

**7 How much physical pain have you had during the past 4 weeks?** (Please tick **one** box)

- None ❑
- Very mild ❑
- Mild ❑
- Moderate ❑
- Severe ❑
- Very severe ❑

**8 During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?** (Please tick **one** box)

- Not at all ❑
- A little bit ❑
- Moderately ❑
- Quite a bit ❑
- Extremely ❑

**9 These questions are about how you feel and how things have been with you during the past 4 weeks. Please give the one answer that is closest to the way you have been feeling for each item.**

| (Please circle **one** number on each line) | | All of the time | Most of the time | A good bit of the time | Some of the time | A little of the time | None of the time |
|---|---|---|---|---|---|---|---|
| 9(a) | Did you feel full of life? | 1 | 2 | 3 | 4 | 5 | 6 |
| 9(b) | Have you been a very nervous person? | 1 | 2 | 3 | 4 | 5 | 6 |
| 9(c) | Have you felt so down in the dumps that nothing could cheer you up? | 1 | 2 | 3 | 4 | 5 | 6 |
| 9(d) | Have you felt calm and peaceful? | 1 | 2 | 3 | 4 | 5 | 6 |
| 9(e) | Did you have a lot of energy? | 1 | 2 | 3 | 4 | 5 | 6 |
| 9(f) | Have you felt downhearted and blue? | 1 | 2 | 3 | 4 | 5 | 6 |
| 9(g) | Did you feel worn out? | 1 | 2 | 3 | 4 | 5 | 6 |
| 9(h) | Have you been a happy person? | 1 | 2 | 3 | 4 | 5 | 6 |
| 9(i) | Did you feel tired? | 1 | 2 | 3 | 4 | 5 | 6 |

**10 During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc)** (Please tick **one** box)

All of the time ❑

Most of the time ❑

Some of the time ❑

A little of the time ❑

None of the time ❑

**11 How TRUE or FALSE is each of the following statements for you?**

| | (Please circle **one** number on each line) | Definitely true | Mostly true | Don't know | Mostly false | Definitely false |
|---|---|---|---|---|---|---|
| 11(a) | I seem to get sick a little easier than other people | 1 | 2 | 3 | 4 | 5 |
| 11(b) | I am as healthy as anybody I know | 1 | 2 | 3 | 4 | 5 |
| 11(c) | I expect my health to get worse | 1 | 2 | 3 | 4 | 5 |
| 11(d) | My health is excellent | 1 | 2 | 3 | 4 | 5 |

**Thank you**

## Appendix 5: Visual Function Questionnaire

### Visual Functioning Questionnaire – 39 (NEI VFQ-39)

### (INTERVIEWER ADMINISTERED FORMAT)

### Instructions:

I'm going to read you some statements about problems that involve your vision or feelings that you have about your vision condition. After each question, I will read you a list of possible answers. Please choose the response that best describes your situation.

Please answer all the questions as if you were wearing your glasses or contact lenses (if any).

Please take as much time as you need to answer each question. All your answers are confidential. In order for this survey to improve our knowledge about vision problems and how they affect your quality of life, your answers must be as accurate as possible. Remember, if you wear glasses or contact lenses for a particular activity, please answer all of the following questions as though you were wearing them.

# VISUAL FUNCTIONING QUESTIONNAIRE – 39

## PART 1 – GENERAL HEALTH AND VISION

1 In general, would you say your overall health is: **(Circle One)**

**Read categories:**

| | |
|---|---|
| Excellent | **1** |
| Very good | **2** |
| Good | **3** |
| Fair | **4** |
| Poor | **5** |

2 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? **(Circle One)**

**Read categories:**

| | |
|---|---|
| Excellent | **1** |
| Good | **2** |
| Fair | **3** |
| Poor | **4** |
| Very poor | **5** |
| Completely blind | **6** |

3 How much time do you worry about your eyesight? **(Circle One)**

**Read categories:**

| | |
|---|---|
| None of the time | **1** |
| A little of the time | **2** |
| Some of the time | **3** |
| Most of the time | **4** |
| All of the time | **5** |

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

**Read categories:**

| | |
|---|---|
| None | **1** |
| Mild | **2** |
| Moderate | **3** |
| Severe | **4** |
| Very severe | **5** |

**PART 2 – DIFFICULTY WITH ACTIVITIES**

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

5 How much difficulty do you have reading ordinary print in newspapers? Would you say you have: **(Circle One)**

**Read categories as needed:**

| | |
|---|---|
| No difficulty at all | **1** |
| A little difficulty | **2** |
| Moderate difficulty | **3** |
| Extreme difficulty | **4** |
| Stopped doing this because of your eyesight | **5** |
| Stopped doing this for other reasons or not interested in doing this | **6** |

6 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: **(Circle One)**

**Read categories as needed:**

| | |
|---|---|
| No difficulty at all | **1** |
| A little difficulty | **2** |
| Moderate difficulty | **3** |
| Extreme difficulty | **4** |
| Stopped doing this because of your eyesight | **5** |
| Stopped doing this for other reasons or not interested in doing this | **6** |

7 Because of your eyesight, how much difficulty do you have finding something on a crowded shelf? **(Circle One)**

**Read categories as needed:**

| | |
|---|---|
| No difficulty at all | **1** |
| A little difficulty | **2** |
| Moderate difficulty | **3** |
| Extreme difficulty | **4** |
| Stopped doing this because of your eyesight | **5** |
| Stopped doing this for other reasons or not interested in doing this | **6** |

8 How much difficulty do you have reading street signs or the names of stores? **(Circle One)**

**Read categories as needed:**

| | |
|---|---|
| No difficulty at all | **1** |
| A little difficulty | **2** |
| Moderate difficulty | **3** |
| Extreme difficulty | **4** |
| Stopped doing this because of your eyesight | **5** |
| Stopped doing this for other reasons or not interested in doing this | **6** |

9 Because of your eyesight, how much difficulty do you have going down steps, stairs, or curbs in dim light or at night? **(Circle One)**

**Read categories as needed:**

| | |
|---|---|
| No difficulty at all | **1** |
| A little difficulty | **2** |
| Moderate difficulty | **3** |
| Extreme difficulty | **4** |
| Stopped doing this because of your eyesight | **5** |
| Stopped doing this for other reasons or not interested in doing this | **6** |

10 Because of your eyesight, how much difficulty do you have noticing objects off to the side while you are walking along? **(Circle One)**

**Read categories as needed:**

| | |
|---|---|
| No difficulty at all | **1** |
| A little difficulty | **2** |
| Moderate difficulty | **3** |
| Extreme difficulty | **4** |
| Stopped doing this because of your eyesight | **5** |
| Stopped doing this for other reasons or not interested in doing this | **6** |

11 Because of your eyesight, how much difficulty do you have seeing how people react to things you say? **(Circle One)**

**Read categories as needed:**

| | |
|---|---|
| No difficulty at all | **1** |
| A little difficulty | **2** |
| Moderate difficulty | **3** |
| Extreme difficulty | **4** |
| Stopped doing this because of your eyesight | **5** |
| Stopped doing this for other reasons or not interested | **6** |

in doing this

12 Because of your eyesight, how much difficulty do you have picking out and matching your own clothes? **(Circle One)**

**Read categories as needed:**

| | |
|---|---|
| No difficulty at all | **1** |
| A little difficulty | **2** |
| Moderate difficulty | **3** |
| Extreme difficulty | **4** |
| Stopped doing this because of your eyesight | **5** |
| Stopped doing this for other reasons or not interested in doing this | **6** |

13 Because of your eyesight, how much difficulty do you have visiting with people in their homes, at parties, or in restaurants? **(Circle One)**

**Read categories as needed:**

| | |
|---|---|
| No difficulty at all | **1** |
| A little difficulty | **2** |
| Moderate difficulty | **3** |
| Extreme difficulty | **4** |
| Stopped doing this because of your eyesight | **5** |
| Stopped doing this for other reasons or not interested in doing this | **6** |

14 Because of your eyesight, how much difficulty do you have going out to see movies, plays, or sports events? **(Circle One)**

**Read categories as needed:**

| | |
|---|---|
| No difficulty at all | **1** |
| A little difficulty | **2** |
| Moderate difficulty | **3** |
| Extreme difficulty | **4** |
| Stopped doing this because of your eyesight | **5** |
| Stopped doing this for other reasons or not interested in doing this | **6** |

15 Now, I'd like to ask about driving a car. Are you currently driving, at least once in a while? **(Circle One)**

| | | |
|---|---|---|
| Yes | 1 | *Skip to part Q 15c* |
| No | 2 | |

15(a) If **NO**, ask: Have you ever driven a car or have you given up driving? **(Circle One)**

| | | |
|---|---|---|
| Never drove | 1 | *Skip to part 3, Q17* |
| Gave up | 2 | |

15(b) **IF 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 part 3, Q17* |
| Mainly other reasons | **2** | *Skip to part 3, Q17* |
| Both eyesight and other reasons | **3** | *Skip to part 3, Q17* |

15(c) **IF CURRENTLY DRIVING:** How much difficulty do you have driving during the daytime in familiar places? Would you say you have: **(Circle One)**

| | |
|---|---|
| No difficulty at all | **1** |
| A little difficulty | **2** |
| Moderate difficulty | **3** |
| Extreme difficulty | **4** |

16(a) How much difficulty do you have driving at night? Would you say you have: **(Circle One)**

**Read categories as needed:**

| | |
|---|---|
| No difficulty at all | **1** |
| A little difficulty | **2** |
| Moderate difficulty | **3** |
| Extreme difficulty | **4** |
| Stopped doing this because of your eyesight | **5** |
| Stopped doing this for other reasons or not interested in doing this | **6** |

16(b) 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: **(Circle One)**

**Read categories as needed:**

| | |
|---|---|
| No difficulty at all | **1** |
| A little difficulty | **2** |
| Moderate difficulty | **3** |
| Extreme difficulty | **4** |
| Stopped doing this because of your eyesight | **5** |
| Stopped doing this for other reasons or not interested in doing this | **6** |

**PART 3 – 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. **(Circle one on each line)**

| **Read categories:** | | **All of the time** | **Most of the time** | **Some of the time** | **A little of the time** | **None of the time** |
|---|---|---|---|---|---|---|
| 17 | Do you accomplish less than you would like because of your vision? | 1 | 2 | 3 | 4 | 5 |
| 18 | Are you limited in how long you work or do other activities because of your vision? | 1 | 2 | 3 | 4 | 5 |
| 19 | How much does pain or discomfort in or around your eyes, for example burning, itching or aching, keep you from doing what you would like to be doing? Would you say: | 1 | 2 | 3 | 4 | 5 |

For each of the following statements, please tell me if it is definitely true, mostly true, mostly false, or definitely false for you or you are not sure. **(Circle One On Each Line)**

| **Read categories:** | | **Definitely true** | **Mostly true** | **Not sure** | **Mostly false** | **Definitely false** |
|---|---|---|---|---|---|---|
| 20 | I stay home most of the time because of my eyesight. | 1 | 2 | 3 | 4 | 5 |
| 21 | I feel frustrated a lot of the time because of my eyesight | 1 | 2 | 3 | 4 | 5 |
| 22 | I have much less control over what I do, because of my eyesight | 1 | 2 | 3 | 4 | 5 |
| 23 | Because of my eyesight, I have to rely too much on what other people tell me | 1 | 2 | 3 | 4 | 5 |
| 24 | I need a lot of help from others because of my eyesight | 1 | 2 | 3 | 4 | 5 |
| 25 | I worry about doing things that will embarrass myself or others, because of my eyesight. | 1 | 2 | 3 | 4 | 5 |



**That's the end of the interview.**

**Thank you very much for your time and your help.**

## Appendix 6: Appendix of Optional Additional Questions

**SUBSCALE: GENERAL HEALTH**

A1 How would you rate your overall health, on a scale where zero is as bad as death and 10 is best possible health? **(Circle One)**

**0 1 2 3 4 5 6 7 8 9 10**

**Worst Best**

**SUBSCALE: GENERAL VISION**

A2 How would you rate your eyesight now (with glasses or contact lens on, if you wear them), on a scale of from 0 to 10, where zero means the worst possible eyesight, as bad or worse than being blind, and 10 means the best possible eyesight? **(Circle One)**

**0 1 2 3 4 5 6 7 8 9 10**

**Worst Best**

**SUBSCALE: NEAR VISION**

A3 Wearing glasses, how much difficulty do you have reading the small print in a telephone book, on a medicine bottle, or on legal forms? Would you say: **(Circle One)**

**Read categories as needed:**

| | |
|---|---|
| No difficulty at all | **1** |
| A little difficulty | **2** |
| Moderate difficulty | **3** |
| Extreme difficulty | **4** |
| Stopped doing this because of your eyesight | **5** |
| Stopped doing this for other reasons or not interested in doing this | **6** |

A5 Because of your eyesight, how much difficulty do you have doing things like shaving, styling your hair, or putting on makeup? **(Circle One)**

**Read categories as needed:**

| | |
|---|---|
| No difficulty at all | **1** |
| A little difficulty | **2** |
| Moderate difficulty | **3** |
| Extreme difficulty | **4** |
| Stopped doing this because of your eyesight | **5** |
| Stopped doing this for other reasons or not interested in doing this | **6** |

**SUBSCALE: DISTANCE VISION**

A6 Because of your eyesight, how much difficulty do you have recognising people you know from across a room? **(Circle One)**

**Read categories as needed:**

| | |
|---|---|
| No difficulty at all | **1** |
| A little difficulty | **2** |
| Moderate difficulty | **3** |
| Extreme difficulty | **4** |
| Stopped doing this because of your eyesight | **5** |
| Stopped doing this for other reasons or not interested in doing this | **6** |

A7 Because of your eyesight, how much difficulty do you have taking part in active sports or other outdoor activities that you enjoy (like golf, bowling, jogging, or walking)? **(Circle One)**

**Read categories as needed:**

| | |
|---|---|
| No difficulty at all | **1** |
| A little difficulty | **2** |
| Moderate difficulty | **3** |
| Extreme difficulty | **4** |
| Stopped doing this because of your eyesight | **5** |
| Stopped doing this for other reasons or not interested in doing this | **6** |

A8 Because of your eyesight, how much difficulty do you have seeing and enjoying programmes on TV? **(Circle One)**

**Read categories as needed:**

| | |
|---|---|
| No difficulty at all | **1** |
| A little difficulty | **2** |
| Moderate difficulty | **3** |
| Extreme difficulty | **4** |
| Stopped doing this because of your eyesight | **5** |
| Stopped doing this for other reasons or not interested in doing this | **6** |

**SUBSCALE: SOCIAL FUNCTION**

A9 Because of your eyesight, how much difficulty do you have entertaining friends and family in your home? **(Circle One)**

**Read categories as needed:**

| | |
|---|---|
| No difficulty at all | **1** |
| A little difficulty | **2** |
| Moderate difficulty | **3** |
| Extreme difficulty | **4** |
| Stopped doing this because of your eyesight | **5** |
| Stopped doing this for other reasons or not interested in doing this | **6** |

**SUBSCALE: DRIVING**

A10 **[This items, "driving in difficult conditions", has been included as item 16a as part of the base set of 25 vision-targeted items.]**

**SUBSCALE: ROLE LIMITATIONS**

A11 The next questions are about things you may do because of your vision.

For each item, I'd like you to tell me if this is true for you all, most, some, a little, or none of the time.

**(Circle One On Each Line)**

| **Read categories as needed:** | | **All of the time** | **Most of the time** | **Some of the time** | **A little of the time** | **None of the time** |
|---|---|---|---|---|---|---|
| (a) | Do you have more help from others because of your vision? | 1 | 2 | 3 | 4 | 5 |
| (b) | Are you limited in the kinds of things you can do because of your vision? | 1 | 2 | 3 | 4 | 5 |

**SUBSCALES: WELL-BEING / DISTRESS (#A12) and DEPENDENCY (#13)**

The next questions are about how you deal with your vision.

For each statement, please tell me if it is definitely true, mostly true, mostly false, or definitely false for you or you don't know. **(Circle One On Each Line)**

| **Read categories:** | | **Definitely true** | **Mostly true** | **Not sure** | **Mostly false** | **Definitely false** |
|---|---|---|---|---|---|---|
| A12 | I am often irritable because of my eyesight | 1 | 2 | 3 | 4 | 5 |
| A13 | I don't go out of my home alone, because of my eyesight | 1 | 2 | 3 | 4 | 5 |

## Appendix 7: Quality of Life After Vitrectomy Study

**OPHTHALMOLOGY DEPARTMENT (GSH)**

**NAME:** .....

**AGE:** .....

**TEL. NO.:** .....

**PREVIOUS PRP:** YES/NO

**DATE OF INTERVIEW:** .....

**VISUAL ACUITY BEFORE SURGERY:**

| OD | OS |
|---|---|
| ..... | ..... |
| **PH** | |
| ..... | ..... |
| **BCVA** | |
| ..... | ..... |
| ..... | ..... |

**VISUAL ACUITY AFTER SURGERY:**

**OD:**

..... ..... .....

**OS:**

..... ..... .....

**CARDIAC DISEASE:** YES/NO

**RENAL DISEASE:** YES/NO

**CVA:** YES/NO

**OTHER DISEASES:** .....

.....

.....

**BLOOD PRESSURE:** .....mmHg

**FOLDER NO.:** .....

**GENDER:** MALE/FEMALE

**CELL NO.:** .....

**AVERAGE REPORTED GLUCOSE IN g/DL:**

.....

**DM:** TYPE I/TYPE II

**DURATION OF DM:** .....

.....

**DATE OF SURGERY:** .....

.....

.....

**DURATION OF SURGERY:** .....

.....

**COMPILATION OF SURGERY**

**INTRAOPERATIVE:** .....

.....

.....

**POSTOPERATIVE:** .....

.....

.....

**INDICATION OF SURGERY:**.....

.....

.....

**DURATION OF COMPLICATION NEEDING VIRECTOMY:** .....

.....

.....

## Appendix 8: Structured Eligibility Questions

1 Why are we doing this study?

2 Why were you asked to take part in this study?

3 What will you be asked to do if you take part?

4 How long will you be involved in the study?

5 What kinds of risks are you going to face by taking part in the study?

6 Are you worried about taking part in the study?

7 What good things can happen if you take part in the study?

8 What will happen if you decide you don't want to be in the study any longer?

9 Who should you contact if you have any questions?

-