QUALITY OF LIFE AFTER OPEN GLOBE INJURY
LEADING TO AMPUTATION OF THE EYE

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ABSTRACT

**Purpose:** The purpose of this study was to explore the quality of life of patients who underwent an eye amputation after open globe injury. The study addressed both general and vision related quality of life, focusing on anxiety and depression. The demographics of the study participants/respondents were compared to similar studies.

**Design and Method:** The study design was a quantitative, prospective cross-sectional study using as a data tool, a self-administered questionnaire with demographic information, an extract of the WHO PBD VF20 questionnaire and the EQ5D. The participants were sampled using the convenience sampling method from the oculo-prosthesis clinic at the St John Eye Hospital, Chris Hani Baragwanath Academic Hospital, Johannesburg, Gauteng, during March 2016 to June 2016. The information was collated and the data analysed using SAS to determine means, distributions and comparisons among the groups.

**Results:** The demographics were comparable to other studies, except that more females were recruited in this current study.

*Vision specific quality of life:* 51% of the respondents experienced no problems, 26.4% experienced problems, sometimes, and 9.3% experienced problems, very often.

*General health quality of life:* 52.3% experienced an ideal life state. Only three respondents experienced a quality of life that was less than 50% of the ideal health state, all of whom indicated that they suffered severe pain. 83.8% of the study
participants/respondents experienced a quality of life that was more than 75% of the ideal health state.

**Conclusion:** Primary evisceration in severe ocular trauma is justified at the St John Eye Hospital due to the high burden of disease on the public health system (>70% of households), provided that certain criteria are met with regards to the visual potential of the eye. The higher female incidence could be due to alcohol misuse and gender violence; however, this will require further research. Despite the majority of the respondents having a health score of more than 75%, those with a higher pain score recorded a lower quality of life score. The participants who sustained open eye injuries leading to amputation were more prone to high levels of anxiety and depression. Continued health surveillance at the oculo-prosthesis clinic is advised with appropriate referrals to a social worker and or a psychologist/psychiatrist and further on-referrals.
KEY WORDS

Anxiety
Demographics
Depression
Enucleation
Eye amputation
Uveal tissue
Evisceration
General health
Ideal health state
Ocular trauma
Oculo-prosthesis
Open globe injury
Ophthalmology
Quality of life
Self-administered questionnaire
Vision specific
LIST OF ABBREVIATIONS

SASSA  South African Social Services Agency
CSVR  Centre for the Study of Violence and Reconciliation
QOL  Quality of life
EuroQol  European Quality of life group
SF36  Short Form Health Survey, 36 questions
NEI VF25  National Eye Institute 25 item Visual Functioning Questionnaire
EQ5D  European Quality of Life Group 5 item Questionnaire
EQ5D VAS  European Quality of life Group Visual Analogue Scale
IHE  Institute for Health Economics
Qualy  Quality of life adjusted years
TTO  Time Trade Off
NPSS  Negative Physical Self Scale
HADS  Hospital Anxiety and Depression Scale
SF12  Short Form 12 item Questionnaire
PSS  Perceived Stress Scale
WHO/PBD VF 20  World Health Organisation, Prevention of Blindness and Disability Vision Functioning 20 item Questionnaire
DECLARATION

I, Helga Inez Abrahamse-Pillay declare that this Research Report is my own, unaided work. This Research Report is being submitted for the degree of Master of Medicine in the branch of Ophthalmology at the University of the Witwatersrand, Johannesburg. The research report has not been submitted before for any degree or examination at this or any other University.

Name: Helga Inez Abrahamse-Pillay

Date: 22 June 2017

Signed: [Signature]

The Research was conducted at the prosthesis clinic, St John Eye Hospital, Chris Hani Baragwanath Academic Hospital, Soweto, Johannesburg.

Permission to conduct the research was granted by the University of the Witwatersrand Human Research Ethics Committee (Medical) Ref Number: R14/49 (Appendix 1).

Permission was also obtained from the University of the Witwatersrand Post Graduate Committee (Appendix 2) and the Chris Hani Baragwanath Medical Advisory Committee (Appendix 3).
DEDICATION

God has brought me thus far and he will continue to be my light and my guide.

For my husband, Denver Pillay, who supports all my endeavours and encourages me to achieve all my dreams.

For Noah and Anders.

For my parents, Carl and Petra.
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CHAPTER ONE

INTRODUCTION AND BACKGROUND

1.1. Introduction

During registrar training at the University of Cape Town, completing disability grant forms for patients after they had lost an eye due to trauma was commonplace. According to the South African Social Services Agency patients who had only lost one eye (equalling to 25% disability\textsuperscript{1,2}) do not qualify for a disability grant, which was confirmed by a senior official at SASSA Head office (2016, personal communication, August). The researcher pondered various questions regarding, why the patients came, were they working after the injury, and were they experiencing a decrease in overall health and health related quality of life, because of the injury. The motivation for this research was born from these questions. The researcher decided to explore both vision and general health specific quality of life, after the traumatic amputation of the eye.

1.2. Background

Violence is commonplace in South Africa. Crime statistics of South Africa reported 18 673 murders, 18 127 attempted murders, 182 933 assaults with intent to do grievous bodily harm, 14 602 car-jackings, 51 895 rapes and 132 527 robberies with aggravating circumstances in 2016.\textsuperscript{3} Violent crimes are thought to be under-reported because of a lack of faith in the Justice system.
Ocular trauma may occur within the context of violence and violent crime. 1-2% of all trauma is ocular.4,5,6 Of all ocular injuries, 0-2% were open globe injuries,5,6,7 on average, with as high an incidence as 80.4% reported in Egypt.8 Ocular trauma may be severe and is an important cause of preventable visual loss. Schrader5 evaluated the aetiology of open globe injuries at the University of Freiburg and Würzburg hospitals, over an 18-year period. It was revealed that ocular trauma requiring medical intervention occurred in 810 people per 100,000 population per year.5

The outcome of an open globe injury is dependent on the severity of the injury.9 An open globe injury may be treated with primary closure, or amputation of the eye.10 The amputation may be performed either at the time of injury, if warranted by the severity of the injury, or at a later stage due to the development of a painful blind eye.10 Amputation of the eye may be performed either with an evisceration11 or an enucleation.11 Evisceration is a process where the uveal tissue is removed and the sclera is retained. A volume replacement ball or a dermis fat graft is placed in the intraconal space or in the scleral bag. The cornea is usually removed.11 The placement of a hydroxyapatite volume replacement device with or without a peg could also be utilised,12 however it is not used at St John Eye Hospital. Enucleation is the removal of the entire globe after the isolation and removal of the extra ocular muscles. A scleral/mesh wrapped volume replacement ball or a dermis fat graft is placed in the cone and the extra ocular muscles are reattached. The procedure of choice in most countries is an evisceration after ocular penetrating injury, perforated corneal ulcers, painful blind eyes and endophthalmitis.9,11,13 An enucleation is performed for intraocular tumours to prevent extra ocular seeding.4,9,14
Koylu et al. examined the indications for eye removal surgery at a military tertiary referral centre in Tatvan, Turkey\(^9\). Medical records of 123 patients, who underwent eye amputation surgery over a 15-year period, were reviewed. The results revealed that 50% of eye amputations were for trauma and eviscerations were performed. 16% of the patients underwent an eye amputation for malignancy and the procedure chosen for all these cases was enucleation\(^9\). The indications for evisceration, according to Du Toit et al.\(^10\) at Groote Schuur Hospital, a tertiary referral centre in Cape Town, South Africa, was that the patient had to be blind in the eye and able to give consent for the surgery. The injury also had to extend beyond 20mm from the limbus and had to be so extensive that primary closure was not possible. According to Du Toit et al.\(^10\) after primary closure of open globe injuries at Groote Schuur Hospital many patients did not have useful vision in the injured eye, with 80% of the patients documented as being blind at 3 months after primary repair of the open globe injury.\(^10\)

To evaluate the situation in the context of this current study, an audit of eviscerations performed was conducted at the St John eye Hospital, a tertiary ophthalmology referral centre in Soweto, Johannesburg (part of the Chris Hani Baragwanath Academic Hospital) from July 2015 to December 2015. This hospital is the third largest in the world, with approximately 3200 beds. This hospital, not only services a large part of Gauteng, but also acts as a referral centre for the surrounding provinces.\(^15\) The purpose of the audit was to determine the percentage of eye evisceration surgeries performed at the St John Eye Hospital for post traumatic open eye injuries. Of the 52 eviscerations performed during that time, records were available for 42. Of these 32 (76.1%) were for penetrating eye injuries.
After the loss of an eye patients lose their three-dimensional ability and are classified as having a 25% disability.\textsuperscript{1,2} The loss of stereoscopic vision was explained by Dhital et al. in their review of elderly patients, as well as their risk of falling after the loss of vision in one eye. They noted that the loss of stereopsis was the strongest risk factor for multiple falls and when monocular blurring was induced, even climbing stairs and walking was negatively affected.\textsuperscript{16} An adaptation period, where the patients learnt to use visual clues, was included to allow the patients to continue functioning normally. This period varied from one month to one year but was commonly accepted as three months.\textsuperscript{1}

1.3. Quality of Life

Quality of life is defined as the general wellbeing of individuals and societies\textsuperscript{17} with reference to health, family, education, employment, wealth, religion, finance and the environment, including both negative and positive features of life. Health related quality of life refers specifically to the individual's health (for example a disease, disability or disorder).\textsuperscript{15} Vision specific quality of life refers to vision related health (for example a poor quality of life because of developmental abnormalities, refractive errors or diseases including trauma). The quality adjusted life year is a measure of quality of life that is converted into a generic burden of disease measure, which is used to calculate the economic burden of a particular entity, such as a province or the public health sector. This measure includes both quality and quantity of life lived. The Time trade off technique is used to calculate this value.\textsuperscript{18} To calculate the Time trade off value, the patient or control is given a scenario where s/he is told to observe his/her current health state and that s/he will live for 10 years with that health state.
Subsequently the patient is asked if s/he has the ideal health state how many years, therefore s/he will in theory live.\textsuperscript{18}

The Visual Analogue scale\textsuperscript{18} is also used to determine the quality adjusted life years. This is a measurement instrument with representation along a scale. This is a subjective measure and denotes the patients’ view of their health state. Quality of life is evaluated by presenting the patient with a questionnaire that has specific questions related to the axis that is being questioned. There is a set response level, which ranges from the best to the worst health state for that question. A composite health score is calculated by the conversion to a quality adjusted life year score.\textsuperscript{18} The results are either used with controls, a normative data set, or compared with other like studies. In the St John study, the results were compared with like studies (Rofail et al. in Australia\textsuperscript{19}, Schrader in Germany\textsuperscript{5}, Rasmussen et al. in Denmark\textsuperscript{4}, Kondo et al. in Japan\textsuperscript{20}, Ye et al. in China\textsuperscript{21} and Yuksel et al. in Turkey\textsuperscript{7}). A quality adjusted life year score was calculated, using Zimbabwean normative data from the Euroqol group.\textsuperscript{18}

1.4. Problem statement

Patients who undergo an eye amputation after open globe injury have a higher level of anxiety and depression about their vision specific quality of life and a worse general quality of life. Studies conducted by Rasmussen et al.,\textsuperscript{4} Kondo et al.\textsuperscript{20} and Ye et al.\textsuperscript{21} support this statement, with the respondents in the respective studies reporting a statistically significant increase in anxiety and depression with respect to vision specific quality of life and a decrease in general health related quality of life after the procedure.
1.5. Aim of the study

The aim of this current study is to explore the general health and vision related quality of life after open globe injury leading to the amputation of the eye. This aim includes examining a shortened form of vision specific health, by using extracts from the WHO PBD VF20 questionnaire.²²

1.6. Objectives of the study

Specific: The primary objective of this study is to ascertain whether general health related quality of life is affected after open eye injury and the subsequent evisceration of the injured eye. Is vision specific quality of life affected and is there anxiety and depression, related to the injury and amputation?

Measurable: The research will take the form of a questionnaire. The results of the questionnaire may be converted to a score that may be compared with like studies.

Achievable: The objectives are achievable with the use of questionnaires administered at an outpatients clinic.

Results focused: The results of the questionnaire are to be used to identify the need for specific interventions in these patients.

Time bound: There were no time constraints applied to the study.

1.7. Significance of the study

This study examines quality of life in various health districts and socio-economic classes. It also compares the demographic distribution, general quality of life and vision specific quality of life (focusing on anxiety and depression) at St John Eye
Hospital, Johannesburg, with other centres. The researcher wishes to highlight that even though there was not a statistically significant difference in the results, 54.5% of the participants experienced a change in general health quality of life and 49% in vision specific quality of life. It would appear therefore, that the needs of the patients are being underestimated and have to be identified in order to provide them with the necessary support.

1.8. Demarcation of study field

The study was conducted at the Ocular Prosthesis Clinic at St John Eye Hospital, Chris Hani Baragwanath Academic Hospital, during March to June 2016.

1.9. Research design and methodology

A quantitative research design was used. The research design and methodology is further explained in Chapter 3 of this thesis.

1.10. Sampling

The study sample was selected from the prosthesis clinic, using convenience sampling, as only patients with open globe trauma were included in the study.

1.11. Data collection

Data was collected by means of self-administered questionnaires at the oculo-prosthesis clinic at the St John Eye Hospital from March 2016 to June 2016. The questionnaire packs were distributed to the participants, who were requested to
return the completed forms to a collection box, located at the clinic. A more detailed description is presented in Chapter 3.

1.12. Data analysis

Data obtained for this study used SAS with Anova for analyses. A more detailed description is provided in Chapter 3.

1.13. Ethical considerations

Permission to conduct the study was obtained from the University of the Witwatersrand Human Research Ethics Committee (Medical) (Appendix 1), the Postgraduate Committee of the University of the Witwatersrand (Appendix 2) and the Chris Hani Baragwanath Hospital Medical Advisory Committee (Appendix 3).

1.14. Chapter outline

In Chapter 1, the study is defined and an introduction into the conducted research is provided. The background to and the reason for conducting the research are explained. The research problem, aims, objectives, ethical considerations and a brief outline of the research methodology used in this study are also included in this chapter.

In Chapter 2, the literature relevant to this study is reviewed. This includes studies that briefly examine demographic distribution, but more importantly, the quality of life after open eye injury and after eye amputation.
In **Chapter 3**, the research approach and methodology to achieve the aims set out for this study are explored. Details of the study design, sampling method, data collection and analysis method are explained.

In **Chapter 4**, the research findings are presented, as well as a discussion of these findings.

In **Chapter 5**, the summary of the results, a discussion around the significance of these results, the conclusion and recommendations are presented. The limitations of the study are also discussed.

### 1.15. Conclusion

In this Chapter the research is introduced, the background to the study is outlined, and the aims and significance of the study are raised. The study design and research methodology are mentioned.

The following chapter will explore the literature review, focussing on quality of life after open globe injury, as well as after eye amputation.
CHAPTER TWO

LITERATURE REVIEW

2.1. Introduction

In this chapter, the literature relating to vision as well as general health quality of life is reviewed to provide context for this study. The purpose of a literature review is to become familiar with the knowledge base that includes defining the scope of review, identifying the sources of the relevant information, reviewing the relevant literature and conducting a review of this literature. In this study, a literature search included a review of data from books, reviews and journal articles available at the University of the Witwatersrand Health Sciences Library, as well as accredited internet sources, after a google search, in order to gather information on the topic. Both South African and international data were sourced. Local data included an article published by Du Toit et al.10 at a specialist eye centre of a tertiary referral hospital in the Western Cape. The rest of the data were related to international studies; however, the range included both third world and first world experiences.

2.2. Review of demographic data related to open eye injuries

Epidemiological studies conducted in Germany by Schrader et al.;6 in Egypt by Soliman et al.;3 in Malaysia by Paramananda et al.;23 in Cape Town by Du Toit et al.10; and in Italy by Fea et al.;6 revealed a male predominance (an average male: female ratio of 80% to 20%), and the most common age group affected, was 20 to 44 year olds (Germany’s higher range was 20).
2.3. Review of quality of life: Introduction

The literature review investigating open eye injuries were divided into 2 groups. The one being a review of open eye injuries with mainly primary closure and occasionally secondary eye amputation and the second; those aimed specifically at eye amputation following open eye injuries. The quality of life in patients after sustaining either open globe injury or amputation of the eye was evaluated in several studies with conflicting results.

2.4. How was the quality of life evaluated?

The studies that explored quality of life did not use the same evaluation tool. Rasmussen et al.\textsuperscript{4} used the SF36 and the Perceived Stress Scale and compared the results with the Danish Health Interview Survey 2005, all validated questionnaires with specific outcome measures. They also used the EQ5D Visual Analogue Scale (VAS) which is difficult to interpret and is a subjective view of how the respondent felt at that specific time. The VAS scores can be converted to a health economic score, but is best used in conjunction with the EQ5D 5 question general health quality of life questionnaire. Ye et al.\textsuperscript{21} in China used the NEI VFQ 25, Facial Appearance Subscale of the Negative Physical Self Scale as well as the Hospital Anxiety and Depression scale. Kondo et al.\textsuperscript{20} used the NEI VFQ 25 as well as the Medical Outcomes Study Short Form 12, both validated questionnaires, assessing vision and general health as well as the relation between the two. Despite the differences, the results were comparable to each other because the questions put to the participants focused on the same areas. General and vision related quality of life as well as anxiety and depression were assessed. The health-related quality of life scale used most frequently was the SF 36 (health related short form 36 questionnaire). The
most common vision related health score used was the National Eye Institute Visual Functioning questionnaire. Other questionnaires used were the Hospital Anxiety and Depression scale, as well as the Perceived Stress Scale.

The pros for using the vision specific questionnaires are a direct correlation to the loss of vision and its relation to quality of life. The general health questions can be affected by unrelated health issues. The anxiety and depression, as well as the perceived stress scales can also have external factors influencing it. Using them together, with a similar result, means that there is a higher correlation and therefore a higher probability that these in fact are related to the ocular injury. The cons to these questionnaires are that they are long and have many variables that need answering including basic demographic information and more than one questionnaire. It is time consuming to complete.

The fact that there is no standardised questionnaire used by all the studies means that direct comparison is difficult as each questionnaire has its own nuances and grading scales. The studies also have different end-points with some using controls and others using a normative data set as comparison.

2.4.1. EQ5D

The EQ5D health questionnaire is used as a data-collacting tool for general health related questions. The EQ5D was developed by the EuroQoL Group to measure health status. It is a five (5)-question tool developed for easy completion and targets the five (5) main groups of general health related questionnaires. The EQ5D was used in Visual impairment studies in Denmark, Australia, Kenya and Bangladesh. The EQ5D was used in the context of
visual impairment as well as its link to poverty.\textsuperscript{25,26} This validated questionnaire compared well to the SF36 Health Related questionnaire.\textsuperscript{27}

The EQ5D can be converted to a single index health score by using matched normative data from a known healthy population with either a Time Trade off Technique or the Visual Analogue Scale. This information gives a quality of life adjusted years value that can be used to calculate economic cost.

\subsection*{2.4.2. Validation of the EQ5D}

The European Quality of Life (EuroQoL) group was established in 1987. They published the EuroQoL- a new facility for the measurement of health-related quality of life. The EuroQoL Group is a network of international multidisciplinary researchers who focus on health status measurements.

The EQ5D was validated as part of the Swedish Institute of Health Economics (IHE)’s contribution to the EuroQoL Groups work\textsuperscript{18}. The EQ5D was designed as a preference based measure of health.\textsuperscript{28} The descriptive system is based on 3 levels: no problems, some problems or severe problems.

\subsection*{2.4.3. EQ5D VAS}

The VAS represents a visual analogue scale of the patient’s current health state when the questionnaire is completed. It gives a global index of the patients’ health state. The visual analogue scale (VAS) has endpoints labelled ‘best imaginable health state’ and ‘worst imaginable health state’. The patients plot their perceived health state on this scale. The visual analogue scale is a psychometric representation and is a subjective value. The level on the VAS is
the level of agreement with the proposed statement. The VAS is sensitive and reproducible.

2.5. Review of quality of life in patients sustaining open globe injuries

Three of the studies explored quality of life after open globe injury. The studies were conducted in well-developed countries. Schrader et al.\textsuperscript{6} in Germany and Rofail et al.\textsuperscript{19} in Australia did not reveal a statistical significant decrease in quality of life. Both study participants were sampled retrospectively and the file audit spanned more than 10 years. Germany was an 18-year review and Australia, a 12-year review. Germany used medical records as a review and sent postal self-reporting questionnaires to 55 participants, who were of working age. The questionnaire used was their own design which explored work, income and quality of life. This study had a 63.6\% response rate. Rofail used a modified Graves Ophthalmopathy questionnaire that was sent by post to 111 patients, who met their inclusion criteria. Only 47\% responded.

For more detail from each study, Schrader et al. explored the quality of life after open globe injury in Germany, but only as a secondary outcome. This study examined an 18-year retrospective file audit for the nature and distribution of open globe injuries. The results revealed that 31 of 35 participants (88.6\%) maintained the same employment, after the injury. Two patients did not continue working (5.7\%) and two were dismissed (5.7\%). Thirty (30) patients continued with normal hobbies and relaxation activities (85.7\%), while sixteen (16) patients experienced no change in their overall quality of life (45.7\%). Ten (10) patients had a minor decrease in quality of life (28.6\%), while seven (7) patients had a major decrease in quality of life (20\%).
and two (2), a severe decrease in quality of life (5.7%). In summary, the results revealed that, although quality of life was affected, it was only in the minority of patients, whose quality of life was minimally affected.\textsuperscript{5}

In the study of Marc Rofail et al.\textsuperscript{19} in Australia, the quality of life after open globe injury in patients over a 12-year retrospective period using a modified Graves’ Ophthalmopathy score was explored. This study revealed that quality of life was largely unaffected, which concurs with the findings of Schrader et al.\textsuperscript{5} in Germany. Fifty-two (52) patients were contactable for the study (47%). Twenty (20) had been enucleated while thirty-two (32) retained the injured eye. Most of the patients had no difficulty with daily living activities. Most noticed a change in their physical appearance but did not mask it. Their self-confidence was not affected. There was no difference in quality of life between the enucleated and the non-enucleated groups. The patients did not have a significant decrease in their quality of life \textsuperscript{19}. In contrast, the study conducted by Yuksel et al.\textsuperscript{7} in Turkey showed a significant decrease in quality of life, both in the general health and vision specific questions. The parameter that was mostly affected was psychological symptoms\textsuperscript{7}.

Additional detail of the study conducted by Yuksel et al.\textsuperscript{7} recorded that fifty-four (54) patients with open globe injuries were enrolled, as well as twenty-six (26) healthy age and gender matched control subjects. The patients were all aged 18 years and older. This study was prospective, which contrasted with the two (2) previous studies that used patient records and postal self-completing questionnaires. The questionnaires used by Yuksel et al.\textsuperscript{7} employed standardized questions that had specific measurable outcomes. These questionnaires were validated. Both vision
specific quality of life and general health related quality of life was reviewed. The patients included suffered open eye injury at least six months prior to the administration of the questionnaire. They had relevant demographic data recorded and were required to complete the Short Form 36 health related quality of life questionnaire, as well as the National Eye Institute visual functioning questionnaire.

This study revealed that the patients with open globe injury experienced a statistically significant decrease in both the visual functioning and the SF36 questionnaires.7 The questions were well answered except the driving related questions where only 11% answered. The vision specific quality of life scores were significantly lower in the injured group, compared with the control group. The general health related quality of life questions were affected by the final vision, social function and emotional status.

In summary, the three (3) studies reviewing the quality of life after open eye injury had two (2) studies conducted with postal questionnaires using non-standardised questions related to the injury over more than 10 years. These still involved a small number of participants and had a low respondent rate. The third study conducted prospectively, with matched controls, involved patients that were at least 6 months into the clinical course of their treatment. Despite the small number of participants, using the standardized questionnaires, a statistical significant difference was observed between those injured and those used as controls. The participants would have learnt three-dimensional clues at the time of the questionnaire and therefore that bias was eliminated.
2.6. Review of studies exploring quality of life after eye amputation specifically

Eye amputation is a significantly more destructive procedure as the eye is removed, thereby removing all hope of eventually recovering sight in that eye, even if the injury had a poor prognosis at the start. The psychological loss of the limb requires more time to accept the injury and therefore represents a greater likelihood of a decreased quality of life score, both in the general health and the vision specific domains. It is therefore no surprise that the three studies assessing the quality of life after amputation all reveal a statistically significant decrease in at least part of the study. The study conducted by Rofail et al. in Australia also referred to the fact that the study participants would not have opted for primary enucleation\textsuperscript{19}. This is supported by the fact that twenty (20) study participants had enucleations (38.5\%) and could express articulately whether they would have preferred the adjustment period before the amputation of their eye.

The studies conducted by Rasmussen et al. in Denmark\textsuperscript{4} and Ye et al. in China\textsuperscript{21} revealed a decrease in the vision specific axes, with anxiety and depression being the areas that were most affected. Rasmussen et al. noted that patients had a worse quality of life score, if it was associated with an increase in pain.\textsuperscript{4} Ye et al. noted that a worse quality of life score was related to younger age groups and those with higher anxiety levels.\textsuperscript{21} The sampling of the prospective studies conducted by Ye et al. in China and Kondo et al.\textsuperscript{20} in Japan employed convenience sampling of the oculoprosthesis clinic. This model was replicated in this current study.

For additional detail, the study conducted in Denmark by Rasmussen et al. maintained a primary outcome that explored general and vision specific quality of
life. This study was conducted as a follow up to the original study, which explored phantom eye syndrome. The study participants were sent quality of life questionnaires by ordinary mail and had to self-complete the questionnaires. They also assessed stress, job separation and socio-economic standing.

The results revealed that patients with the loss of an eye scored lower than the control population of the Danish health Interview survey 2005, and that those with poor vision in the remaining eye scored even worse. Emotional problems and mental health issues were mostly affected. The differences noted were statistically significant. This is in accordance with the preposition that amputation is a more destructive procedure and the patient therefore takes a longer time to adjust to the loss of the limb.

Anxiety and Depression after having had an enucleation were mostly evident in the study conducted by Ye et al. in China. This study assessed the Quality of life and appearance concerns that were associated with anxiety and depression after the loss of an eye. Trauma was the cause of 62.5% of all enucleations included. The results highlighted that more anxiety was experienced with younger age groups, those with appearance concerns and those with poorer quality of life scores. Despite this, the absolute values still revealed that most patients had normal levels of anxiety and depression (both more than 60% of the total). The patients who had an increased anxiety and depression score had a lower level of education, and those who were infuriated about the loss of their eye, had poorer quality of life scores. These two specific differences were statistically significant. The recommendations were to assess the root-cause levels of depression and anxiety.
before interventions were implemented. Other causes of a statistical difference in patients who had an amputated eye were the loss of peripheral vision and role difficulties. The loss of peripheral vision also speaks to the loss of stereopsis, as discussed previously.\textsuperscript{21}

The Japanese study conducted by Kondo et al., as mentioned previously, was a prospective qualitative study with patients sampled at the oculo-prosthesis clinic. Twenty-nine (29) monocular patients were enrolled and 25 patient escorts were enrolled as the control group. The inclusion criterion was that the vision in the remaining eye was 20/40, or Snellen 6/12 (that is, normal or near normal vision in the remaining eye). These patients reported a lower health score when compared to the control subjects in the role difficulties as well as the peripheral vision questions which were statistically significant. There was no statistical difference between the study group and controls regarding mental health and the NEI VFQ 25 General Health Subset Scores.\textsuperscript{18}

To summarize, of the three (3) studies assessing the amputation of the eye, two (2) studies were prospective, with convenience sampling of patients at the oculo-prosthesis clinic. The third study was a follow on from a previous study assessing quality of life as a secondary outcome by using postal questionnaires. All 3 studies used vision as well as general health related, validated questionnaires with a set response level which are easier to use comparatively even though the questionnaires used were different. All had some aspect of the study that revealed a statistically significant drop in quality of life.
2.7. Summary of quality of life Research Articles

In summary, of all six (6) quality of life studies the physical removal of the eye appears to have a more profound effect on the decrease in quality of life and increase in depression and anxiety levels. All the studies recognised that some patients had a decrease in quality of life, even if the difference was not statistically significant. Both vision specific and general quality of life were affected. Anxiety and depression were negatively affected. Pain was a predictive factor for a decreased quality of life. Younger patients had a lower quality of life score. Loss of three-dimensional vision was not adequately evaluated but loss of peripheral vision and driving was negatively affected.

2.8. Conclusion

In this chapter, the available scientific articles were reviewed, their data collection tools observed and adopted for data collection in this current study as well as the reasons for using them.

In Chapter 3 the research methodology is discussed regarding the fulfilling of the research aims, sampling and analysis of the data.
CHAPTER THREE

RESEARCH METHODOLOGY

3.1. Introduction

In this chapter, an overview of the research methodology that was used to achieve the research aims is presented. The research aims were to assess the general health and vision specific quality of life after open eye injury leading to amputation of that eye. A quantitative research approach was used but standardized general health and vision specific questionnaires were employed with specific end-points.

The participants completed a self-reporting questionnaire (EQ5D- Appendix 4) as well as a demographic sheet with the additional questions specifically related to loss of vision, as an extract from the WHO PBD VF20 questionnaire. Permission to use the EQ5D was obtained from the Euroqol Group (Appendix 5). The participants were not negatively affected if they did not answer the questionnaire. The blank questionnaires were not returned and the completed ones were placed in the box provided in the clinic. The questionnaire was accompanied by a Demographic Detail form (Appendix 6), a Participant Information Sheet (Appendix 7) and a Participant Consent Form (Appendix 8).

The participants’ confidentiality was maintained in the following are ways:

- No identifying data was on the questionnaire, only on the consent form.
- A number was assigned to the consent form and the patient demographic data. These are being kept separately.
Access to the data is restricted, unless requested by the Ethics or Medical Advisory committee.

The information generated in this study will be made available to all the patients attending the prosthesis clinic, whether or not they had participated in the study. The questionnaires will be stored for 2 years if published and 6 years if unpublished in accordance with Health Professionals Council of South Africa regulations.

3.2. Quantitative research

Quantitative research is a method of systematic empiric investigation that employs statistical analysis and is represented in numeric form expressed as percentages.

3.3. Research methodology

3.3.1. Research study design

The study design was a prospective, cross-sectional study of patients receiving treatment at the St John Eye Hospital Prosthesis clinic after open globe injury and subsequent evisceration for severe ocular trauma. The results from this study were compared to the general trends noted in the literature review regarding the aims and objectives.

3.3.2. Study population

The study population were patients attending St John Eye Hospital. According to the University of the Witwatersrand website, four hundred (400) patients are seen at St John each day. These patients drain mostly from the
surrounding areas with a total population of just under 1.3 million according to Census 2011. The patients enrolled in the study were all 18 years of age or older, who attended the ocular prosthesis clinic at the St John Eye Hospital and had had an evisceration for severe open globe injury secondary to trauma. They all consented to participate in answering the questionnaire in this current study. Patients are referred to the ocular prosthesis clinic one to two months after evisceration. This is not standard as patients attend from other facilities and are not necessarily referred within this period. The adaptation period is recorded as at least one month and as such most patients would have had time to adjust to the loss of the eye by the time they are at the ocular prosthesis clinic.

3.3.3. Study sample

Convenience sampling was used. Sample size calculation was done using a 95% confidence interval with an 10% margin of error and 1.3 million as the population size. The 10 % margin of error equates to 90% power to find a decrease in vision and general health with 95% confidence. The sample size was calculated at 97 patients. The patients attending the ocular prosthesis clinics between March and June 2016 and who met the inclusion criteria were enrolled in the study. One hundred and fifty questionnaires were distributed at the clinic. The higher number was to account for questionnaires not completed nor returned. Exclusion criteria were blank questionnaires that were not returned, patients who were under 18 years of age and patients who had lost their eye for other reasons.
3.3.4. Data collection

Data collection was done over a four-month period from March to June 2016. The sister employed at the clinic assisted with the data collection by translating the questions in the patients’ home language. Any questions that arose were immediately answered at the clinic. The same sister assisted in each of the four clinics and was informed of the nature of the study and the questions. The EQ5D is available in local languages but was not used as many languages are spoken and patients were not always literate. English was used as this was the primary communication language with all the patients.

Questionnaire packs with participant information sheets, demographic data and consent forms were handed to patients at the ocular prosthesis clinic and a box was placed at the clinic for the return of forms.

The variables collected were age, gender, vision, income status and vision specific questions regarding anxiety and depression. The EQ5D asked questions about self-care, activities of daily living, pain and general health anxiety and depression.

The questionnaires were numbered and the consent forms were removed from the rest of the pack to ensure anonymity and confidentiality. The participants/respondents’ right to autonomy was respected and participation was voluntary. Written consent ensured that the ethical principles for participation and dissemination of data were given to the patient to read.
3.3.5. Data analysis

Data was collected and organised. The questionnaires of those who did not meet inclusion criteria were removed from the sample. The results were tabulated and converted into numeric values, which were used during statistical analysis (coding of data). The emerging trends were analysed and tabulated to be able to give a visual representation of the trends. Here the data was interpreted.

Analysis Plan:

- Comparing the age and gender of injured patients with reference to trends.
- Determining the effect of the injury on economic independence.
- Comparing vision specific anxiety and depression with gender and age groups.
- Comparing general health questions with gender and age groups.

The above addressed the background variables (age and gender), exposure variable (eye amputation) and outcome variables (EQ5D, Vision and General Health scores).

3.3.6. Scoring the EQ5D

The EuroQol Group designed a scoring system with 243 possible health states, each recorded with a five-digit code. The EQ5D was converted into a single summary health index (appendix 9). The five-digit code, if looked at individually would make sense, but not as a random set of numbers. Therefore, these numbers were converted into a quality-adjusted life year score. The score was one or less than one, as the patients recorded a less than ideal health state with one being a perfect health score. The value recorded is a fraction of 1 and
can be converted into a percentage of the ideal health score. An example of the percentage conversion is \(0.88 = 88\%\) of the ideal health state. This is an effortless way to compare the health state of the respondents. Value sets have been derived for several countries using a Time Trade Off valuation technique. This can be extrapolated to calculate the economic cost of the less than ideal quality-adjusted life years and is used with the calculation of economic data. A scoring to convert to a single health score was done using an excel spreadsheet provided by the EuroQol Group. The TTO conversion for a control population was already completed and the data inserted into the online calculator. There was no South African control. Zimbabwe was the closest match and therefore was used for the calculation. The results using the different variables were presented using tables and graphs and were used to compare with the studies in the literature review.

3.3.7. Scoring the WHO PBD VF20

The scoring of the WHO/PBD VF20 Questionnaire extract included is in the realms of mental well-being, dependency and limitations in social functioning, which speak to depression and anxiety. The scoring was on a 1-5 scale.

3.3.8. Statistical analysis

Data was analysed in SAS Studio Release 3.4, copyright held by SAS Institute Inc., Cary, NC, USA. This software was used to analyse numeric values with one or more variables to ascertain if there was a trend in the results of the patients enrolled in the study. As an initial step, the data set was converted into numeric variables which were analysed for the mean (Proc Means), to assess the distribution of the data within a normal range and to identify any outliers.
The relationships between the variables were analysed (Proc Univariate). Regression analyses for multivariate results were done and a mean comparison with more than one group applied (Procedure GLM, ANOVA analysis technique).\(^{31,32}\) ANOVA was developed by Ronald Fisher in 1918 and is the extension of the \(t\) and the \(z\) test. Factorial ANOVA is robust in that data can be balanced or unbalanced; the same number of subjects could be employed in each group, (balanced) or not (unbalanced). ANOVA is a one-way analysis of variance used to determine if there is a statistical significant difference between the means of three or more unrelated groups.

Specifically, it tests the null hypothesis:

\[
H_0: \mu_1 = \mu_2 = \mu_3 = \cdots = \mu_k
\]

where \(\mu\) = group mean and \(k\) = number of groups. If the one-way ANOVA returns a significant result, we accept the alternative hypothesis \((H_A)\), which implies that there are at least two (2) group means, significantly different from each other. The Chi square and the Kolmogorov- Smirnov goodness of fit tests were applied to determine whether the sample data was consistent with the hypothesized distribution and whether the sample data was within the probability distribution. These tests check the reliability and repeatability of the answers.

### 3.4. Conclusion

In this chapter, the research study design, the study population, sample selection and data collection was presented, as well as the analysis of the data using SAS
with ANOVA for both the EQ5D general health related questionnaire and the extract of the WHO PBD VF20 questionnaire.

The next chapter comprises the results of this current research study regarding the demographics, Who PBD VF20 extract, the EQ5D and VAS.
CHAPTER FOUR

RESULTS

4.1. Introduction

A total of one-hundred-and-fifty (150) questionnaires were distributed at four (4) consecutive ocular prosthesis clinics. There were one-hundred-and-thirty-nine (139) respondents (92.6%). Of these, sixteen (16) were excluded because the loss of vision was not due to trauma (7), being under the age of 18 (8) and a patient completed two (2) questionnaires (1). One-hundred-and-twenty-three (123) participants were eligible to be included in the study. This equates to 82 %, which is a desirable respondent inclusion rate. A 60% or more respondent rate was required.

The participants were enrolled with missing age values based on built in check mechanisms of the questionnaire. The fact that the participant was employed signified that they were at least 16 years of age, according to our countries employment rules. This was supported by the fact that most learners are 17 or 18-years-old when they complete their schooling. One injury occurred at school. This respondent was included because the questionnaire did not specify the period from the injury to the time of consultation at the prosthesis clinic.

4.2. Distributions

The demographic data collected was analysed using the SAS programme to determine percentages of the sample population for comparison with similar variables from the literature review.
4.2.1. Demographic Distribution

The age groups used were based on Erik Erickson’s developmental theories. Erickson has eight (8) developmental stages, however, the three (3) stages relevant to this current study are:

- Early Adulthood 20-39 years - Intimacy vs Isolation
- Adulthood 40-64 years - Generativity vs Stagnation
- Maturity 65+ years - Ego integrity vs Despair

These divisions were useful and correlated to the age groups used in the studies where demographics were explored. These groups represent the different phases in life and focus on romantic love and being young in a career with a learning curve in the 20-39-year age group. The 40-64-year age group is more established in-home life, often with children and more settled in work life with experience and knowledge related to this. The 64+ group is at retirement age and represents the period when the children have left home and a different phase of life.

Table 1 shows the relationship of gender and age concerning the injury. The comparison was done to assess whether there was a correlation between the age and the gender of the patient, regarding the incidence of injuries, as well as whether there was a gender predominance that matched those of the other studies used as controls. The younger patients were predominantly affected with more than 50% of the participants falling into that group. The older age group had the least number of recorded injuries in both gender groups. This question was well answered with 11 missing values across the variables. A
high number of females were enrolled in this study, 41% representing female participants.

Table 1: Age and Gender of Respondents

<table>
<thead>
<tr>
<th>Age</th>
<th>18-39</th>
<th>40-64</th>
<th>64+</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>41(36.6%)</td>
<td>23(20.5%)</td>
<td>2(1.8%)</td>
<td>66(58.9%)</td>
</tr>
<tr>
<td>Female</td>
<td>23(20.5%)</td>
<td>18(16.1%)</td>
<td>5(4.5%)</td>
<td>46(41.1%)</td>
</tr>
<tr>
<td>Total</td>
<td>64(55.2%)</td>
<td>41(36.6%)</td>
<td>7(6.0%)</td>
<td>112</td>
</tr>
</tbody>
</table>

Frequency missing 11

Table 2 reflects the relationship of the injury on work. The questions relating to this were included to assess whether the injury had a direct effect on the patient's ability to earn money and be independent. The fact that the patient was working before and after could suggest that the injury, in fact, did not have an impact on the patients' ability to be economically independent. Where the injury occurred was included as a comparison with the other studies used as controls.

If the patients lost their job after the injury an inference could have been made that the loss of employment was due to the injury and that this could have a more profound effect on negatively affecting the overall quality of life. These questions were poorly answered with fifty-nine (59) of the one-hundred-and-twenty-three (123) patients not answering whether they had work after the injury. Because this question had such a large number of missing values, no conclusions and no inference related to work and injury could be made. The question relating to injury at work only produced 11 missing values; therefore, reflecting that the majority of injuries did not occur at work.
Table 2: Respondents relationship with Work Before, At time of injury and After

<table>
<thead>
<tr>
<th>Response</th>
<th>Work Before</th>
<th>Injury at Work</th>
<th>Work After</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>53 (52.0%)</td>
<td>37 (33.0%)</td>
<td>29 (45.3%)</td>
</tr>
<tr>
<td>No</td>
<td>49 (48.0%)</td>
<td>75 (67.0%)</td>
<td>35 (54.7%)</td>
</tr>
<tr>
<td>Missing Values</td>
<td>21</td>
<td>11</td>
<td>59</td>
</tr>
</tbody>
</table>

The question relevant to visual acuity was not answered by any patients. The patients, most probably, did not understand the question as it was very specific requesting an actual Snellen visual acuity. The later clinics sampled requested the patients to respond if they had poor or good vision in their remaining eye. This was not answered again. This question would have been relevant to assess the quality of life of patients who had poor vision in the remaining eye and whether they had a negative quality life.

4.3. Vision Specific Quality of life

The extract of the WHO PDB VF20 used was the four (4) questions focusing on anxiety and depression related to the loss of vision in one eye. The first question addressed the impact that the loss of sight had on the patient’s ability to interact with other people on a social level. This question related to how the participants felt concerning how other people responded to them after they lost their eye and whether they were ostracised because of their injury. The majority of participants responded that they never had problems with social interactions (46.3%, see Figure 1). Despite the fact that 46.3% of participants felt that they never had problems after the eye injury, there was a decrease in the overall quality of life with a worsening in the 64 and over age group, however, this was not statistically significant with a p-
value of 0.915. The female patients had a slightly lower overall quality of life score (see Figure 2).

Figure 1: Bar Graph illustrating Hesitation to participate in Social Functions

Figure 2: Interaction plot for hesitation to participate in social functions
The second question pertained to the feeling of shame and embarrassment because of the loss of vision, in this case, because of the amputation. This question follows from the previous question and again speaks to how the patient responds to how they think people will perceive them. This likely spoke to the patients’ feelings that they look disfigured or ugly and would be ridiculed by others. The trends were the same for this question with most patients reporting that they never had any feelings of being ashamed or embarrassed (47.9%). There was one missing value in this question (see Figure 3). The age trends were that the group 18-39 years of age had the worst health state with those who were 64 years old and older faring slightly better. The p-value was 0.4, which was not significant. The males had a slightly worse health state (see Figure 4).

![Distribution of Shame](image-url)

**Figure 3: Bar Graph for feeling embarrassed or ashamed after loss of vision**
The third question addressed the feeling of being a burden on others because of the loss of vision in the eye. The loss of the eye could have meant the loss of financial independence after the loss of employment. This correlation could not be made because of the poorly answered work-related questions. The question still speaks to both financial and emotional burden to others, as the injury affected change in the patients’ life. The trend again was the same with most patients reporting that they never had any feelings of being a burden because of the loss of the eye (56.9%). Only four (4) values were missing in this subset which represents 3.2% of the sample size of 123 participants (see Figure 5). The trend observed was that the quality of life scores improved with age. Here females had a lower score than males which was also not significant (p-value 0.22, see Figure 6).

Figure 4: Interaction plot for feeling embarrassed or ashamed after loss of vision.
Figure 5: Bar graph to feeling as if you are a burden after loss of an eye

Figure 6: Interaction plot as to feeling a burden after loss of an eye
The last of the questions from the WHO PBD VF20 extract addressed the fact that patients worried about losing sight in their remaining eye. This spoke to the implication of being totally blind and suddenly totally dependent of other people; the blindness being a very scary reality where you could not see colour, daytime or the people you loved and cared about. The trend was the same with the majority of patients responding that they never had any problems with worrying about losing the vision in their remaining eye (52.8%). This subset had three (3) missing values (see Figure 7). The 18-39-year age group had a lower quality of life score and improved in the 40-64-year age group. The 64-year and over age group again had a slight worsening of their quality of life scores. The males had a lower health score which was not statistically significant (p-value 0.489, see Figure 8).

**Figure 7: Bar graph for worrying about loss of sight in the remaining eye**
4.4. General Quality of life adjusted score

The last component of the Quality of life questionnaire was the EQ5D component. This was a composite number derived from the answers of the five (5) questions asked. These questions addressed mobility, self-care, usual activities of daily living, pain or discomfort experienced and anxiety and depression. Each answer had three (3) levels with examples of tasks from no problem to extreme difficulty. The answers of all the questions combined provided a composite health score that was converted into a quality of adjusted life year score. This was a global general health assessment of each individual. This health index has been used to calculate economic data in other areas.
The Time Trade off Technique used Zimbabwe normative data as none was available for South Africa. This was the closest match to similar populations. The Visual Analogue scale was asked but was not used as a reasonable comparison of data could not be made. The results of the Visual analogue scale are presented in Table 3 where most the patients reported a more than 75% health state. The VAS is a slice in time and represents the patients’ health state at the time of completing the questionnaire. The TTO is derived from the answers of five (5) questions, which represents a composite score. Of the Quality of life adjusted scores calculated there were 18 missing values. If a single question of the five (5) sub-groups was omitted, the quality-of-life-years calculation became incorrect. This explained why the missing values were so high, as one hundred and five participants (85.3%) were included in this study. Fifty-five (52.3%) patients had an ideal health state. Three patients (2.9%) had a health state lower than 50%. The 3 participants that had a decrease in quality of life adjusted years, below 50%, all had high pain scores. In total, 88 patients (83.8%) reported an overall health state of more than 75%. The 40-64-year age group had the best health state (mean 0.89), followed by the 18-39-year age group (mean 0.88), and lastly the 64-year and over age group (mean 0.84). The results were in keeping with the burden of disease of the younger age group, with more than 50% in that group. Surprisingly, the 64+ age group had the lowest health score. The differences were minimal (see Table 4). Regarding gender distributions, males had a marginally lower quality of life adjusted score with a mean of 0.87, compared to their female counterparts (mean 0.91, see Figure 9). The p-value was 0.19. The male participants consistently had a lower score than females in all 3 age groups. The p-value was 0.48 (see Figure 10).
Table 3: Comparison table of Quality of life regarding the Time Trade off technique and the Visual Analogue Scale, as well as assessing Gender distributions

<table>
<thead>
<tr>
<th></th>
<th>TTO 18-39</th>
<th>TTO 40-64</th>
<th>TTO 64+</th>
<th>VAS 18-39</th>
<th>VAS 40-64</th>
<th>VAS 64+</th>
<th>Male  VAS</th>
<th>Male  TTO</th>
<th>Female  VAS</th>
<th>Female  TTO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ideal</td>
<td>28</td>
<td>22</td>
<td>4</td>
<td>9</td>
<td>2</td>
<td>2</td>
<td>4</td>
<td>28</td>
<td>4</td>
<td>24</td>
</tr>
<tr>
<td>&gt;75%</td>
<td>18</td>
<td>10</td>
<td>1</td>
<td>41</td>
<td>29</td>
<td>3</td>
<td>42</td>
<td>19</td>
<td>29</td>
<td>8</td>
</tr>
<tr>
<td>50-75</td>
<td>11</td>
<td>3</td>
<td>/</td>
<td>14</td>
<td>12</td>
<td>1</td>
<td>16</td>
<td>9</td>
<td>12</td>
<td>4</td>
</tr>
<tr>
<td>&lt;50%</td>
<td>/</td>
<td>2</td>
<td>1</td>
<td>/</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Missing</td>
<td>21</td>
<td>/</td>
<td></td>
<td>7</td>
<td>/</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

N=patient numbers. Note: some respondents did not include age or gender and thus these totals differ slightly from the ones mentioned above as all the data entered in the TTO section was used in analysis.

Table 4: The mean of EQ5D Quality of life Adjusted years according to age

<table>
<thead>
<tr>
<th>Age</th>
<th>Quality of life adjusted years/Zim</th>
</tr>
</thead>
<tbody>
<tr>
<td>18-39</td>
<td>0.880</td>
</tr>
<tr>
<td>40-64</td>
<td>0.889</td>
</tr>
<tr>
<td>64+</td>
<td>0.847</td>
</tr>
</tbody>
</table>
Figure 9: Quality of life adjusted years scores divided by gender

Figure 10: Interaction plot of age and gender using Quality of life scores
4.5. Conclusion

The results of the data collection for this current research study were presented as relevant groups with demographic data – the results of the WHO PBD VF20 vision specific quality of life questionnaire extract and its relevance as well as the EQ5D general health quality of life questionnaire and the EQ5D VAS.

The final chapter follows, in which the relevance of these results, its significance relative to other studies, the conclusion and the limitations of this study are discussed.
CHAPTER FIVE

DISCUSSION

5.1. Introduction

The loss of an eye is a traumatic event and is equated to losing a limb. The magnitude of the injury is often underestimated with both the appearance and confidence of the person being compromised. The person, therefore, should have an increase in anxiety and depression and a decrease in quality of life. The results of this study support the increase in anxiety and depression and a decrease in quality of life but the deviation from an ideal health state is not statistically significant.

5.2. Respondent rate

The respondent rate of the participants was good. The prospective nature of the study allowed an adaptation period after the loss of the eye for the patients to learn three-dimensional clues. Once these clues had been learnt, a better reflection of the patients’ disability could be gleaned, as well as a more accurate reflection of the patients’ quality of life.

In general, the questions were well answered by the patients. The missing values on the questionnaire could be due to some patients not being fluent in English as a first language, even though English is taught at schools as a first or a second language in South Africa. The questionnaires might have been too long, even with only part of the WHO PBD V20 questionnaire being used, along with a five-question quality of
life questionnaire. It could be that the questions were not explained adequately, even with appropriate staff being available to answer questions and do translations.

The question regarding vision in the remaining eye was not answered at all despite a modification of this question after the first prosthesis clinic. The omission of this answer means that no correlation between poor vision and a poor quality of life could be made. This would have been a useful comparison. Another poorly answered question was work in relation to the injury. The majority of patients said that they were not injured at work, which did little to influence the effect the loss of the eye had on their work as 21 respondents did not state whether they were employed before the accident and 59 (47.9%) did not communicate whether they were employed after the accident.

5.3. Demographics

The demographics at St John Eye Hospital differ on gender incidence, compared to the studies assessed in the literature review.\textsuperscript{5,6,8,10,23} The studies that were used as comparisons have an average 80% male predominance. This current study has a 40% female inclusion. This could be sampling bias; however, the reason for this discrepancy can only be speculated on and requires further research. Some ideas that have been proposed were explored by Setlalentoa et al.\textsuperscript{34} in their study on social aspects of alcohol misuse/abuse in South Africa where women were considered part of the high-risk drinkers. Thirty per cent of these women were aged between 15 and 24 years. Another cause proposed for the high number of women in our study is gender-based violence\textsuperscript{35}. Dunkle et al. in their study on Prevalence and patterns of gender-based violence in ante natal clinics in Soweto stated that 30.1% of their study
participants reported having been physically or sexually assaulted by a male partner in the preceding year, with 55.5% having been assaulted at least once in their lives. The high incidence of alcohol abuse and gender-based violence could be the reason for the high number of women enrolled in this current study.

Despite external factors leading to high violence rates and trauma leading to eye amputation, this current study population reported a high percentage of the participants maintaining a near ideal health state. This was explored in both the vision specific and general quality of life questions.

5.4. Vision specific quality of life

The vision specific quality of life scores addressed mainly issues of anxiety and depression. These domains were shown to be significantly involved in other studies. About half of patients did not experience a drop in any of the vision specific questions asked, with an average of 51.0% across all the questions. This figure should not be the only focus as the remaining 49%, who experienced a drop in vision specific quality of life, should be explored. The answers reflected that even if the respondents did not always have problems, their lives, in fact, were impacted by the loss of the eye. These questions had very few missing values and therefore represented a true reflection of the patients’ vision specific quality of life. Despite this drop, there was not a significant statistical difference and would probably require a larger sample size to determine this.

The females had a lower health score in the areas of hesitation to participate in social functions (probably due to altered appearance), as well as the feeling that they
were a burden after the loss of the eye. These differences probably need further research that addresses them specifically. The same is true for the males in the remaining two questions, where they felt more shame and embarrassment as well as fear of losing the remaining eye.

The quality of life trend was to decrease as age increases for the questions related to feelings of shame and embarrassment as well as the feeling of being a burden to others. As age progresses, the more likely individuals are prone to depend on others, as the pension grant may not be enough for sustain the individual. The anxiety associated with this could lead to a lower quality of life score. However, the youngest age group had the lowest quality of life score concerning the hesitation of participating in social functions, which could be because young people frequent social events, meet potential life partners and are self-aware of their appearance. This phenomenon also requires further research for substantiations, as currently, it is speculatory.

5.5. EQ5D converted into single health index

Despite the fact that the participants had eye amputation surgery, the majority of patients (83.8%) had a quality of life adjusted years above 75% per cent. Forty-seven percent had a decrease in health state, but this was not statistically significant. The percentage does make up a substantial portion of the total. The above results are reassuring with 83.8% reporting a quality of life of more than 75%, considering that the participants of the studies where eye amputations were performed (Denmark, Japan and China\textsuperscript{4,20,21}) all had statistically significant decreases in quality of life. The participants, who reported a poor quality of life, also reported a high pain
score. The concurrence of pain needs to be evaluated further, while the specific isolation and treatment of pain needs to be explored, to improve the overall quality of life. In our study, pain, in fact, was related to a lower quality of life score. Despite the correlation of pain, no other correlation could be made between gender and age, as the differences between the groups were very minimal, judging by the mean values, and were not statistically significant.

The fact that the studies reviewed in the literature review where eye amputations were primarily performed had a statistically significant decrease in quality of life, has led to advocacy that traumatic open eye injuries are primarily closed, and that evisceration be performed as a secondary procedure. The study by Rofail et al.\textsuperscript{19}, as a recommendation, included that open eye injuries should primarily be closed to allow the patient to come to terms with the loss of the eye and only as a secondary procedure, to have their eye removed\textsuperscript{19}. This may not be financially feasible in the St John Eye Hospital context because of the high burden of disease in the South African context with as many as 70\% of households accessing the public health system\textsuperscript{36}. Although the reference is more than 5 years old, the distribution of health facilities accessed remains the same. In light of the high burden of disease on the public health system; with elective lists often having more than a one year waiting time and little space on the emergency lists to accommodate more than just the urgent trauma cases, as well as more than 80\% of patients having a health state of more than 75\%, it is justifiable for St John Eye Hospital to perform primary eviscerations on open eye injuries, which have been severely injured within reasonable criteria, as suggested by Du Toit et al\textsuperscript{10}. 
5.6. The limitations of the study

There were no questions that specifically addressed stereopsis or binocularity, which could have a marked impact on the employment of the patients. Their quality of life could also be affected, especially if they needed these for work, namely public drivers, those working at heights or on building sites, as well as those working underground in mines. The vision in the remaining eye of the patients was not documented, although it was included in the questions. The question was probably too specific, and not broad enough, just to comment whether they experienced good or bad vision. As such, a useful part of the analyses was not executed. The comparison of the quality of life scores, regarding good versus poor vision, therefore also, was not executed.

5.7. Conclusion

Primary evisceration in severe ocular trauma is justified at the St John Eye Hospital, due to the high burden of disease in the public health sector, in light of the long waiting lists and difficulty to accommodate more than urgent trauma cases. Patients, who have a high pain-score after the amputation of an eye, must have the pain attended to, as a high pain-score is associated with a low quality of life score. The cause of the pain needs to be identified and treated accordingly. Despite the patients in this current study having a high overall quality of life score (83.8%) in general health questions, they are at risk of suffering high anxiety and depression levels, as only 51% of participants reported an ideal vision specific health state. The individual patient must be assessed and referred for appropriate intervention to the psychology or psychiatry departments. A possible solution would be to continue the health assessment questionnaires at the oculo-prosthesis clinic and to have a social worker
and psychologist in attendance at the clinic to assess the patients who require further intervention. The increased numbers would also induce statistical significance and augment the study to reveal a true reflection of the quality of life of patients.
REFERENCES


https://www.crimestatssa.com/national.php


APPENDICES

Appendix 1: Human Research Ethics Committee Clearance Certificate

R14/49 Dr Helga Abrahamse-Pillay

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
CLEARANCE CERTIFICATE NO. M151127

NAME: Dr Helga Abrahamse-Pillay
(Principal Investigator)

DEPARTMENT: Ophthalmology
St John Eye Hospital
Chris Hani Baragwanath Academic Hospital

PROJECT TITLE: Quality of Life After Open Globe Injury

DATE CONSIDERED: 27/11/2015

DECISION: Approved unconditionally

CONDITIONS:

SUPERVISOR: Dr Susan Williams

APPROVED BY: Professor P Cleaton-Jones, Chairperson, HREC (Medical)

DATE OF APPROVAL: 27/01/2016

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS
To be completed in duplicate and ONE COPY returned to the Research Office Secretary in Room 10004, 10th floor, Senate House/2nd Floor, Phillip Tobias Building, Parktown, University of the Witwatersrand.
I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. I agree to submit a yearly progress report.

Principal Investigator Signature Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES
Appendix 2: Approval of Title

Dr Hi Abrahamse-Pillay
3 Rose Place
Glenwaba
Johannesburg
2091
South Africa

Dear Dr Abrahamse-Pillay

Master of Medicine: Approval of Title

We have pleasure in advising that your proposal entitled Quality of life after open globe injury has been approved. Please note that any amendments to this title have to be endorsed by the Faculty's higher degrees committee and formally approved.

Yours sincerely

[Signature]

Mrs Sandra Benn
Faculty Registrar
Faculty of Health Sciences
Appendix 3: Medical Advisory Committee permission

MEDICAL ADVISORY COMMITTEE
CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL

PERMISSION TO CONDUCT RESEARCH

Date: 12 October 2015

TITLE OF PROJECT: Quality of life after open globe injury

UNIVERSITY: Witwatersrand

Principal Investigator: H Abrahamse-Pillay

Department: Ophthalmology

Supervisor (If relevant): S Williams

Permission Head Department (where research conducted): Yes

Date of start of proposed study: October 2015
Date of completion of data collection: December 2017

The Medical Advisory Committee recommends that the said research be conducted at Chris Hani Baragwanath Hospital. The CEO/management of Chris Hani Baragwanath Hospital is accordingly informed and the study is subject to:-

- Permission having been granted by the Human Research Ethics Committee of the University of the Witwatersrand.
- the Hospital will not incur extra costs as a result of the research being conducted on its patients within the Hospital
- the MAC will be informed of any serious adverse events as soon as they occur
- permission is granted for the duration of the Ethics Committee approval.

Recommended
(On behalf of the MAC)
Date: 12 October 2015

Approved/Not Approved
Hospital Management
Date: [Signature]
Appendix 4: EQ5D Questionnaire

Health Questionnaire

English version for South Africa
**EQ5D Questionnaire**: By placing a tick in one box in each group below, please indicate which statements best describe your own state of health TODAY.

<table>
<thead>
<tr>
<th>Mobility</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>I have no problems in walking about</td>
<td></td>
</tr>
<tr>
<td>I have some problems in walking about</td>
<td></td>
</tr>
<tr>
<td>I am confined to bed</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Self-Care</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>I have no problems with self-care</td>
<td></td>
</tr>
<tr>
<td>I have some problems washing or dressing myself</td>
<td></td>
</tr>
<tr>
<td>I am unable to wash or dress myself</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Usual Activities <em>(e.g. work, study, housework, family or leisure activities)</em></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>I have no problems with performing my usual activities</td>
<td></td>
</tr>
<tr>
<td>I have some problems with performing my usual activities</td>
<td></td>
</tr>
<tr>
<td>I am unable to perform my usual activities</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pain / Discomfort</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>I have no pain or discomfort</td>
<td></td>
</tr>
<tr>
<td>I have moderate pain or discomfort</td>
<td></td>
</tr>
<tr>
<td>I have extreme pain or discomfort</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Anxiety / Depression</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>I am not anxious or depressed</td>
<td></td>
</tr>
<tr>
<td>I am moderately anxious or depressed</td>
<td></td>
</tr>
<tr>
<td>I am extremely anxious or depressed</td>
<td></td>
</tr>
</tbody>
</table>
To help people say how good or bad their state of health is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale, in your opinion, how good or bad your own health is today. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your state of health is today.

Your own state of health today
Appendix 5: EuroQol Permission

Dear Ms/Mr. Abrahamse-Pillay,

Thank you for registering your research at the EuroQol Group Foundation's website.

As the study you registered involves low patient numbers (150) you may use the EQ-5D-3L instrument (Paper version) free of charge. Please note that separate permission is required if any of the following is applicable:

- Funded by a pharmaceutical company, medical device manufacturer or other profit-making stakeholder;
- Number of respondents ≥ 5000
- Routine Outcome Measurement;
- Developing or maintaining a Registry;
- Digital representations (e.g. PDA, Tablet or Web)

Please find attached the requested EQ-5D-3L versions (word format). A brief user guide is downloadable from the EuroQol website (www.euroqol.org).

Best regards,

Mandy van Reenen
Communications Specialist
EuroQol Research Foundation
Appendix 6: Demographic Data Sheet

**TITLE: QUALITY OF LIFE AFTER OPEN GLOBE INJURY 2015-2017**

Participant Demographic Data:

1. **AGE**
   - 18-39
   - 40-64
   - 65 +

2. **GENDER**
   - Male
   - Female

3. **WORKING**
   - Prior to Accident
     - YES
     - NO
   - Currently
     - YES
     - NO
   - Did the Injury Happen at Work
     - YES
     - NO
   - If NO, where did injury occur?

4. **VISION IN REMAINING EYE**
   - Unaided
   - Pinhole

5. Please tick the correct answer.
   1. Because of your eyesight, how often have you been hesitant to participate in social functions?
      - 1 Never
      - 2 Rarely
      - 3 Sometimes
      - 4 Often
      - 5 Very often
   2. Because of your eyesight, how often have you found that you are ashamed or embarrassed?
      - 1 Never
      - 2 Rarely
      - 3 Sometimes
      - 4 Often
      - 5 Very often
   3. Because of your eyesight, how often have you felt that you are a burden on others?
      - 1 Never
      - 2 Rarely
      - 3 Sometimes
      - 4 Often
      - 5 Very often
   4. Because of your eyesight, how often do you worry that you may lose your remaining eyesight?
      - 1 Never
      - 2 Rarely
      - 3 Sometimes
      - 4 Often
      - 5 Very often
Appendix 7: Participant Information Sheet

**STUDY**: QUALITY OF LIFE AFTER OPEN GLOBE INJURY

**YEAR**: 2015-17

**PARTICIPANT INFORMATION SHEET**

Good day. I am Dr Helga Abrahamse-Pillay. I am currently working at St John’s Eye Hospital, Chris Hani Baragwanath Academic Hospital, as a Specialist Ophthalmologist.

I am doing research on how your life changes after having lost useful vision in your eye. Research is a way to find answers to questions. In this study, I want to find out if your life (personal, work and social) has changed after your injury. I will be asking if your work situation, friends, state of well-being and independence has changed since your injury.

I am inviting you to take part in this research study? You must be over 18 years old and have sustained a severe eye injury where your eye was open.

If you would like to be part of the study, you will be given a questionnaire to answer yourself in your own time. I will be asking 150 people, like you, that attend the ocular prosthesis clinic at St John Eye Hospital to fill in the questionnaire. The questionnaire should take you 5 minutes to answer.

There is no risk to you. Your information will be kept private. Only the doctors involved in the study will know it. We will give you a number to ensure your privacy so that nobody will know the answers you give to the questions but we can use the information to understand how losing an eye affects people like you.

The study may show us that people who have had severe eye injuries need further help. This could possibly be to be assisted by the occupational therapy department, the social work department or the psychology/psychiatry department. If this is the case, we may contact you.

You do not need to be part of this study unless you would like to be. We will tell you about the study and ask you to participate in a private area of the clinic. This is where you can give us your written permission to be a part of the study. If you decide not to join the study, you will not be disadvantaged or penalised. You may also decide not to be part of the study at any time even after you have filled out the questionnaire, we will take out and destroy your questionnaire and we will not use it. If you do not want to participate, you can leave the blank form in the box/basket provided.

You will not need to pay for anything. The questionnaire will be given to you at your usual clinic visit.

Your information will be kept confidentially. No names will be recorded on the demographic data. Your name and signature will be used for the consent. The data will be coded. Absolute confidentiality cannot be guaranteed. Personal information may be disclosed if required by law. The Wits Human Research Ethics Committee and the Chris Hani Baragwanath Academic Hospital Medical Advisory Committee may inspect and/ or copy the results for quality assurance and data analysis. If the research is published, the hospital and clinic used for sampling will be recorded. No individual names will be mentioned.

If the data is published, the results will be saved for 2 years. If it is not published, the results will be saved for 6 years. This is in accordance with the Health Professionals Council of South Africa.

Once you have completed the questionnaire, please place the sheets in the basket/ box provided or hand them to myself (Dr Helga Abrahamse-Pillay) in the clinic.

For Queries Please Contact:

<table>
<thead>
<tr>
<th>Role</th>
<th>Name</th>
<th>Contact Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Researcher</td>
<td>Dr H Abrahamse-Pillay</td>
<td>081 894 2390/ 011 933 8774</td>
</tr>
<tr>
<td>Supervisor</td>
<td>Dr S Williams</td>
<td>011 717 2549</td>
</tr>
<tr>
<td>HREC: Chairperson</td>
<td>Prof P Cleaton Jones</td>
<td>011 717 2301</td>
</tr>
<tr>
<td>HREC: Administrator</td>
<td>Ms Z Ndlovu</td>
<td>011 717 2700</td>
</tr>
</tbody>
</table>
Appendix 8: Consent Form

TITLE: QUALITY OF LIFE AFTER OPEN GLOBE INJURY

YEAR: 2015-2017

CONSENT FORM: Use of clinical information for research purposes.

Dear Participant, you are currently attending the ocular prosthesis clinic at St John’s Eye Hospital, Chris Hani Baragwanath Academic Hospital after the loss of your eye. St John’s Eye Hospital provides treatment but also conducts research to improve the quality of care rendered. St John’s Eye Hospital will collect information from patients to aid in this regard.

The use of the information is subject to approval from Wits Human Research Ethics Committee and The Medicines Advisory Committee for Chris Hani Baragwanath Academic Hospital. The participant’s identity is not revealed unless specific consent is obtained, or required by law.

While we may not need all the information currently, we may need it in the future. Do we have permission to use the information at a later stage, if needed? This is subject to the approval by the above mentioned Committees.

If you do not wish to participate, you will not be adversely affected. If you withdraw consent at any time, you will not be adversely affected.

You will be contacted if any new benefits become available as a result of the research.

If you wish to contact the researcher at any stage, please contact Dr Helga Abrahamse-Pillay at cell phone number 081 894 2390 or St John’s Eye Hospital on 011 933 8774.

A. Consent Given

I___________________________________ hereby give consent for my information to be used as per the above mentioned conditions for the purposes of research:

PATIENT: _____________________ DATE: _____________________
Appendix 9: Health Index Calculator

**EQ-5D index calculator**

This model estimates the EQ-5D index score for a given health state defined by the user. Index scores are based on general population valuation surveys that used TTO or VAS methods in various countries as presented in the book: Szende, Opper, Devin (eds.), EQ-5D Value Sets: inventory, comparative review, and users guide.

**Please enter health state description:**

- Mobility: 3
- Self-care: 3
- Usual activities: 3
- Pain/Discomfort: 3
- Anxiety/Discomfort: 3

**Select country/survey of interest:**

- **Zimbabwe**
  - **TTO Score**: -0.145
  - **VAS Score**: Not available

**Results for all countries/surveys:**

<table>
<thead>
<tr>
<th>Country</th>
<th>TTO Score</th>
<th>VAS Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Belgium</td>
<td>Not available</td>
<td>-0.158</td>
</tr>
<tr>
<td>Denmark</td>
<td>-0.624</td>
<td>-0.187</td>
</tr>
<tr>
<td>Finland</td>
<td>Not available</td>
<td>-0.011</td>
</tr>
<tr>
<td>Germany</td>
<td>-0.207</td>
<td>0.021</td>
</tr>
<tr>
<td>Japan</td>
<td>-0.111</td>
<td>Not available</td>
</tr>
<tr>
<td>Netherlands</td>
<td>-0.329</td>
<td>Not available</td>
</tr>
<tr>
<td>New Zealand</td>
<td>Not available</td>
<td>-0.085</td>
</tr>
<tr>
<td>Slovenia</td>
<td>Not available</td>
<td>-0.242</td>
</tr>
<tr>
<td>Spain</td>
<td>-0.664</td>
<td>-0.076</td>
</tr>
<tr>
<td>UK</td>
<td>-0.594</td>
<td>-0.073</td>
</tr>
<tr>
<td>USA</td>
<td>-0.109</td>
<td>Not available</td>
</tr>
<tr>
<td>Zimbabwe</td>
<td>-0.145</td>
<td>Not available</td>
</tr>
<tr>
<td>Europe</td>
<td>Not available</td>
<td>-0.074</td>
</tr>
</tbody>
</table>
Appendix 10: Title change letter

Dear Dr Abrahamse-Pillay

Master of Medicine: Change of title of research

I am pleased to inform you that the following change in the title of your Research Report for the degree of Master of Medicine has been approved:

From: Quality of life after open globe injury
To: Quality of life after open globe injury leading to amputation of the eye

Yours sincerely

[Signature]

Mrs Sandra Benn
Faculty Registrar
Faculty of Health Sciences
Appendix 11: Editorial Certificate

27 March 2017

To whom it may concern

Dear Sir/Madam

RE: Editorial Certificate

This letter serves to prove that the thesis listed below was language edited for proper English, grammar, punctuation, spelling, as well as overall layout and style by myself, publisher/proprietor of Aquarian Publications, a native English speaking editor.

Thesis title
QUALITY OF LIFE AFTER OPEN GLOBE INJURY LEADING TO AMPUTATION OF THE EYE

Author
Helga I. Abrahamse-Pillay

The research content, or the author’s intentions, were not altered in any way during the editing process. However, the author has the authority to accept or reject my suggestions and changes.

Should you have any questions or concerns about this edited document, I can be contacted at the listed telephone and fax numbers or e-mail addresses.

Yours truly

[Signature]

E H Lendt
Publisher/Proprietor
Appendix 12: Turnitin report

CHAPTER ONE

INTRODUCTION AND BACKGROUND

1.1. Introduction

During registrar training, at the University of Cape Town, completing disability grant forms for patients, after they had lost one eye, due to trauma, was commonplace. According to the South African Social Services Agency, patients, who had only lost one eye (equaling to 25% disability15), do not qualify for a disability grant, which was confirmed by a senior official at SASSA Head office (2016, personal communication, August). The researcher pondered various questions regarding why the patients came, were they working after the injury, and were they experiencing a decrease in overall and health related quality of life, because of the injury. The motivation for this research was born from these questions. The researcher decided to explore both vision and general health specific quality of life, after the traumatic amputation of the eye. 1.2. Background literature is commonplace in South Africa, for example, in 1990 the

Centre for the Study of Violence and Reconciliation (CSVR),

3 reported that homicide occurred at a rate of 1 in 100 000, compared to 1 in 100 000 in the United Kingdom

for the same period. The South African Police Service reported about 20 000

murders, 28 555 attempted murders, 12 800 car-jagings, 58 401 rapes and 20 333 child sex crimes.