

https://dspace.org/

Satisfaction in ocular prosthesis wearers: a comparison between stock eyes and custom eyes at the artificial eye centre, Krugersdorp

Gnanapragasam, U. D.

2020
https://hdl.handle.net/10539/29977

Downloaded from a DSpace repository. https://dspace.org/

Satisfaction in Ocular Prosthesis Wearers: A Comparison Between Stock Eyes and Custom Eyes at the Artificial Eye Centre, Krugersdorp

Dr U. D Gnanapragasam

9700343F

Supervisor: Dr S. E. I Williams

A Research Report Submitted to the Faculty of Health Sciences, at the University of the Witwatersrand, Johannesburg, in Partial Fulfillment of the Requirements for the Degree of Master of Medicine in Ophthalmology

November 2019

Dedication

I dedicate this research report to God Almighty, my Creator, my strong pillar, my source of wisdom, knowledge and understanding. He has been the source of my strength throughout this project, and on His wings I soared.

I also dedicate this work to my wife Sudarshini, who has encouraged me all the way. Her encouragement has ensured that I give it my all to see to it that I finish what I started. My mother has been a pillar of strength in my studies since childhood. Dear mom, thank you for your love, prayers and resilience as I faced an avalanche of challenges during the course of my studies. To my daughter Amritha Abigail, who has been affected in every way possible by this quest. Thank you. My love for you all can never be quantified. God Bless you.

Abstract

Purpose: The study is about understanding the level of satisfaction, quality of life and complications experienced by people wearing either custom or stock eyes. It is also aimed at determining which variables were correlated to their level of satisfaction and if visible amputation of an eye is associated with a wide range of psychosocial stressors. It was motivated by the fact that the problems encountered by ocular prosthesis wearers with eye conditions are under-reported in Africa. Thus, the study also sought to establish the extent and type of psychosocial stressors and complications experienced by these two types of prosthesis wearers.

Setting: Artificial Eye Centre, Krugersdorp, Johannesburg, South Africa.

Methods: The study was a cross-sectional, descriptive study, using a questionnaire to gather information on patients who had destructive eye surgeries, including evisceration and enucleation, and who were wearing artificial eyes.

Results: There were 104 participants in this study with majority (57.3%) of them being men. About two thirds of the respondents (66.3%) were less than 40 years of age. The participants who were wearing custom eyes were 53 in total (55%) and those who had stock eyes were 51 in total (53%). Custom eye wearers were older than the stock eye wearers. Mean scores for psychological adjustment were within the normal range for both custom and stock eye-wearers. More of the custom eye-wearers felt their facial appearance had greatly improved compared to the stock eye wearers (99% versus 78%). Likewise, the custom eye-wearers had a higher percentage (53%) of face appearance satisfaction in contrast to the stock eye wearers (14%). Ocular discharge was a frequent complication experienced by both custom and stock eye-wearers. There was a statistically significant difference ($P<0.05$) in the colour and viscosity of discharge between two types of prosthesis. There was a statistically significant association

(P<0.05) between the type of ocular prosthesis worn and Quality of Life. Significant findings from the Quality of Life questionnaire were that slightly more than two thirds (66%) of the custom eye wearers were not affected by night driving compared to 35% of the stock eye-wearers. Furthermore, evidence from this study indicated that the custom eye-wearers were more comfortable compared to the Stock eye-wearers.

Conclusion: Custom eyes are associated with a better Quality of Life than stock eyes and should, wherever possible, be made available to the anophthalmic patients. However, levels of depression and anxiety in this group were low irrespective of prosthesis type, suggesting that in a resource constrained setting, the provision of stock eyes is an acceptable compromise.

Declaration

I declare that this research project is my own unaided work. It is submitted for the degree of Master of Medicine at the University of Witwatersrand, South Africa. It has not been submitted before for any other degree or examination at any other University.

U.D Gnanapragasam

10th December 2019

The Research was conducted at the Artificial Eye Centre in Krugersdorp, Johannesburg.

Permission to conduct the research was granted by the University of the Witwatersrand Human Research Ethics Committee (Medical) Ref Number M151155 (Appendix B).

Permission was also obtained from the Director of Artificial Eye Centre Krugersdorp to conduct interviews at the centre (Appendix C).

Acknowledgements

The Research was conducted at the Artificial Eye Centre in Krugersdorp.

The permission was also obtained from the Director of Artificial Eye Centre in Krugersdorp.

I would like to thank my supervisor, Dr S E Williams, for her guidance and patience during the research process. Dr Williams' comments and suggestions were valuable. It was my pleasure working with Dr Williams.

I am grateful to Hanlie Jorgen, for her assistance during data collection at the Artificial Eye Centre in Krugersdorp.

Kennedy Mwai, Tesleem Babalola, Sikhuphukile Gillian Mahati, thank you very much for assisting me with statistical analysis of the data.

I would also like to express my gratitude to Dr Stanford T Mahati, Lindelani Madonsela and Linda Mampuru for their assistance during completion of this research report.

CONTENTS

Dedication ii

Abstract iii

Declaration v

Acknowledgements vi

Contents vii

List of tables x

List of figures x

List of Abbreviations and Acronyms xi

1 **CHAPTER 1 BACKGROUND** 1

1.1 Problem statement 2

1.2 Literature review 3

1.2.1 Historical overview of artificial eyes 3

1.2.2 Removal of an eye and QOL 3

1.2.3 Indications and types of destructive eye surgeries 4

1.2.4 Types of prostheses 6

1.2.5 Assessment tools regarding the QOL of the artificial eye wearer 7

1.3 Research question 9

1.4 Aims and objectives 9

1.4.1 Aim 9

1.4.2 Specific Objectives 9

2 **CHAPTER 2 METHODOLOGY** 10

2.1 Introduction 10

2.2 Study population 10

2.3 Study Design and Data management 11

2.4 Sample Size 11

2.5 Data management and analysis 11

2.6 Outcome and explanatory variables 12

2.7 Ethical clearance 12

3 **CHAPTER 3 RESULTS** 13

3.1 Introduction 13

3.2 Demographic information of the participants (Table 1) 13

3.3 Anxiety and depression assessment of the participants (Table 2 and 3) 16

3.4 Prosthetic eye history of the participants (Table 4) 19

3.5 Association between participants levels of satisfaction and type of ocular prosthesis (Table 5) 21

3.6 Difficulties with prostheses and prosthesis care 24

3.7 Quality of life (QOL) 27

4 **CHAPTER 4 DISCUSSION AND CONCLUSION** 30

4.1 Discussion 30

4.1.1 Satisfaction 30

4.1.2 Complications 31

4.1.3 Quality of life 33

4.1.4 Limitations 34

4.2 Conclusion 34

5 **REFERENCES** 36

6 **APPENDICIES** 40

APPENDIX A: Questionnaire 40

APPENDIX B: Ethics clearance 54

APPENDIX C: Consent 55

List of tables

Table 1 Demographic Information of Respondents.....14

Table 2: Anxiety assessment for Respondents.....17

Table 3: Depression assessment for Respondents 18

Table 4 Prosthetic eye history.....20

Table 5 Association between Level of Satisfaction and type of ocular prosthesis wore.....23

Table 6 Characteristics of Discharge (Descriptive statistics) 26

Table 7 Characteristics of Discharge based on the type of ocular prosthesis worn.....27

Table 8 Relationship between QOL and type of ocular prosthesis worn 29

List of figures

Figure 1: Age distribution by type of prosthesis.....15

Figure 2. Employment of the participants by type of prosthesis 16

Figure 3: Overall Anxiety and Depression level of Respondents.....19

Figure 4 Types of implant done.....21

Figure 5: Difficulties in wearing of a prosthesis.....24

Figure 6: Cleaning frequency by type of prosthesis 25

Figure 7 Discharge frequency by type of prosthesis.....25

Figure 8 Frequency of extent of discharge by type of prosthesis 26

Figure 9: General effect of vision condition on some QOL indicators of wearers of ocular prosthesis.....28

List of Abbreviations and Acronyms

DAS	Derriford Appearance Scale
HADS	Hospital Anxiety and Depression Scale
HRQOL	Health-Related Quality of Life
MP	Motility Peg
QOL	Quality of Life
PMMA	Poly Methyl Methacrylate
SO	Sympathetic Ophthalmia
TV	Television
BCE	Before the Common Era

1 CHAPTER 1 BACKGROUND

Eyes are vital organs, important for interpersonal communication and for signalling to others when speaking and listening. Eyes are also an important part of physical attractiveness and are important to a person's self-esteem and image. Given the important roles that the eyes play in communication and in perceived attractiveness, not enough is known about the emotional impact on an individual who lost an eye for various reasons (1, 2).

Irreparable trauma to the eye, an ocular tumour, or a painful non-functioning eye are some of the reasons that an individual may undergo destructive eye surgery (such as evisceration or enucleation), rendering the orbit anophthalmic. Ocularists and ophthalmologists play a crucial role in the rehabilitation of ophthalmic sockets/orbits and in simulating mirror-image symmetry between artificial eyes and normal eyes. This rehabilitation usually takes place in two steps. Firstly, often at the time of destructive eye surgery, an implant (or artificial eyeball) is inserted in the socket. An artificial eyeball takes the shape of a convex eyeball and replaces the absent eye. It is usually covered by conjunctival tissue. Good ocular motility can be achieved by attaching the extra-ocular muscles to the implant (3). A conformer shell is inserted at the time of surgery to maintain the conjunctival fornixes and to prevent conjunctival prolapse. An alginate impression of the socket is subsequently taken, and from this, an artificial eye or ocular prosthesis is made (4).

This is the second step. Ocular prosthesis are made up of polymeric materials, which the patient places between the eyelids and the conjunctiva. The outer surface of the prosthesis is painted with an iris and a pupil to look like a normal eye. In practice, some movements can be transmitted to overlying prosthesis if the extra ocular muscles are attached to orbital implant (5).

Prostheses can be removed for cleaning before a patient goes to sleep. Ocular prosthesis can be classified into stock and custom-made prosthesis. Custom-made prosthesis are tailor-made according to the individual's cosmetic requirements and are painted to match the contralateral normal eye. Custom-made artificial eyes are recommended by ocular plastic surgeons and ocularists because the physical requirements and individual characteristics of the wearer are taken into consideration. Stock eyes, as the name implies, are pre-fabricated and are fitted by trial and error. Stock eyes are manufactured in large scale in a variety of standard sizes, shapes and iris colours. Fitters of stock eyes must try several different shapes and sizes into the socket in an effort to find the one with the most comfortable fit that looks most like the fellow normal eye.

1.1 Problem statement

In many developing countries, access to custom eyes is very limited because of affordability, making stock eyes the most available and affordable prosthesis. Less attention is therefore paid to the satisfaction level and comfort experience of the artificial eye wearers of both stock and custom eyes in South Africa and on the African continent in general. Ours is a resource-constrained setting. Therefore, we are obliged to use more stock eyes, but we have not evaluated the effect this has on our patients' quality of life (QOL). Exploring and validating the different experiences of anophthalmic patients (both those with custom and stock eyes) will provide information for reviewing existing policies on caring for anophthalmic patients before and after supplying ocular prosthesis.

Furthermore, patients who undergo an eye removal after open globe injury have a higher level of depression and anxiety about their vision-specific quality of life and a worse general quality of life (6). Studies undertaken by Ramussen et al. support this statement, with the respondents reporting a statistically significant increase in depression and anxiety with respect to vision-

specific quality of life and a decrease in general health-related quality of life after the procedure (6).

1.2 Literature review

1.2.1 Historical overview of artificial eyes

The art of making artificial eyes has been practised from ancient times. Egyptian priests made the first ocular prostheses called ecblepharons, as early as the 5th century BCE (7). The first orbital implants were placed by Mules in 1885 using hollow glass, gold, or silver spheres (5). From that time, many different types of materials have been used for orbital implants. The invention of poly methyl methacrylate (PMMA) in the 1940s has revolutionised the field of both implants and ocular prostheses.

1.2.2 Removal of an eye and QOL

The removal of an eye, as with any organ, is expected to affect an individual's QOL. Loss of an eye has physical, socioeconomic and psychological effects on the person concerned. Following destructive surgeries, anophthalmic patients go through changes in emotions and in mental and psychological responses and also experience changing relationships in society. The Royal Institute for the Blind emphasises that losing an eye can be difficult to cope with as it can affect so many aspects of a person's life. These include feeling depressed or angry, feeling a drop in confidence when every task becomes a challenge and finding themselves becoming withdrawn and wanting to avoid people(8). An important factor at play is the visible disfigurement associated with the loss of an eye.

Visible loss of an eye as a social disability has been described as the "last bastion of discrimination in the United Kingdom"(9). There is a general acceptance that loss of an eye is associated with a range of psychological challenges (9). Facial appearance contributes to the

sense of identity. Therefore, the psychosocial and emotional impact of the loss of an eye is particularly severe.

Research suggests that adjusting to life with an ocular prosthesis can be challenging. To some extent, the adjustment process can take between one and six months for about 40% of patients. However, this process can also take up to two years or more because of individual variability in the adaptation process. Such variability might be attributable to socio-demographic and psychological factors (10, 11). The changes in routine associated with wearing and maintaining an artificial eye come with considerable challenges in maintaining QOL (12).

A study on psychological factors and QOL after removal of an eye in Egypt showed a strong relationship between eye removal and QOL and the psychosocial state of patients (13). This is corroborated by McBain et al. who found that patients who felt that their artificial eyes were imperceptible had a greater level of satisfaction, regardless of the type of surgery or orbital implant (10).

Loss of income and the costs of rehabilitation resulting from ocular trauma are a cost to society (2). Concerns over the socioeconomic implications of eye injuries increase when the person affected is the main breadwinner in the household.

1.2.3 Indications and types of destructive eye surgeries

A badly traumatised eye has been found to be the commonest indication for removal of the eye in Africa (14). Research has found that the general pattern of risk of losing an eye varies by age (15). The distribution seems to be bimodal with peaks at the two extremes of one's lifetime. This is to say, the risk of losing an eye is higher at a younger age and again at an older age. At a younger age, the peak is observed in people between 5 and 25; at an older age, the risk is much higher among 70-year-olds (2). Less commonly in Africa, an eye may be removed

because it has a tumour. Enucleation or evisceration of an eye is also recommended as an acceptable therapeutic modality for blind, end-stage ocular diseases that are not responding to a therapeutic treatment.

Eyes can be removed through various surgical procedures, and these are evisceration, enucleation and exenteration. Patient's satisfaction in orbital implant surgery is determined by the type of surgery patient had undergone...

An evisceration entails excising the cornea, eviscerating the contents of the eye, but maintaining the scleral shell and the extraocular muscles in situ. Evisceration is the type of surgery that is most widely performed in our setting because it preserves orbital anatomy and offers enhanced cosmesis and mobility.

The second type of surgery is enucleation. In this procedure, the entire eye globe is removed, including the attachments of the extra-ocular muscles. In order to preserve mobility, an implant may be used to which the extra-ocular muscles may be attached.

An American survey by Levine reported that majority of patients opted for enucleation to evisceration, it was possibly due to the risk of acquiring sympathetic ophthalmia (SO) after evisceration (15). However, in the same study, patients who had evisceration had a very low risk of developing a SO; this finding was confirmed in more recent studies. Eviscerations are being widely performed with increasing frequency in Europe, but a similar trend has not been shown in the United States, possibly due to the risk of SO (15). The incidence of SO is estimated at 0.19% (range 0.1%-0.3%) after ocular trauma in which primary enucleation was not performed (11).

Exenteration, the final surgical option for removal of an eye, entails removal of the entire contents of the orbit. This requires a different cosmetic solution that will not be covered in this

study. Besides destructive eye surgery, an ocular prosthesis may be required in other circumstances. The indications for ocular prosthesis may be divided into two broad categories, namely congenital and acquired deformities (16).

- Congenital deformities include anophthalmia and microphthalmia.
- Acquired deformities include *phthisis bulbi*, *atrophic bulbi*, *staphyloma*, post-evisceration, post-enucleation, post-chemical injuries, contracted socket following radiation, post-orbital exenteration.

Oculo-plastic surgeons and ocularists specialise in anophthalmic cosmesis.

1.2.4 Types of prosthesis:

A correct placement of ocular prosthesis should allow the normal opening of the eye, support the eyelids, restore a reasonable degree of ocular movement and be aesthetically satisfying. Stock eyes are produced in large numbers in a factory, whilst custom-made ocular prosthesis are custom-made for individual requirements.

The use of a stock ocular prosthesis of an appropriate colour and size, adapted by selective grinding or additions of acrylic resin, has been recommended by Laney and Gardner (15). Resin is commonly used to manufacture prosthesis because of its “light weight, translucency, better fracture resistance, ease of fabrication, easy adjustability, and its capability for intrinsic and extrinsic colouring” (17). Relining a stock eye shell can improve the fit of the prosthesis to underlying tissue, whilst sclera contour and iris position would still be compromised (18). There are several techniques documented in the literature for fitting and fabricating the artificial eye. Standard techniques can produce satisfactory results for majority of patients, provided the operator has an adequate choice of stock eyes. But stock eye prosthesis may have several

disadvantages, for example, poor fit and constant tissue irritations due to bacterial overgrowth, all of which compromise the aesthetic outcome (15).

Because of individual variations and the various nature of ocular injuries, some patients would benefit more from a custom-made artificial eyes that is modified to the individual's requirements (16). Research studies on ocular prostheses have shown that good apposition between the ocular prostheses and the conjunctival tissue is needed to distribute even pressure, so prefabricated stock eyes should be avoided (19). Prefabricated prostheses collect debris and mucus, which can irritate mucosa and act as a potential source of infection, which is minimised in custom-made prosthesis (19).

Custom ocular prosthesis provide a good fit, enhanced aesthetics, proper eyelid fullness, accurate scleral contour and iris colour match and positioning. Poly methyl methacrylate (PMMA) resin and glass are generally used for custom ocular prosthesis fabrication. Ocular prostheses custom-made to the tissue bed provide maximum comfort and restore full physiologic function to the rest of the orbital structures in an ophthalmic socket (20).

1.2.5 Assessment tools regarding the QOL of the artificial eye wearer

Several assessment tools have been used in other studies. These include the hospital anxiety and depression scale (HADS) Appendix1, the Derriford Appearance Scale (DAS), the health-related QOL (HRQOL) scale and the Medical Outcome Study Short-Form 36-Item Health Survey (SF-36). The HADS was developed initially to identify anxiety and depression symptoms in patients who are admitted to non-psychiatric hospitals on an outpatient basis and healthy people. The HADS was limited to 14 items divided into anxiety and depression subscales (21). In the context of this investigation, I have chosen to use the HADS tool because previous studies have shown that patients with ocular prostheses display greater level of anxiety

and depression that are within the normal range. Although the HADS is not the only proven and reliable tool, it presents the following advantages: it is easy to score and simple to analyse and interpret. It also provides clear cut-off scores to indicate the severity of the disorder that would aid in making appropriate interventions. McPherson and Martin conducted a systematic review of studies using the HADS scale and came to the conclusion that it had a suitable structure, adequate internal consistency and retest reliability (22). Details on the scoring scales are provided in Appendix A.

1.3 Research question

Is there a difference in the level of satisfaction, quality of life and medical complications among patients who wear stock eyes compared to those that wear custom eyes?

1.4 Aims and objectives

1.4.1 Aim

The aim of this research is to establish the level of satisfaction in patients who are wearing ocular prosthesis and to compare the satisfaction levels between stock eyes and custom-made ocular prostheses. In addition, the study also aims to investigate the effect of psychosocial stressors and ocular complications in patients wearing ocular prosthesis at the Artificial Eye Centre in Krugersdorp.

1.4.2 Specific Objectives

1. To assess, by means of a questionnaire, the level of satisfaction of ocular prosthesis wearers with their prosthesis;
2. To assess, by means of a questionnaire, the extent of complications experienced by ocular prosthesis wearers with their prosthesis;
3. To assess, by means of a questionnaire, the QOL experienced by ocular prosthesis wearers regarding their health and functioning aspects; and
4. To compare the above between wearers of custom eyes and those of stock eyes.

2 CHAPTER 2 METHODOLOGY

2.1 Introduction

The study gathered information on patients who had destructive eye surgeries, including evisceration and enucleation and who were wearing artificial eyes. The study was population-based, including all patients who consented to take part in the study in Krugersdorp.

2.2 Study population

Krugersdorp is an old mining city in the West Rand, Gauteng Province, South Africa, founded in 1887 by Marthinus Pretorius. Following the discovery of Gold on the Witwatersrand, there was a need for a major town adjacent to gold mines.

The Artificial Eye Centre in Krugersdorp has been in existence for just over 25 years, and the ocularist who owns and runs this practice has fitted more than 15 000 patients with stock eyes and 5000 patients with custom eyes over this period. He has also fitted numerous stock eyes at the St John Eye Hospital over the last 25 years. Patients are referred to this centre from nearby private ophthalmologists and government hospitals, including St John Eye Hospital from Soweto.

The ocularist at the Artificial Eye Centre Krugersdorp was approached prior to the start of the study. This was done to convey the objectives of the study and to seek the assistance of the ocularist in facilitating meetings with patients to distribute the questionnaire, as well as in making patient's clinical notes available to obtain further information if necessary, on the artificial eyes.

2.3 Study Design and Data management

The study was a cross-sectional, descriptive study, using a questionnaire to gather information on patients who had had destructive eye surgeries, including evisceration and enucleation and who were wearing artificial eyes.

2.4 Sample Size

The study sample was selected from the prosthesis clinic, using convenience sampling. This implies that participants included in the study were selected based on ease of accessibility and availability.

2.5 Data management and analysis

Data was captured using EpiData and later imported to Excel. For data analysis and management, Stata 13 was used.

Baseline characteristics were described using frequency measures and percentages for categorical variables, means and standard deviations for continuous variables. Pie charts and/or bar charts were used to portray categorical variables, whilst histograms were used to show the graphical distribution of continuous variables.

Associations were investigated between socio-demographic variables and levels of satisfaction using the Pearson Chi-Square test or the Fisher exact test. An independent t-test for equality of means or the Mann Whitney test were used to document differences in the level of satisfaction across categorical variables. Furthermore, other objectives were achieved using the Pearson Chi-Square test or the Fisher exact test to investigate the association between complications

To assess the validity of the instrument, Cronbach's alpha test was used.

An independent t-test was used to compare the mean level of satisfaction between patients who were wearing the two different types of prostheses.

2.6 Outcome and explanatory variables

We had 3 main outcomes of interest to achieve the objectives which were;

1) Level of satisfaction of the patient
2) Quality of life of the patient
3) Complications

The main predictor variable in our study was the type of prosthesis (custom or stock eye) a participant was wearing.

2.7 Ethical clearance

This study was granted ethical clearance by the University of the Witwatersrand's Committee for Research on Human Subjects, under ethics clearance number M151155, as shown in Appendix 3. Additionally, we obtained consent from the Krugersdorp Artificial Eye Centre, as shown in Appendix 4. Finally, the patient provided consent during the data collection process.

3 CHAPTER 3 – RESULTS

3.1 Introduction

This chapter presents the results of the characteristics of the participants, as shown in Table 1. Additionally, this is followed by results of the comparison of the level of satisfaction, complications experienced, and QOL with the outcome variable "type of ocular prosthesis worn" as shown in tables 2, 3 and 4. The hospital anxiety and depression scale (HADS) data collection tool was tested for reliability test using Cronbach's alpha reliability test. The Cronbach's alpha value was 0.814. This shows that there was good internal consistency among the items of the tool. Thus, the questionnaire was adequate and reliable.

3.2 Demographic information of the participants (Table 1)

There were 104 participants in this study. Almost all the participants (99%) answered the questionnaires correctly. Slightly more than half of the population (56.9%) were single, and nearly three quarters of them (71.3%) had secondary education.

The mean age of the respondents is 37.71 years ±16.53, with 57.3% of the participants being male. Most of the respondents (66.3%) were less than 40 years of age. The custom eye wearers, were older than the stock eye wearers. The distribution of the respondents shows that they mostly had secondary education. Most (59.0%) were employed and a similar proportion (52.0%) were earning more than R50,000 a year. The majority of the participants were black (77.7%).

Table 1 Demographic Information of Respondents

Variables	Frequency	Percentage (%)
Age (yrs.) (n=104)		
≤ 20	16	15.4
21 – 30	23	22.1
31 – 40	30	28.8
41 – 50	13	12.5
51 – 60	11	10.6
> 60	11	10.6
Mean ±SD **= 37.71 ± 16.53 years**		
Maximum = **79 years**		
Minimum = **3 years**		
Gender (n=103)		
Male	59	57.3
Female	44	42.7
Marital status (n=102)		
Single	58	56.9
Married	42	41.2
Divorced	1	1.0
Widow	1	1.0
Level of Education (n=101)		
No Education	4	4.0
Primary	10	9.9
Secondary	72	71.3
University	13	12.9
Postgraduate	2	1.9
Occupation (n=100)		
Unemployed	41	41.0
Employed	59	59.0
Income category (n=75)		
< 50,000	36	48.0
> 50,000	39	52.0
Ethnicity (n=103)		
White	15	14.5
Indian	4	3.9
Coloured	4	3.9
Black	80	77.7

Figure 1 shows the participants' age distribution by the type of prosthesis worn and gender. The results show that there is a difference in median age among males who wore custom eyes compared to those with stock eyes.

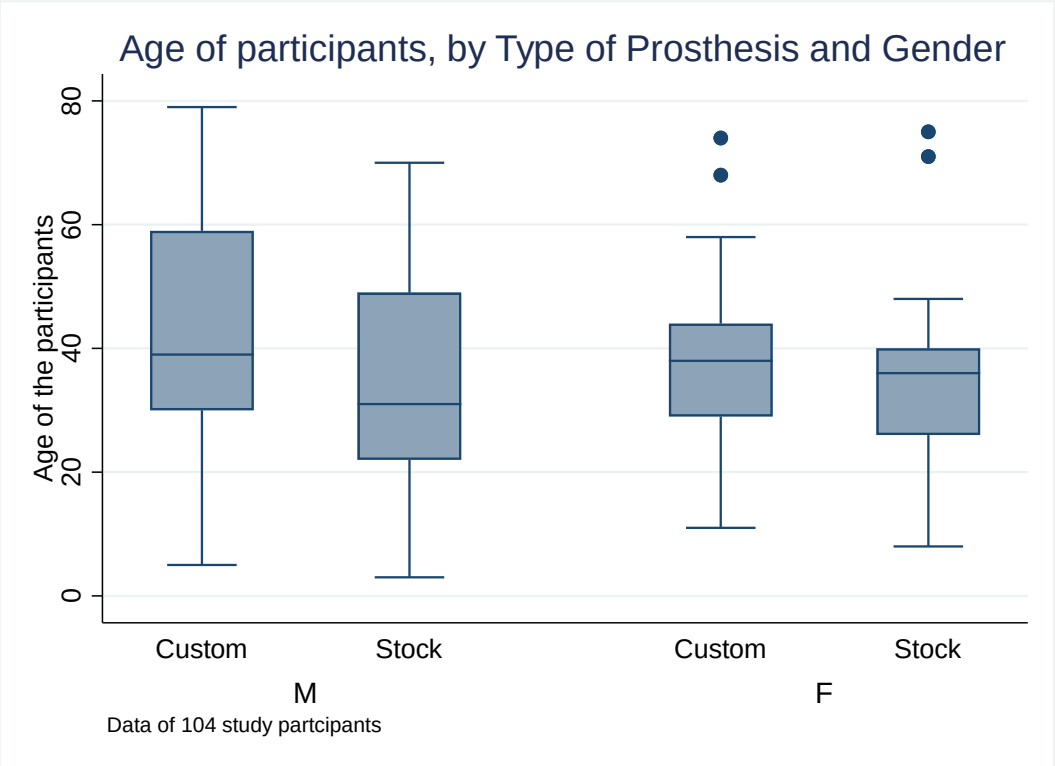

Figure 1: Age distribution by type of prosthesis

Figure 2 shows the employment distribution among the participants by the type of the prosthesis. The results show that majority of custom eye wearers were employed compared to stock eye wearers

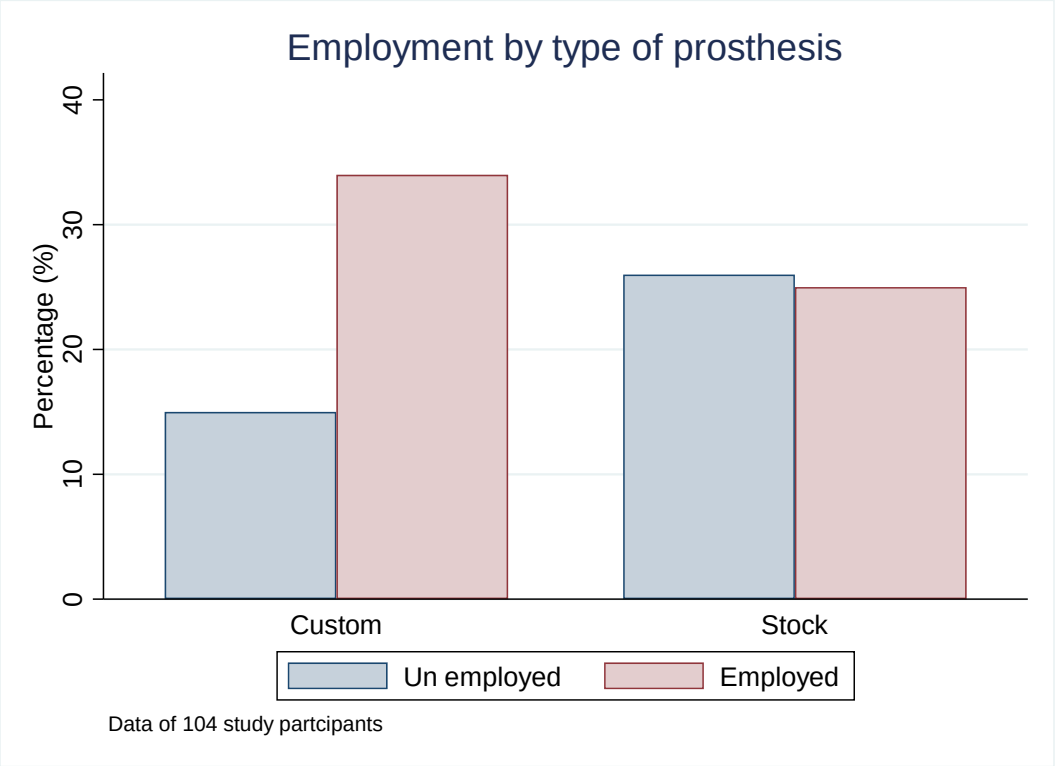

Figure 2. Employment of the participants by type of prosthesis

3.3 Anxiety and depression assessment of the participants (Table 2 and 3)

Based on the anxiety assessment components (Table 2), most of the respondents had a low level of anxiety. The anxiety coping strategy used by highest proportion of the respondents (82.9%) was “looking forward with enjoyment to things”.

Table 2: Anxiety assessment for Respondents

Indicators	Frequency (n=76)	Percentage (%)
I feel tense or 'wound up':		
Always	6	7.9
A lot of the time	5	6.6
From time to time, occasionally	27	35.5
Not at all	38	50.0
Worrying thoughts go through my mind:		
A great deal of the time	6	7.9
A lot of the time	3	3.9
From time to time but not too often	22	28.9
Only occasionally	45	59.2
I can sit at ease and feel relaxed		
Definitely	46	60.5
Usually	22	28.9
Not often	6	7.9
Not at all	2	2.6
I get a sort of frightened feeling like 'butterflies' in the stomach		
Not at all	45	59.2
Occasionally	25	32.9
Quite often	2	2.6
Very often	4	5.3
I feel restless as if I have to be on the move		
Very much indeed	17	22.4
Quite a lot	12	15.8
Not very much	47	61.8
I look forward with enjoyment to things		
As much as I ever did	63	82.9
Rather less than I used to	11	14.5
Definitely less than I used to	2	2.6
Hardly at all	0	0.0

The depression assessment (Table 3) shows that the majority of respondents engaged in activities that could reduce their predisposition to depression. The major coping mechanisms, as indicated by most of the respondents were; “laughing and seeing the funny side of things” and enjoying a good book or radio or television (TV) programme. Also, the majority (88.2%) said they take just as much care as ever when it comes to their appearance.

Table 3: Depression assessment for Respondents

Indicators	Frequency (n=76)	Percentage (%)
I still enjoy the things I used to enjoy		
Definitely as much	48	63.2
Not quite so much	19	25.0
Only a little	8	10.5
Hardly at all	1	1.3
I can laugh and see the funny side of things:		
As much as I always could	63	82.9
Not quite so much now	11	14.5
Definitely not so much now	1	1.3
Not at all	1	1.3
I feel cheerful		
Not at all	4	5.3
Not often	2	2.6
Sometimes	18	23.7
Most of the time	52	68.4
I feel as if I am slowed down		
Nearly all the time	4	5.3
Very often	5	4.8
Sometimes	25	32.9
Not at all	42	55.3
I have lost interest in my appearance		
Definitely	2	2.6
I don't take as much care as I should	3	3.9
I may not take quite as much care	4	5.3
I take just as much care as ever	67	88.2
I can enjoy a good book or radio or TV programme		
Often	67	88.2
Sometimes	7	9.2
Not often	0	0.0
Very seldom	2	2.6

Figure 3 shows the overall anxiety and depression level of the respondents. The graph shows that most of them (69.7%) were at normal level, 13.2% were at a borderline abnormal level while 17.1% of them were at an abnormal level.

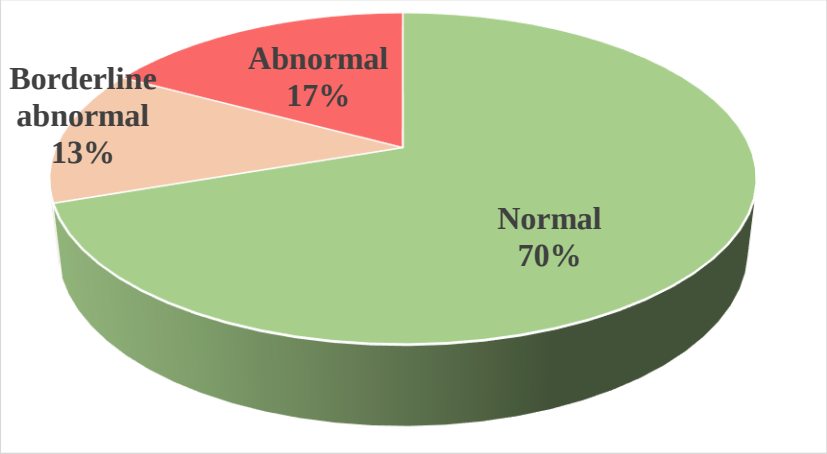

Figure 3: Overall Anxiety and Depression level of Respondents

3.4 Prosthetic eye history of the participants (Table 4)

The major reason given by the respondents for having a prosthetic eye was injury, and the prosthetics were done on either eye. Most (84.9%) of the respondents had an evisceration. The majority (55.4%) had an implant, and approximately half had the implant done at the time of surgery.

Table 4 Prosthetic eye history

Variables	Frequency	Percentage (%)
Reason for the prosthetic eye (n=103)		
Injury	81	78.6
Cancer	9	8.7
Others	13	12.6
Prosthetic eye (n=103)		
Right	51	49.5
Left	50	48.5
Both	2	1.9
Procedure (n=86)		
Evisceration	73	84.9
Enucleation	13	15.1
Was there an implant (n=92)		
Yes	51	55.4
No	41	44.6
Was the implant implanted during the time of surgery or as a secondary procedure? (n=39)		
Time of surgery	21	53.8
Secondary procedure	18	46.2

Figure 4 shows the types of implant done. The result shows that the major type of implant done was Silicone.

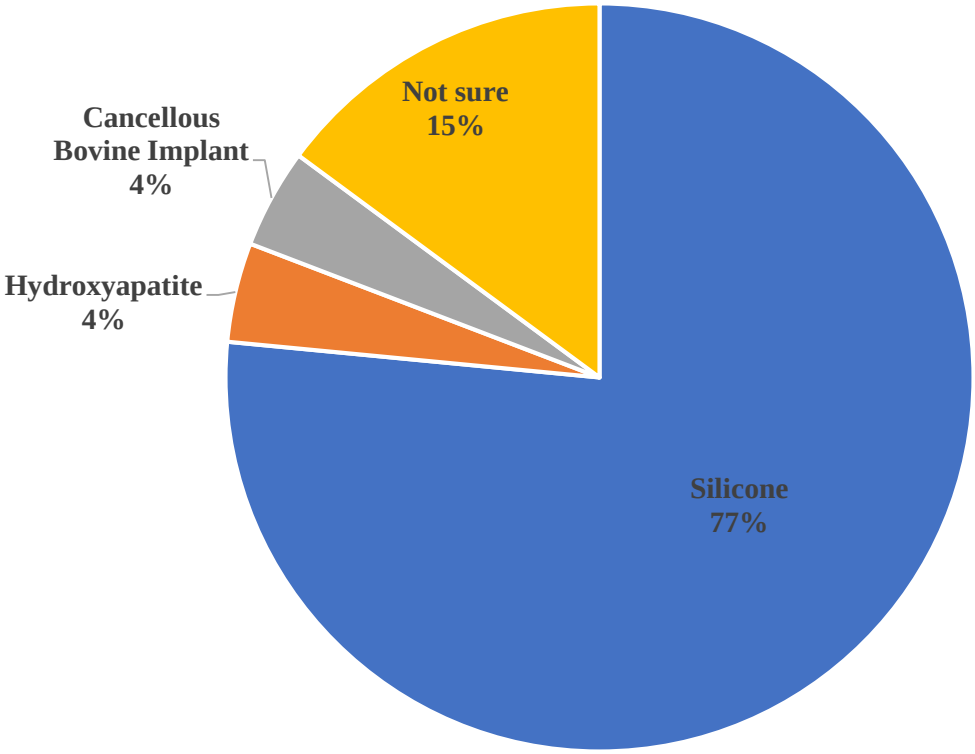

Figure 4 Types of implant done

3.5 Association between participants levels of satisfaction and type of ocular prosthesis (Table 5)

The ocular prosthesis satisfaction survey questionnaire was tested for reliability using Cronbach's alpha reliability test. The Cronbach's alpha value was 0.658. This shows that there was relatively good internal consistency among the items of the tool.

There was an association between the type of prothesis and different levels of satisfaction. A significant association between the type of prosthesis and the satisfaction of facial improvement was observed ($P<0.01$). Most of the custom eye wearers felt their facial appearance had greatly improved (n=52, 98.8%) compared to the stock eye wearers (n=37

,78.72%) (P<0.003). Additionally, we also observed in the detailed answers that the custom eye wearers had a high percentage, approximate 53%, of face appearance satisfaction compared to the stock eye-wearers approximate 14% (P<0.001). We observed that 72% (n=38) of custom eye wearers felt that their facial appearance was “natural” compared to 33% of the stock eye wearers (n=17). This difference was also statistically significant (P<0.01). The individuals were asked as to whether the public or other people could notice whether they were wearing a prosthesis or not. The majority of custom eye-wearers 81% (n=43) responded that people could not notice that they were wearing prosthesis compared to 33.33% (n=17) of stock eye-wearers with again a significant association (P<0.001).

When the respondents were asked about whether prosthesis treatment was worthwhile for them, all the custom eye-wearers responded as yes, compared to 94% (n=48) of the stock eye-wearers. Additionally, all the custom eye-wearers responded by saying they would recommend this treatment to others who have already lost an eye. In contrast, two stock eye wearers responded that they would not recommend this treatment to others without giving any reasons for their response. More of the custom eye-wearers wore a conformer than stock eye-wearers but the P-value was not significant (P=0.226). The majority of custom eye-wearers were very comfortable with their prosthesis 83% (n=43) compared with only 35% (n=16) of stock eye wearers who were similarly ‘very comfortable’ (p<0.05). Most of the participants were satisfied with the fit of the prosthesis during household activities (for example cooking, cleaning and gardening) and also during sleep. Both the custom eye and stock eye-wearers had been shown daily hygiene of the prosthesis, but most did not remove the prosthesis at night.

Table 5 Association between Level of Satisfaction and type of ocular prosthesis wore

Variables	**Custom eye**	**Stock eye**	**P. value**
	n (%)	**n (%)**	
Was the appearance of your face improved by the implant of your ocular prosthesis?	**52 (51.48)**	**47 (46.53)**	
Yes	51 (98.08)	37 (78.72)	0.003
No	1.00 (1.92)	10 (21.28)	
Were you pleased with the appearance of your face after the ocular prosthesis was inserted/implanted?	**53 (55.12)**	**51 (53.04)**	
Not at all	0 (0.00)	8 (15.69)	
Somewhat	1 (1.89)	9 (17.65)	
Moderately	5 (9.43)	13 (25.49)	0.0001
Very much	19 (35.85)	14 (27.45)	
Completely	28 (52.83)	7 (13.73)	
Did you regard the appearance of your face as "natural" (no noticeable signs of ocular prosthesis implant)?	**53 (55.12)**	**51 (53.04)**	
No	2 (3.77)	10 (19.61)	
Somewhat	13 (24.53)	24 (47.06)	0.0001
Yes	38 (71.70)	17 (33.33)	
Do you think others can notice that you are wearing a prosthesis?	**53 (55.12)**	**51 (53.04)**	
No	43 (81.13)	17 (33.33)	
Somewhat	5 (9.43)	20 (39.22)	0.0001
Yes	5 (9.43)	14 (27.45)	
Was the prosthesis treatment worthwhile for you or not?	**53 (55.12)**	**51 (53.04)**	
Yes	53 (100.00)	48 (94.12)	0.114
No	0 (0.00)	3 (5.88)	
Would you recommend this treatment to others who have already lost an eye?	**53 (55.12)**	**51 (53.04)**	
Yes	53 (100.00)	49 (96.08)	0.238
No	0 (0.00)	2 (3.92)	
Did you wear a conformer?	**49 (47.04)**	**47 (45.12)**	
Yes	30 (61.22)	23 (48.94)	0.226
No	19 (38.78)	24 (51.06)	
How comfortable is your prosthesis?	**52 (50.48)**	**51 (49.51)**	
Very uncomfortable	0 (0.00)	6 (11.76)	
Somewhat uncomfortable	0 (0.00)	10 (19.61)	
Neither comfortable nor uncomfortable	0 (0.00)	1 (1.96)	0.0001
Somewhat comfortable	9 (17.31)	16 (31.37)	
Very comfortable	43 (82.69)	18 (35.29)	
How well/poorly does your prosthesis stay in during household activities (for example cooking, cleaning and gardening)	**53 (51.96)**	**49 (48.03)**	
Poorly	0 (0.00)	3 (6.12)	

Well and Very Well	47 (88.6)	42 (85.71)	0.113
Not Applicable	6 (11.32)	4 (8.16)	
How well/poorly does your prosthesis stay in while sleeping?	**53 (52.47)**	**48 (47.52)**	
Poorly	0 (0.00)	8 (16.67)	0.002
Well and Very well	53 (100)	39 (81.25)	
Not applicable	0 (0.00)	1 (2.08)	
Were you shown daily hygiene on your ocular prosthesis?	**53 (55.12)**	**51 (53.04)**	
Yes	52 (98.11)	47 (92.16)	0.156
No	1 (1.89)	4 (7.84)	
Do you remove your prosthesis at night?	**53 (51.96)**	**49 (48.03)**	
Yes	13 (24.53)	12 (24.49)	0.999
No	40 (75.47)	37 (75.51)	

3.6 Difficulties with prostheses and prosthesis care

Most of the participants found wearing the prosthesis easy (Figure 5)**.**

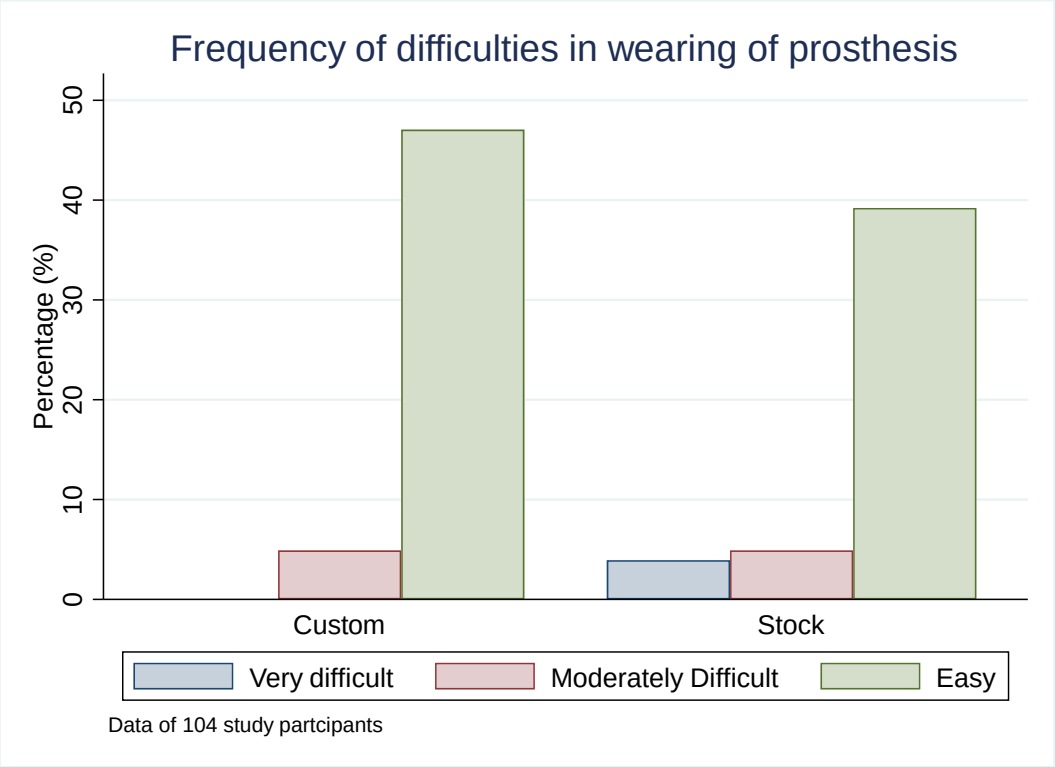

Figure 5: Difficulties in wearing of a prosthesis

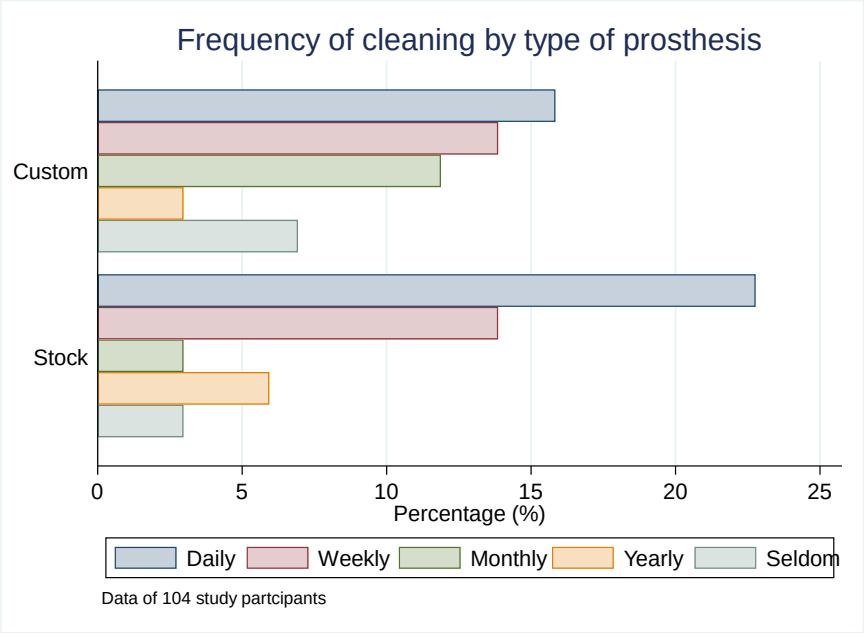

Figure 6: Cleaning frequency by type of prosthesis

An ocular discharge was a frequent complication experienced by both custom and stock eye wearers (figure 7).

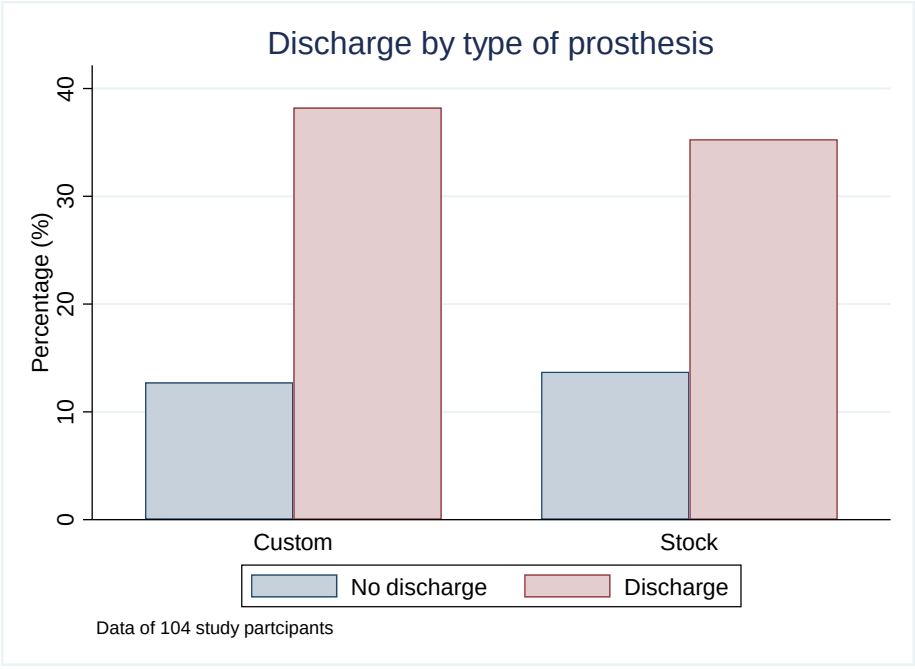

Figure 7 Discharge frequency by type of prosthesis

For the respondents who were experiencing discharge, the most frequent occurrence was on a daily basis (Figure 8)

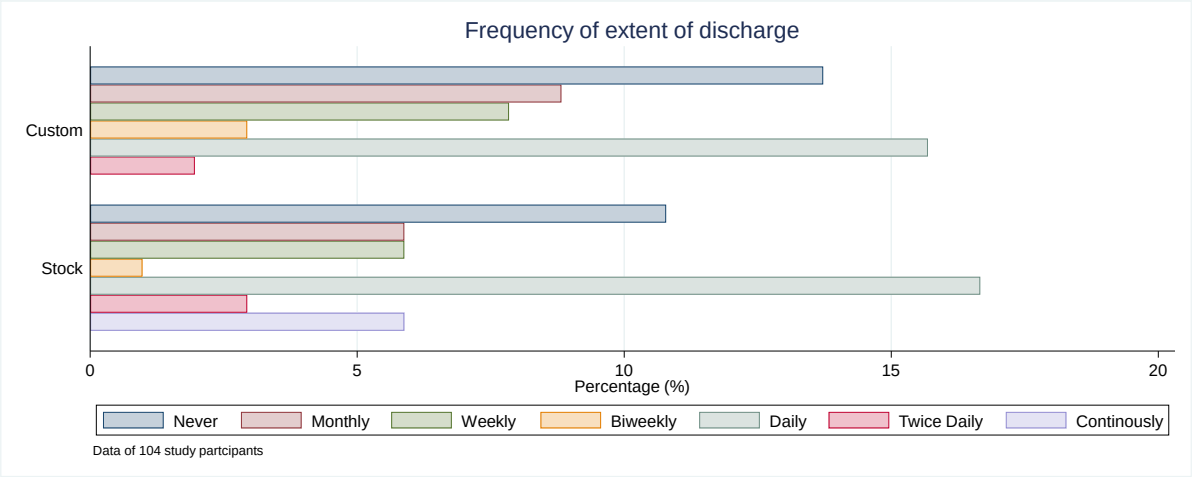

Figure 8 Frequency of extent of discharge by type of prosthesis

A scale of "0 to 10" was used to assess colour, volume and viscosity of the discharge experienced by the respondents (table 6). The mean score of 3.47 and a standard deviation of 2.60 for the colour of discharge shows that the respondents mainly experience a whitish discharge to creamy discharge. The volume of discharge experienced was minimal with an average score for viscosity that reflects a stringy discharge.

Table 6 Characteristics of Discharge (Descriptive statistics)

Descriptive Statistics	**Colour of Discharge**	**Volume of Discharge**	**Viscosity (Stickiness/thickness)**
Mean	3.47	2.34	3.35
Standard deviation	2.60	2.27	2.46
Minimum	0.0	0.0	0.0
Maximum	10.0	9.50	10.0
Skewness	0.741	1.405	0.502

There was a statistically significant difference (P<0.05) in the colour and viscosity of discharge between the two wearers (table 7). This showed that the mean score difference of 1.30 (4.12 –

2.82) for the colour of discharge between the custom-made eye-wearers and the stock eye wearers was statistically significant. Similarly, the mean score difference of 1.14 (3.93 – 2.79) for the viscosity of discharge between the custom-made eye-wearers and the stock eye-wearers was also statistically significant

Table 7 Characteristics of Discharge based on the type of ocular prosthesis worn

Descriptive Statistics	**CUSTOM-MADE EYE**			**STOCK EYE**		
	Colour of Discharge	Volume of Discharge	Viscosity of Discharge	Colour of Discharge	Volume of Discharge	Viscosity of Discharge
Mean	2.82	1.89	2.79	4.12	2.80	3.93
Standard deviation	1.97	1.56	2.17	3.00	2.77	2.63
Minimum	0.00	0.00	0.00	0.00	0.00	0.00
Maximum	9.50	8.00	10.00	10.00	9.50	7.50
Skewness	0.87	1.61	1.03	0.370	0.98	0.04

3.7 Quality of Life (QOL)

In terms of the QOL questionnaire, the respondents reported that “driving at night”, “work” and “sport’ were the most affected daily activities as a result of their vision whilst “driving at day time” was the least affected (figure 9).

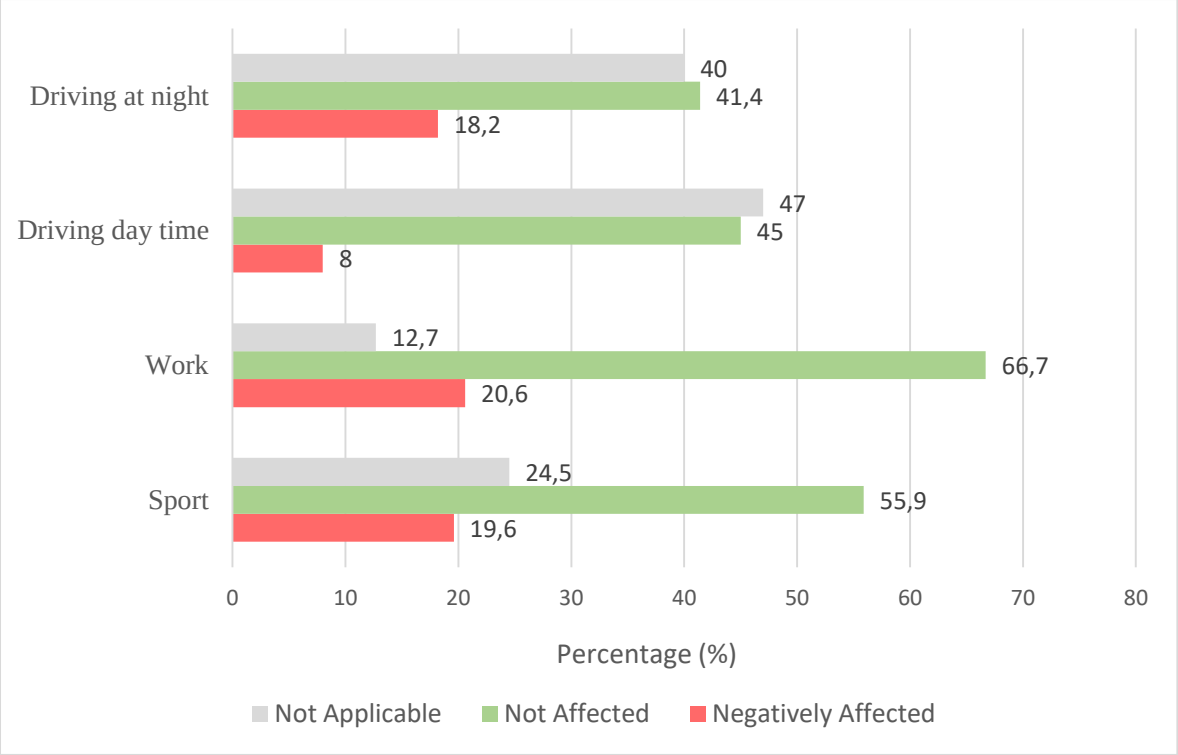

Figure 9: General effect of vision condition on some QOL indicators of wearers of ocular prosthesis.

There was a statistically significant association (P<0.05) between the type of ocular prosthesis worn and particular activities (table 8). Approximately 66% of the custom eye-wearers were not affected by night driving compared to 35% of the stock eye-wearers. This similar characteristic was observed in day time driving.

The majority whose work was affected because of their vison used stock eyes (76.2%). Equal proportions of those whose sporting activity was affected as a result of their vision used stock and custom-made eyes. This suggests that wearers of both stock and custom-made eyes experienced some decline in QOL (table 8).

Table 8 Relationship between QOL and type of ocular prosthesis wore

	Type of ocular prosthesis worn		Total	Chi-square	P-value
	Custom-made eye	Stock eye			
	Freq. (%)	Freq. (%)			
Do you accomplish less than you would like to because of your vision?					
Driving at Night					
Yes	8 (44.4)	10 (55.6)	18 (100.0)	**7.935**	**0.019***
No	27 (65.9)	14 (34.1)	41 (100.0)		
Not Applicable	14 (35.0)	26 (65.0)	40 (100.0)		
Total	**49 (49.5)**	**50 (50.5)**	**99 (100.0)**		
Driving day time					
Yes	5 (62.5)	3 (37.5)	8 (100.0)	**6.785**	**0.034***
No	28 (62.2)	17 (37.8)	45 (100.0)		
Not Applicable	17 (36.2)	30 (63.8)	47 (100.0)		
Total	**50 (50.0)**	**50 (50.0)**	**100 (100.0**		
Work					
Yes	5 (23.8)	16 (76.2)	21 (100.0)	**8.685**	**0.013***
No	41 (60.3)	27 (39.7)	68 (100.0)		
Not Applicable	6 (46.2)	7 (53.8)	13 (100.0)		
Total	52 (51.0)	50 (49.0)	102 (100.0)		
Sport					
Yes	10 (50.0)	10 (50.0)	20 (100.0)	**17.861**	**<0.001***
No	38 (66.7)	19 (33.3)	57 (100.0)		
Not Applicable	4 (16.0)	21 (84.0)	25 (100.0)		
Total	**52 (51.0)**	**50 (49.0)**	**102 (100.0)**		

***=statistically significant**

.

4 CHAPTER 4 DISCUSSION AND CONCLUSION

4.1 Discussion

The main aim of wearing an ocular prosthesis is to improve the quality of life of the wearers. An ocular prosthesis can either be prefabricated (stock eye) or custom made. The close adaptation and characterisation of the custom-made ocular prosthesis provides maximum comfort, aesthetics, and also maintains its orientation when the patient performs various movements (23, 24). Unfortunately, these custom prostheses are expensive and time-consuming to manufacture and are not necessarily available in resource-constrained settings. In this situation, commercially-produced stock acrylic prostheses are available. These stock eyes are trimmed and fitted so that they approximate the periphery of the eye socket. This is a much shorter and simpler procedure (25). This study sought to assess whether there is a difference in the level of satisfaction, quality of life and medical complications among patients who wear stock eyes compared to those that wear custom eyes with the ultimate goal of establishing whether stock eyes are a viable alternative in South Africa.

4.1.1 Satisfaction

There were significant differences in satisfaction levels in respondents with custom eyes and stock eyes in this study. Specifically, the custom eye respondents were more satisfied with their facial appearance, the appearance of the eye and they were more comfortable with their daily life activities. Similarly, a study by Song et al (26) in the Korea University Hospital that evaluated patient satisfaction with an ocular prosthesis after evisceration or enucleation showed a that patients with a motility peg were largely very satisfied (26). This is corroborated in a further study from Germany where it was observed that individuals who had lost an eye and were wearing cryolite glass prosthetic eyes were more satisfied with their appearance than polymethylmethacrylate (PMMA) artificial eye wearers. The degree of satisfaction of custom

eye-wearers in these studies contributes to the preferential recommendation for custom prostheses made by Sykes et al (16).

4.1.2 Complications

Anophthalmic participants in this study wearing ocular prostheses predominantly found wearing the prosthesis easy. They complained of various symptoms, the most frequent complaint being an ocular discharge that was experienced often by both custom and stock eye wearers.

A discharging eye is a frequent complaint in the anophthalmic patient. Song et al. (26) reported that more than 70% of the participants in their study reported eye discharge, and it was the most common complaint in their study. Interestingly, the presence of eye symptoms was not correlated with patient satisfaction. Our patients were also predominantly satisfied despite frequent eye discharge. This may imply that patient satisfaction is not influenced by eye symptoms and anophthalmic patients are able to tolerate mild symptoms such as eye discharge (26).

Pine et al., likewise explored discharge in an anophthalmic group (27). They observed an average severity score (using a visual analogue scale like the one used in this study with a minimum of zero and a maximum of ten) for discharge frequency and colour of about 5 and discharge volume and viscosity about 4. A troubling one-third of that study population reported severity scores of more than 7 for discharge frequency and as many as 9% experienced severity scores of more than 7 for both volume and frequency (27). By contrast, our respondents had lighter coloured discharge (3.47), lower volume (2.39) and less viscous discharge (3.35). The stock eye-wearers in our study had more discharge that was darker and more viscous than the custom eye-wearers. Pine et al., (27) identified associations between eye discharge frequency

and cleaning regimens and they found that more frequent cleaning was associated with more frequent discharge.

They further found that colour of discharge was associated with age and years of wearing, with many years of wearing a prosthesis and older individuals reporting lighter coloured discharge (27). The majority of our participants had been shown to clean their prostheses on a daily basis. Removing and then cleaning the prosthesis may, in fact, be counter-productive. It seems that the mucous coat on a prosthesis may actually minimise irritation and mucous production. Unfortunately, our study did not seek to make any correlations between frequency of prosthesis removal and cleaning and volume, viscosity or colour of discharge. Furthermore, we did not evaluate the length of time (in years) that participants had been wearing their prostheses, so we could not correlate discharge characteristics with length of wear.

Evidence about the cause of eye discharge may be related to the physical contact between the prosthesis and the conjunctiva (27). Physical, chemical and biologic properties of the conjunctiva, deposits, and the socket fluids that cover the prosthesis may contribute to the discharge. The differences we observed in discharge between custom eye-wearers and stock eye-wearers may therefore be related to the different physical properties of these two prostheses and consequently the physical relationship between the prosthesis and the conjunctiva of the custom and stock eye wearers.

It has been recommended that complications, such as allergic conjunctivitis, giant papillary conjunctivitis, viral and bacterial conjunctivitis must be checked at an early stage to allow for the best fit of an artificial eye (28). Following these recommendations of checking for complications before inserting an ocular prosthesis may avoid more severe discharge. Unfortunately, a standardised treatment protocol for discharge associated with ocular

prosthesis wear is lacking. Further research is needed to establish an evidence-based standardised treatment protocol for ocular discharge associated with ocular prosthesis wear.

Ocular prosthesis wearers face challenges with care and maintenance of their prostheses. Artificial eyes should be rinsed "two or three times per day with clean water" (29). The majority of respondents in this study cleaned their prostheses daily. The patients were apparently well-oriented on handling and cleaning their artificial eyes to reduce the incidence of conjunctival inflammation. By contrast, Song et al. (26). found that the majority of patients in their study did not know how to sterilise their prosthesis, which illustrates a failure in their offering of treatment to patients.

According to Pathak C et al. the artificial eye-wearer, post insertion of ocular prosthesis should visit an ocularist once in every six months to polish his prosthesis. We did not evaluate this in our study(30).

4.1.3 Quality of life

Loss of an eye can cause a negative psychosocial impact and that can directly affect the quality of life. It has been reported that anxiety and depression represent a risk to the quality of life and health since anxious or depressed individuals report pain, limitation of daily activities, limitations for physical and mental health and problems with energy levels and sleep (31). It is conceivable that anophthalmia and an ocular prosthesis may be associated with both anxiety and depression. Fortunately, there was generally a low level of anxiety and depression among the respondents of this study irrespective of prosthesis type. In 2008, a cross-sectional study was done in Moorfields Eye Hospital (United Kingdom) on the psychosocial impact of having a prosthesis (11). Like our study, they focused on mood and appearance-related issues. In their study, about 18% of the participants were experiencing significant levels of distress and clinical

anxiety (11). This is very similar to the 17% with overall anxiety and depression indicators in this study.

Interestingly, Goiato et al. (31) found that rehabilitation with an artificial eye can cause a positive impact in patients life and that this can be associated with psychological improvement. The psychological effect caused by loss of an eye may be reduced by shortening the interval between the destructive surgery and prompt rehabilitation. In this study, in terms of QOL indicators, we identified difficulties with work, sport and night driving in about 20% of our respondents. This is an anticipated finding, since loss of depth perception and reduced visual range have been found to be of concern for many ocular prosthetic wearers (32). Both wearers of stock and custom-made eyes experienced some decline in QOL, but the stock eye-wearers were significantly more affected.

4.1.4 Limitations

The study was carried out at a Private Artificial eye centre in South Africa, which may not represent the true demographic distribution of the country.

The custom prosthesis-wearers were older than the stock eye-wearers. This may account for some of the differences we observed since it is possible that older adults cope better with disfigurement than younger adults (32).

4.2 Conclusion

The aim of the study was to address the lack of information about artificial eye wearers in South Africa. The study found significantly higher satisfaction levels, fewer complications and better QOL with custom eyes than with stock eyes. This suggests that, wherever possible, custom eyes should be made available to the anophthalmic patient. The anopthalmic patient

should be educated about cost, availability and implications of custom versus stock eyes to enable an informed decision. It is, however, reassuring that levels of anxiety and depression in this South African study were low irrespective of prosthesis type. This suggests that in a resource constrained setting, the provision of stock eyes is an acceptable compromise.

5 REFERENCES

1. Clarke, A., Rumsey, N., Collin, J. R., Wyn-Williams, M. Psychosocial distress associated with disfiguring eye conditions. Eye (London, England). 2003;17(1):35-40. DOI: 10.1038/sj.eye.6700234.

2. Négrel, A. D., Thylefors, B. The global impact of eye injuries. Ophthalmic epidemiology. 1998;5(3):143-69.

3. Ashworth, J. L., Rhatigan, M., Sampath, R., Brammar, R., Sunderland, S., Leatherbarrow, B. The hydroxyapatite orbital implant: A prospective study. Eye (London, England). 1996;10 (Pt 1):29-37. DOI: 10.1038/eye.1996.4.

4. Ferry, D. Oxford textbook of ophthalmology. 1st edition ed: NY: Oxford University Press; 1999.

5. Chalasani, R., Poole-Warren, L., Conway, R. M., Ben-Nissan, B. Porous orbital implants in enucleation: A systematic review. Survey of ophthalmology. 2007;52(2):145-55. DOI: 10.1016/j.survophthal.2006.12.007.

6. Rasmussen, M. L., Ekholm, O., Prause, J. U., Toft, P. B. Quality of life of eye amputated patients. Acta ophthalmologica. 2012;90(5):435-40. DOI: 10.1111/j.1755-3768.2010.02092.x.

7. Somkuwar, K., Mathai, R., Jose, P. Ocular prosthesis: Patient rehabilitation: A case report. People's Journal of Scientific Research. 2009;2(2):21-6.

8. Tlale, R. D. The emotional experiences of patients following removal of the eye (enucleation or evisceration) 2007.

9. Rumsey, N., Harcourt, D. Body image and disfigurement: Issues and interventions. Body image. 2004;1(1):83-97. DOI: 10.1016/S1740-1445(03)00005-6.

10. Mcbain, H. B., Ezra, D. G., Rose, G. E., Newman, S. P. The psychosocial impact of living with an ocular prosthesis. Orbit. 2014;33(1):39-44. DOI: 10.3109/01676830.2013.851251.

11. Moshfeghi, D. M., Moshfeghi, A. A., Finger, P. T. Enucleation. Survey of ophthalmology. 2000;44(4):277-301. DOI: 10.1016/S0039-6257(99)00112-5.

12. Pine, K., Sloan, B., Stewart, J., Jacobs, R. J. Concerns of anophthalmic patients wearing artificial eyes. Clin Exp Ophthalmol. 2011;39(1):47-52. DOI: 10.1111/j.1442-9071.2010.02381.x.

13. El Shafie, T. M., Shelil, A. E., Ahmed, I. K. Psychological and quality-of-life changes after removal of the eye in a sample of adult patients, egypt, 2013. Middle East Current Psychiatry. 2014;21(3):152-9. DOI: 10.1097/01.XME.0000449845.56119.07.

14. Adenuga, O., Wade, P., Ewuga, R., Abuba, T. Indications for surgical removal of the eye in lafia. Jos Journal of Medicine. 2010;5(1):23-5. DOI: 10.4314/jjm.v5i1.62017.

15. Yousuf, S. J., Jones, L. S., Kidwell Jr, E. D. Enucleation and evisceration: 20 years of experience. Orbit. 2012;31(4):211-5. DOI: 10.3109/01676830.2011.639477.

16. Sykes, L., Essop, A., Veres, E. Use of custom-made conformers in the treatment of ocular defects. The Journal of prosthetic dentistry. 1999;82(3):362-5. DOI: 10.1016/s0022-3913(99)70095-8.

17. Putanikar, N. Y., Patil, A. G., Shetty, P. K., Nagaral, S., Mithaiwala, H. I. Prosthetic rehabilitation of a patient with ocular defect using semi-customized prosthesis: A case report. Journal of international oral health: JIOH. 2015;7(4):81.

18. Smith, R. M. Relining an ocular prosthesis: A case report. Journal of Prosthodontics. 1995;4(3):160-3. DOI: 10.1111/j.1532-849x.1995.tb00333.x.

19. Gunaseelaraj, R., Karthikeyan, S., Kumar, M. N., Balamurugan, T., Jagadeeshwaran, A. Custom-made ocular prosthesis. Journal of pharmacy & bioallied sciences. 2012;4(Suppl 2):S177. DOI: 10.4103/0975-7406.100264.

20. Kumar, P., Aggrawal, H., Singh, R. D., Chand, P., Jurel, S. K., Alvi, H., et al. A simplified approach for placing the iris disc on a custom made ocular prosthesis: Report of four cases. The Journal of Indian Prosthodontic Society. 2014;14(1):124-7. DOI: 10.1007/s13191-012-0179-9.

21. Zigmond, A. S., Snaith, R. P. The hospital anxiety and depression scale. Acta psychiatrica scandinavica. 1983;67(6):361-70. DOI: 10.1111/j.1600-0447.1983.tb09716.x.

22. Mcpherson, A., Martin, C. R. Is the hospital anxiety and depression scale (HADS) an appropriate screening tool for use in an alcohol-dependent population? Journal of Clinical Nursing. 2011;20(11-12):1507-17. DOI: 10.1111/j.1365-2702.2010.03514.x.

23. Cain, J. R. Custom ocular prosthetics. The Journal of prosthetic dentistry. 1982;48(6):690-4. DOI: 10.1016/S0022-3913(82)80030-9.

24. Beumer, J., Marunick, M. T., Esposito, S. J. Maxillofacial rehabilitation: Prosthodontic and surgical management of cancer-related, acquired, and congenital defects of the head and neck: Quintessence Pub.; 2011.

25. Welden, R. B., Niiranen, J. V. Ocular prosthesis. Journal of Prosthetic Dentistry. 1956;6(2):272-8. DOI: 10.1016/0022-3913(56)90120-2.

26. Song, J. S., Oh, J., Baek, S. H. A survey of satisfaction in anophthalmic patients wearing ocular prosthesis. Graefes Arch Clin Exp Ophthalmol. 2006;244(3):330-5. DOI: 10.1007/s00417-005-0037-0.

27. Pine, K. R., Sloan, B., Jacobs, R. J. Biosocial profile of New Zealand prosthetic eye wearers. The New Zealand Medical Journal. 2012;125(1363).

28. Rokohl, A. C., Mor, J. M., Trester, M., Koch, K. R., Heindl, L. M. Rehabilitation of anophthalmic patients with prosthetic eyes in Germany today-supply possibilities, daily use, complications and psychological aspects. Klinische Monatsblatter fur Augenheilkunde. 2019;236(1):54-62.

29. Figueiredo, L. a. D. A., Sampaio, A. A., Souza, S. E., Ferreira, F. J. R., Buzzá, E. P., Rizzatti-Barbosa, C. M. The role of prosthesis spacer for ocular prostheses. Journal of Craniofacial Surgery. 2017;28(4):e360-e3. DOI: 10.1097/SCS.0000000000003657.

30. Pathak, C., Pawah, S., Singh, G., Yadav, I., Kundra, S. Prosthetic rehabilitation of completely blind subject with bilateral customised ocular prosthesis: A case report. Journal of

clinical and diagnostic research: JCDR. 2017;11(1):ZD06. DOI: 10.7860/JCDR/2017/24434.9151.

31. Goiato, M. C., De Caxias, F. P., Dos Santos, D. M. Quality of life living with ocular prosthesis. Expert Review of Ophthalmology 2018;13(4):187-9. DOI: 10.1080/17469899.2018.1503534.

32. Pine, N. S., De Terte, I., Pine, K. R. An investigation into discharge, visual perception, and appearance concerns of prosthetic eye wearers. Orbit. 2017;36(6):401-6. DOI: 10.1080/01676830.2017.1337201.

6 APPENDECIES

APPENDIX A: QUESTIONNAIRE

Questionnaire 1: The Hospital Anxiety and Depression Scale (HADS)

Patients are asked to choose one response from the four given for each interview. They should give an immediate response and be dissuaded from thinking too long about their answers. The questions relating to anxiety are marked "A", and to depression "D". The score for each answer is given in the right column. Instruct the patient to indicate which answer currently describes their feelings.

A	**I feel tense or 'wound up':**	
	Always	3
	A lot of the time	2
	From time to time, occasionally	1
	Not at all	0

D	**I still enjoy the things I used to enjoy:**	
	Definitely as much	0
	Not quite so much	1
	Only a little	2
	Hardly at all	3
D	**I can laugh and see the funny side of things:**	
	As much as I always could	0
	Not quite so much now	1
	Definitely not so much now	2
	Not at all	3

A	**Worrying thoughts go through my mind:**	
	A great deal of the time	3
	A lot of the time	2
	From time to time, but not too often	1
	Only occasionally	0

D	**I feel cheerful:**	
	Not at all	3
	Not often	2
	Sometimes	1
	Most of the time	0

A	**I can sit at ease and feel relaxed:**	
	Definitely	0
	Usually	1
	Not Often	2
	Not at all	3

D	**I feel as if I am slowed down:**	
	Nearly all the time	3
	Very often	2
	Sometimes	1
	Not at all	0

A	**I get a sort of frightened feeling like 'butterflies' in the stomach:**	
	Not at all	0
	Occasionally	1
	Quite Often	2
	Very Often	3

D	**I have lost interest in my appearance:**	
	Definitely	3
	I don't take as much care as I should	2
	I may not take quite as much care	1
	I take just as much care as ever	0

A	**I feel restless as if I have to be on the move:**	
	Very much indeed	3
	Quite a lot	2
	Not very much	1

D	**I can enjoy a good book or radio or TV programme:**	
	Often	0
	Sometimes	1
	Not often	2
	Very seldom	3

	I look forward with enjoyment to things:	
	As much as I ever did	0
	Rather less than I used to	1
	Definitely less than I used to	2
	Hardly at all	3

	Scoring (add the As = Anxiety. Add the Ds = Depression). The norms below will give you an idea of the level of anxiety and depression.	
	0-7 = Normal	
	8-10 = Borderline abnormal	
	11-21 = Abnormal	

Questionnaire 2: Ocular Prosthesis Satisfaction Survey at Artificial Eye Centre

Patient ID : ……..

Age : ……..

Gender : ……..

Marital Status : ……..

Level of Education : ……..

Occupation : ……..

Income category : ……..

Ethnicity : ……..

Today's Date : …….

Reason for prosthetic eye? (Extracted from the file)

- Injury ☐
- Cancer ☐
- Other (Specify): …….

Prosthetic eye? (Extracted from the file)

- Right ☐
- Left ☐
- Both ☐

Date of surgery : ……. (from patients file)

Procedure? (Extracted from the file)

- Evisceration ☐
- Enucleation ☐
- Exenteration ☐

Was there an implant? Yes / No

If yes, what type of implant? (Extracted from the patient file)

- Silicone ☐
- Hydroxyapatite ☐
- Porous Implant ☐
- Not sure ☐

Was the implant implanted during the time of surgery or as a secondary procedure?
(Extracted from the file)

- Time of surgery ☐
- Secondary procedure ☐

Satisfaction survey

1. How long did you have to wait from the time of surgery for the ocular prosthesis?

..... (Months)

2. Was the appearance of your face improved by the implant of your ocular prosthesis?
   - Yes ☐
   - No ☐

3. If yes rate the degree of improvement
   - Minimal ☐
   - Modest ☐
   - Very Good ☐
   - Beyond Expectations ☐

4. Were you pleased with the appearance of your face after the ocular prosthesis was inserted/implanted?
   - Not at all ☐
   - Somewhat ☐
   - Moderately ☐
   - Very much ☐
   - Completely ☐

5. Did you regard the appearance of your face as “natural” (no noticeable signs of ocular prosthesis implant)?
   - No ☐
   - Somewhat ☐
   - Yes ☐

6. Do you think others can notice that you are wearing prosthesis?
   - No ☐
   - Somewhat ☐

- Yes ☐

7. Was the prosthesis treatment worthwhile for you or not?
   - Yes ☐
   - No ☐

8. Would you recommend this treatment to others who have already lost an eye?
   - Yes ☐
   - No ☐

9. Were people looking at you more when you had no prosthesis? ☐
   - Yes ☐
   - No

☐

10. Do people look at the same way after you had prosthesis fitted? ☐
    - Yes ☐
    - No ☐

11. Did you wear a conformer?
    - Yes
    - No

12. If yes to 11, did you adapt to prosthesis quicker because you had a conformer?
    - Yes ☐
    - No ☐

13. How comfortable is your prosthesis?
    - Very uncomfortable ☐
    - Somewhat uncomfortable ☐
    - Neither comfortable nor uncomfortable ☐

- Somewhat comfortable ☐
- Very comfortable ☐

14. How well does you prosthesis fit?
    - Poorly ☐
    - Well ☐
    - Very Well ☐

15. Does your prosthesis pop out by itself?
    - Yes ☐
    - No ☐

16. If the answer to 15 was yes, how often does your prosthesis come out?
    - Often ☐
    - Sometimes ☐
    - Seldom ☐

17. How well/poorly does your prosthesis stay in during household activities (for example, cooking, cleaning and gardening)
    - Poorly ☐
    - Well ☐
    - Very Well ☐
    - Not Applicable ☐

18. How well/poorly does your prosthesis stay in during exercising (for example running, going to the gym, playing sport)

- Poorly ☐
- Well ☐
- Very Well ☐
- Not Applicable ☐

19. How well/poorly does your prosthesis stay in while sleeping?

- Poorly ☐
- Well ☐
- Very Well ☐

20. How well/poorly does your prosthesis stay in during sneezing/coughing?

- Poorly ☐
- Well ☐
- Very Well ☐

21. Were you shown daily hygiene on your ocular prosthesis?

- Yes ☐
- No ☐

22. What type of ocular prosthesis are you wearing?

- Custom-made eye ☐
- Stock eye ☐

23. Do you remove your prosthesis at night?

- Yes ☐

- No ☐

24. How often is the ocular prosthesis removed for cleaning?

- Daily ☐
- Weekly ☐
- Monthly ☐
- Yearly ☐
- Seldom ☐

25. How easy/difficult is it to insert your prosthesis?

- Very difficult ☐
- Moderately difficult ☐
- Easy ☐

26. How easy/difficult is it to remove your prosthesis?

- Very difficult ☐
- Moderately difficult ☐
- Easy ☐

27. Do you have any eye discharge? (Yes or No)

- Yes ☐
- No ☐

If ‘yes’ above can you describe the nature and frequency of any discharge you are currently experiencing?

Discharge characteristics

a) Frequency of discharge

- Never ☐
- Monthly ☐
- Weekly ☐
- Twice weekly ☐
- Daily ☐
- Twice daily ☐
- Continuously

b) Colour of discharge

Clear White Cream Yellow

0 1 2 3 4 5 6 7 8 9 10

c) Volume of discharge

Minimal Profuse

0 1 2 3 4 5 6 7 8 9 10

d) Viscosity (Stickiness / thickness) of discharge

Runny Stringy Moderately thick Very thick

0 1 2 3 4 5 6 7 8 9 10

28. Do you think you have lost your peripheral vision?

- Yes ☐
- No ☐

29. Do you accomplish less than you would like to because of your vision?

a) Driving at night
- Yes ☐
- No ☐
- Not applicable ☐

b) Driving day time
- Yes ☐
- No ☐
- Not Applicable ☐

c) Work
- Yes ☐
- No ☐
- Not Applicable ☐

d) Sport
- Yes ☐
- No ☐
- Not Applicable ☐

30. Does your ocular prosthesis feel dry?
- Yes ☐
- No ☐

Thank you for your participation in this survey

APPENDIX B: ETHICS CLEARANCE

R14/49 Dr Damien Gnanapragasm

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M151155

NAME: (Principal Investigator)	Dr Damien Gnanapragasm
DEPARTMENT:	Ophthalmology Artificial Eye Centre, Krugersdorp
PROJECT TITLE:	Satisfaction In Ocular Prosthesis Wearers: A Comparison Between Stock Eyes and Custom Eyes at Artificial Eye Centre, Krugersdorp
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:	18/01/2016

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 Secretary in Room 10004, 10th floor, Senate House, University.
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 C: CONSENT

Consent to Allow a Survey to be Conducted for the Purposes of Research

To: Director of the Artificial Eye Centre, Krugersdorp,

This document hereby serves as a permission for Dr Damien Gnanapragasam, student number 9700343F, to undertake a research study on the topic chosen: **SATISFACTION IN OCULAR PROSTHESIS WEARERS: A COMPARISON BETWEEN STOCK EYES AND CUSTOM EYES AT THE ARTIFICIAL EYE CENTRE, KRUGERSDORP**

My objective in this study

- To assess by means of a questionnaire, the level of satisfaction of ocular prosthesis wearers with their prostheses;
- To assess the extent of complications experienced by ocular prosthesis wearers with their prostheses;
- To assess the quality of life experienced by ocular ocular prosthesis wearers regarding their health and functioning aspects; and
- To compare the above between wearers of custom eyes and stock eyes.

I intend to use my off-duty, annual leave time and research time to undertake my study. I have provided you with a copy of my research protocol, which includes copies of the questionnaire and consent forms to be distributed prior to the study. All data collection will be performed after approval by the Human Research Ethics Committee of the University of the Witwatersrand.

This research will be conducted under the supervision of my supervisor Dr Sue Williams.

The intended research will be fully funded by the applicant and will not interfere with the daily running of the Artificial Eye Centre.

Director, Artificial Eye Centre:

Name Jorgen Geslik Date 4/11/2015

Signature