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Response of the Anophthalmic Socket to Prosthetic Eye Wear

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A thesis submitted in fulfilment of the requirements for the degree of

Doctor of Philosophy in Optometry.

The University of Auckland, 26th August, 2012.
Abstract

A regular complaint of anophthalmic patients is excessive mucoid discharge associated with their prosthetic eyes. This problem has received little attention in the literature and no evidence-based treatment protocol has been developed to deal with it. This unsatisfactory situation has provided the motivation for the studies reported in this thesis and its two broad aims which are: to investigate mucoid discharge associated with prosthetic eye wear and to help address gaps in the literature by reporting findings that impact on current clinical practice.

The thesis provides a background to the field of ocular prosthetics and describes the results of a systematic set of individual investigations that guide the research towards a greater understanding of the response of the socket to prosthetic eye wear. The data for the research was obtained from two surveys of New Zealand prosthetic eye wearers, from clinical evaluations and interventions and from in-vitro experiments. Equal interval photographic grading scales to measure conjunctival inflammation in anophthalmic sockets and the intensity and extent of deposits on prosthetic eye surfaces were developed and used for the first time in this research programme.

Mucoid discharge associated with prosthetic eye wear was found to be prevalent in the anophthalmic population of New Zealand and a major concern for prosthetic eye wearers. Surface deposits accumulate on prosthetic eyes that are not cleaned frequently. The results of the investigations in this thesis showed that the presence of these deposits improved the wetting characteristics of the prosthetic eye surface and facilitated the lubricating function of socket fluids. This evidence provided a causal link for the association between more discharge and more frequent cleaning and was a key finding that led to the development of a simple three phase model of the response of the socket to prosthetic eye wear and an evidence based protocol for managing mucoid discharge.

The work reported in this thesis has resulted in the preparation of six published papers and nine future research opportunities were identified.
Acknowledgements

This work is a team effort that could not have been accomplished without the support and encouragement of a large number of people and organisations.

I should firstly like to thank my supervisors: Associate Professor Robert Jacobs, Department of Optometry and Vision Science and Mr Brian Sloan, practicing Ophthalmologist and Oculoplastic specialist. Their personal styles were very different but their professionalism, wisdom and dedication were an inspiration to me as they patiently guided my work and co-authored the six papers presented in this thesis.

Ms Joanna Stewart, Senior Research Fellow, Department of Epidemiology & Biostatistics contributed hugely to three of the papers as co-author and statistics expert. Thank you Joanna.

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I should like to thank the prosthetic eye wearers from throughout New Zealand who responded to the survey questionnaires and in particular, the 330 prosthetic eye wearers who volunteered to participate in the clinical evaluations and interventions.

Finally, I should like to thank my extraordinary wife Jenny who took such great care of me and the rest of our family while I was preoccupied with this project.
# Table of Contents

Abstract ii  
Acknowledgements iii  
Table of Contents iv  
Co-Authorship Forms ix  

Chapter 1 Introduction 1  
1.1 History of prosthetic eyes 1  
1.2 Anatomy and physiology 6  
1.2.1 Facial architecture 7  
1.2.2 The anophthalmic socket 7  
1.2.3 Eyelids 8  
1.2.4 Extra-ocular muscles 9  
1.2.5 The conjunctiva 11  
1.2.5.1 The substantia propria of the conjunctiva 13  
1.2.5.2 The epithelium of the conjunctiva 14  
1.2.5.4 Goblet cells 15  
1.2.5.5 Conjunctiva of the anophthalmic socket 16  
1.2.6 The lacrimal apparatus 17  
1.2.7 Tears 18  
1.2.7.1 Tear film 19  
1.2.7.2 Tear output 19  
1.2.7.3 Tear distribution in a natural eye 20  
1.2.7.4 Tear distribution with a prosthetic eye 21  
1.2.7.5 Function of tears 22  
1.2.7.6 Function of mucus 23  
1.3 Dry eye, tear protein deposits and papillary conjunctivitis associated with contact lenses and prosthetic eyes 23  
1.4 Eye loss 25
1.4.1 Monocular vision 26
1.4.2 Eye removal 27
1.4.2.1 Enucleation 27
1.4.2.2 Eviseration 28
1.4.2.3 Enucleation versus evisceration 28
1.4.3 Intra-orbital implants and post-surgical conformers 29
1.4.3.1 Intra-orbital Implants 29
1.4.3.2 Post-surgical conformers 31
1.5 Prosthetic eyes 32
1.5.1 Making and fitting a custom moulded prosthetic eye 32
1.5.2 The difference between stock and custom fit prosthetic eyes 33
1.5.3 Prosthetic eye motility 34
1.6 Aims of the thesis 35
1.7 Thesis organisation 37

Chapter 2 Concerns of anophthalmic patients wearing artificial eyes 39
2.1 Preface 39
2.2 Published Paper: Concerns of anophthalmic patients wearing artificial eyes 39
2.3 Additional material (unpublished) 46
2.3.1 Questionnaire sent to 278 anophthalmic patients. 46
2.3.2 Analysis of free comments provided by patients 49
2.4 Contribution and significance 52
2.5 Next steps 52

Chapter 3 Biosocial profile of New Zealand prosthetic eye wearers 54
3.1 Preface 54
3.2 Published paper: Biosocial profile of New Zealand prosthetic eye wearers 54
3.3 Additional material (unpublished) 65
3.3.1 Survey questionnaire 65
3.3.2 Investigation of the concerns of prosthetic eye wearers 69
3.3.2.4 Discussion 72
3.4 Contribution and significance 73
3.5 Next steps 73

Chapter 4 A survey of prosthetic eye wearers to investigate mucoid discharge 75
4.1 Preface 75
4.2 Published paper: A survey of prosthetic eye wearers to investigate mucoid discharge 75
4.3 Additional material (unpublished) 83
4.3.1 Full summary of opinions about mucoid discharge provided by ocularist websites 83
4.4 Contribution and significance 91
4.5 Next steps 91

Chapter 5 Measuring tools for prosthetic eye research 92
5.1 Preface 92
5.2 Published paper: The development of measurement tools for prosthetic eye research 92
5.3 Additional material (unpublished) 100
5.3.1 Cleaning prosthetic eyes 100
5.4 Contribution and significance 101
5.5 Next steps 101

Chapter 6 The response of the anophthalmic socket to prosthetic eye wear 102
6.1 Preface 102
6.2 Published Paper: The response of the anophthalmic socket to prosthetic eye wear 102
6.3 Additional material (unpublished) 109
6.3.1 Investigation of tear volume in anophthalmic sockets 109
6.3.1.2 Background 109
6.3.1.3 Method 109
6.3.1.4 Results 109
6.3.1.5 Discussion 110
<table>
<thead>
<tr>
<th>Chapter 7 Deposit build-up on prosthetic eyes and the implications for conjunctival inflammation and mucoid discharge</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.1 Preface</td>
</tr>
<tr>
<td>7.2 Published paper: Deposit build-up on prosthetic eyes and the implications for conjunctival inflammation and mucoid discharge</td>
</tr>
<tr>
<td>7.3 Additional material (unpublished)</td>
</tr>
<tr>
<td>7.3.1 Deposit build-up and wettability of prosthetic eyes incubated in artificial tear solution.</td>
</tr>
<tr>
<td>7.3.1.1 Background</td>
</tr>
<tr>
<td>7.3.1.2 Methods</td>
</tr>
<tr>
<td>7.3.1.3 Results</td>
</tr>
<tr>
<td>7.3.1.4 Discussion</td>
</tr>
<tr>
<td>7.4 Acknowledgement</td>
</tr>
<tr>
<td>7.5 Contribution and significance</td>
</tr>
<tr>
<td>7.6 Next steps</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chapter 8 Protocol for managing mucoid discharge associated with prosthetic eye wear</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.1 Introduction</td>
</tr>
<tr>
<td>8.2 Proposed model of the response of the socket to prosthetic eye wear</td>
</tr>
<tr>
<td>8.2.1 The initial phase after prosthesis insertion when homeostasis is being established (or re-established) within the micro-environment of the socket</td>
</tr>
<tr>
<td>8.2.2 The equilibrium phase</td>
</tr>
<tr>
<td>8.2.3 The breakdown phase where there is an increasing likelihood of harm from continued wear</td>
</tr>
<tr>
<td>8.3 Recommended cleaning regime for prosthetic eyes</td>
</tr>
<tr>
<td>8.4 Recommended protocol for managing mucoid discharge</td>
</tr>
<tr>
<td>8.5 Contribution and significance</td>
</tr>
<tr>
<td>8.6 Next steps</td>
</tr>
<tr>
<td>Chapter 9 Future research</td>
</tr>
<tr>
<td>--------------------------</td>
</tr>
<tr>
<td>9.1 The psychological impact of eye loss</td>
</tr>
<tr>
<td>9.2 Biosocial profile of prosthetic eye wearers in different countries</td>
</tr>
<tr>
<td>9.3 The effect of different cleaning regimes and methods on the surface finish of prosthetic eyes.</td>
</tr>
<tr>
<td>9.5 The duration of effects associated with removing and re-inserting prosthetic eyes</td>
</tr>
<tr>
<td>9.6 The physiology of anophthalmic sockets with a prosthetic eyes</td>
</tr>
<tr>
<td>9.7 The characteristics of deposits in the inter-palpebral zone of prosthetic eyes</td>
</tr>
<tr>
<td>9.8 The function of tears in anophthalmic sockets with prosthetic eyes</td>
</tr>
<tr>
<td>9.9 Tear characteristics in anophthalmic sockets with prosthetic eyes</td>
</tr>
</tbody>
</table>

| Chapter 10. References | 148 |
Chapter 1
Introduction

The loss of an eye through accident, disease or from congenital causes is a major event that impacts on a person’s self-image and wellbeing. It requires perceptual adaptations because of the loss of binocular cues to depth and the reduction in visual field on the affected side. It also requires changes in routine associated with wearing and maintaining a prosthetic eye, which is a device that occupies the anterior part of an anophthalmic socket. A prosthetic eye is designed to restore the appearance of the eyeball and the function of the eyelids. While the term ‘prosthetic eye’ is used throughout this thesis, other terms ‘ocular prosthesis’ and ‘artificial eye’ are synonyms. It is important that these terms not be confused with ‘bionic eye’ which is a device designed to produce artificial vision (Bionic Vision Australia, 2012). A variant of the prosthetic eye is a scleral shell prosthesis which fits over an existing eyeball or eyeball remnant.

This introductory chapter begins with a history of prosthetic eyes and goes on to describe aspects of anatomy and physiology of a normal eye and an anophthalmic socket, the perceptual changes that occur with eye loss, the procedures used by surgeons to remove a damaged eye and finally the manufacture of custom made prostheses. This background information sets the scene for addressing the main aims of the thesis which are to investigate mucoid discharge associated with prosthetic eye wear and to help address the gaps in the literature about prosthetic eyes by reporting findings that impact on current clinical practice.

1.1 History of prosthetic eyes

This summary is primarily sourced from a recent authoritative paper written by Neil Handley (2006) although the history of prosthetic eyes has been well documented in a range of other publications (Conroy & Hulterstrom, 1978; Enoch, 2007; Conroy, 1993; Martin & Clodius, 1979; Reisberg & Habakuk, 1990; Roman, 1994; Schirmer, 1961; Valauri, 1992; Wilson, 1972).

The earliest known prosthetic eye was found buried with a woman in Shahr-I Sokhta, Iran. It dated back to 2900–2800 BC and was probably made of bitumen paste which was covered with a thin layer of gold,
engraved with a central iris from which lines radiated out like the rays of the sun. Tiny holes were drilled at opposite sides near the edges of the circle and evidence of wear around the holes shows that it was probably held in place by a gold thread and worn like a conventional eye patch. Further evidence of the earliest prosthetic eyes being worn outside the socket comes from Egyptian and Roman priests who were making prosthetic eyes from painted clay attached to a cloth in the fifth century BC. The Greek term for this type of prosthesis was ‘ekblepharon’.

In the 1500’s, Frenchman Ambroise Paré described a prosthetic eye that was fastened to the end of a metal rod which bent around the back of the head to hold the eye in place (Wolff, 1968). This prosthesis was illustrated in his 1614 book which was published after his death. Paré was also associated with the first prosthetic eyes worn inside the socket (termed ‘hypoblepharae’) although an hypoblephara (undated) in a private British collection, made from wood and ivory suggests that the idea was not new. The 16th century prosthetic eyes worn inside the socket were made from gold or silver, with coloured enamel coatings but by the late 16th century, Venetian glass blowers were making more realistic prosthetic eyes from glass. These early glass eyes were fragile and easily broken. They were made by skilled glassblowers and lens makers who belonged to trade guilds. Glass eyes were also produced in Augsburg near Munich which was also an historic optical manufacturing centre until the 30 Years War (1618 to 1648) which destroyed many German states.

There were few British glass eye manufacturers, however, an advertisement for prosthetic eyes appearing in the September 1679 publication of ‘True Domestick Intelligence’, proclaimed William Boyse of London as,

‘the only person expert in making artificial eyes of enamel, covered after nature... which not only fitted for socket with ease to the wearer, but turned with all the facility of the real organ of vision’.

An advertisement two years later in ‘Merlin’s Ephemeris’ proclaimed him,

‘the only English operator in glass and the most expert in making artificial eyes so exact as not to be distinguished from the natural, they are of enamel with colour mixt the same, without either paint or lead, and worn with much ease, and so curious that they have the motion of the natural eye, being exactly made to the colour or bigness of the same which renders them very ornamental and commodious, the like was never made in England.’ (The College
For a brief period in the 1700s, the centre of manufacture for artificial eyes was Paris where, for example, Auguste Boissenneau’s prostheses could be purchased by mail order or by appointment in Paris. His thin enamel shells were designed to be worn over an atrophied eye. Dr Heister of Nuremberg, in 1752 recorded that he would prefer glass eyes to metal eyes because metal eyes repelled tear fluid and lost their brightness (The College of Optometrists, 2012). This may be the earliest mention of the wettability of prosthetic eyes which is discussed in Chapter 7. Friedrich Phillip Ritterich (1787 to 1866), a doctor and teacher at the University of Leipzig was appalled at the cost of artificial eyes from Paris and advocated for the establishment of a glass eye industry in Germany. For 30 years, he had imported artificial eyes from Paris which he visited at least twice to negotiate the purchase of stock. He carried 400 to 500 sample glass eyes in his general medical practice and charged his patients a pittance compared to the price being charged in Paris at the time. Ritterich encouraged German glassblowers to make glass eyes and even organised classes in glassblowing technique. He also established a free glass eye service at the Leipzig Eye Institute where glass eyes were custom manufactured for individual patients. This was the first time that the supply and fitting of glass eyes was seen as a service and where glass eyes were no longer a commodity to be purchased from stock.

By the mid19th century, the centre for glass eye manufacture had moved to Germany and in 1832 Ludwig Müller-Uri, a glassblower who made dolls eyes at the famous Lauscha Glass factory in Sonneberg, developed the cryolite glass eye which was more durable than previous glass eyes. In 1880, Hermann Snellen a Dutch eye surgeon, developed the ‘Reform’ eye in response to an increase in the number of enucleations being carried out following the introduction of anaesthesia and asepsis. The Snellen invention was a hollow glass eye with rounded edges. This was more full than the earlier shell-like glass eyes and facilitated the restoration of socket volume and improved wearing comfort. Cryolite glass eyes from the Lauscha Glass factory were exported all over the world, including to New Zealand where optometrists such as Peacock Optometrists who practised in Auckland in the early 1900s were importing stocks of glass eyes from Germany. They came in trays and clients would select the best fitting eye from an assortment. It was unfortunate if the colour or size did not match up.

A new material, poly (methyl methacrylate) (PMMA) was introduced by ICI in 1930 and marketed under
various trade names such as Plexiglas, Lucite and Perspex (Kollewe & Wearden, 2007; Chen, 2001). A medical grade PMMA was quickly adopted by dentists as a superior alternative to vulcanite rubber from which denture bases were made at the time. PMMA, a thermoplastic is a transparent synthetic polymer of methyl methacrylate. It is well tolerated by bodily tissues (provided it is polymerised correctly) and the techniques for moulding and curing were similar to that used for vulcanite. When German glass eyes became unavailable at the start of World War Two, British Royal Navy dental technicians investigated the use of PMMA for prosthetic eyes. At the same time Fritz W. Jardon, a German dental technician who immigrated to the United States in 1932 joined the American Optical Company in Southbridge, Massachusetts and became director of the Monoplex eye division (Le Grand Associates, 2012). Fritz Jardon and the Royal Navy technicians developed PMMA prosthetic eyes at about the same time (Handley, 2006). In Britain the Ministry of Pensions Plastic Eye Unit was established to provide ex-servicemen with PMMA eyes and in the United States the American Optical Company began mass producing them for the many US veterans who lost eyes in the war (Science museum, 2012). PMMA proved to be a more durable material than glass. Its working properties also enabled prosthetic eyes to be custom made for the first time from an impression of the patient’s socket. In the latter half of the 20th century PMMA eyes supplanted the 350-year-old glass eye industry although a small number of glass eye manufacturers still exist in Europe.

The history of contact lenses and scleral shell prostheses parallels the history of prosthetic eyes from about 1845 when earlier theoretical ideas began to develop into clinical experiments. In 1887 Friedrich Müller and Albert Müller, specialist glass blowers and prosthetic eye makers, created a protective shell for a patient. The patient had skin cancer which had necessitated the removal of the right lower lid and the temporal part of the upper lid causing the cornea to be permanently exposed. The Müllers fitted a clear glass shell which retained fluid around the cornea preventing it from drying out. The transparent shell also maintained the vision and 21 years later the patient wrote a letter reporting that he had worn the lens continually for 18 to 24 months at a time with no apparent corneal damage. The Müllers went on to mass produce thin glass lenses with a white body and clear corneal centres with variable optics. In 1888 Adolf Fick, a German ophthalmologist began making moulds of the corneas of rabbits’ eyes and constructing glass lenses. He progressed to human cadavers using glass scleral lenses made by Professor Ernst Abbe at Zeiss Optical and later on described six patients on whom he had tried his lenses. Fick created the
first scleral shell prosthesis for a patient with a blind, unsightly eye and was the first to document that the cornea bulged forward from the flatter curvature of the sclera. About 1946, Joseph Dallos and Norman Bier working independently, formulated the ‘ventilated’ scleral lens and in 1946, Keven Touhy, an optical dispenser created the first corneal contact lens. Touhy was making a regular scleral lens when the corneal portion cracked away by accident. He polished the edges and tried it on his wife who was myopic. The ultimate success of corneal lenses, however was due to the invention of PMMA which revolutionised contact lens and scleral shell manufacture in the same way as it revolutionised prosthetic eyes (Lamb & Sabell, 2007).

Until the introduction of PMMA all glass prosthetic eyes and shells were made and fitted by members of the optometry profession but dental technicians were more familiar with the new PMMA technology when it was introduced. Over the next 70 years (at least in the UK) dental technicians increasingly dominated and extended the field within a new discipline called maxillofacial prosthetics. Optometrists continued with contact lens manufacture for seeing eyes but mostly retreated from the care of patients whose eyes were blind. Since WW2, the different origins of PMMA prosthetic eyes appear to have resulted in two main schools for manufacturing artificial eyes. The US school centred on the American Society of Ocularists and the English school which is rooted in dental technology.

In the USA, the American Society of Ocularists (ASO) was established in 1957 and began to certifying ocularists in 1971. Existing ocularists were automatically certified, while newcomers were required to complete a five year apprenticeship plus 750 hours of related instruction approved by the ASO. In 1980, the National Commission of Health Certifying Agencies created the National Examining Board for Ocularists to conduct certifying examinations. Board certified ocularists are required to be recertified every three years (Handley, 2006).

In the UK, training in ocular prosthetics is carried out within the Master of Maxillofacial Technology degree programme. This training is a post graduate course for those with bachelor of dental technology degrees. Another way of obtaining training is provided by the National Artificial Eye Service (NAES) which originated in the Army Spectacle Depot during WW1. The NAEA trains its own specialised eye fitters and technicians and is managed by the Blackpool Teaching Hospitals NHS Foundation Trust (Handley, 2006).
In New Zealand in the late 1940s, the technique for making PMMA prosthetic eyes was introduced to dental technicians at Burnham Military Camp by Sir William Manchester, a plastic surgeon who observed the process while serving at Queen Victoria Hospital, East Grinstead, England during WW2. The technique was carried to Auckland when Sir William founded the Plastic Surgical Unit at Middlemore Hospital in 1952. Ocular prosthetics is currently taught as part of the Bachelor of Dental Technology degree course at the University of Otago and is included in registered dental technicians’ scopes of practice. A post graduate diploma course in maxillofacial technology (including prosthetic eyes) was introduced at the University of Otago in 2009.

The Ocularists Association of Australia, the American Society of Ocularists, the Canadian Society of Ocularists, the Ocularists Association of Southern Africa and the Association of European Ocularists are organisations that promote the professional development of ocular prosthetists by hosting conferences and disseminating information about prosthetic eyes (Ocularists.net, 2012).

The small number of ocular prosthetists and the technological and professional dislocation that the change from glass eyes to custom made PMMA prostheses brought about by the invention of PMMA 70 years ago may be a reason why prosthetic eye wear is under-investigated and under-reported in the present day scientific literature.

### 1.2 Anatomy and physiology

An appreciation of the anatomy and physiology of the orbit is a necessary precursor to understanding prosthetic eye performance, and the socket’s response to prosthetic eye wear, including discharge response. Unless otherwise cited, anatomical descriptions of the natural eye in section 1.2 have been referenced from Wolff (1968) and, as no literature has been found specifically describing the anatomy and physiology of the anophthalmic socket, un-referenced statements about anophthalmia and prosthetic eyes are based on my clinical observations.
1.2.1 Facial architecture

Overall facial dimensions and proportions are important in the context of prosthetic eye fitting as the eyes are one of the main aesthetic units that determine facial symmetry and expression. The face is seldom perfectly symmetrical, but the ideal face is said to have a slightly oval shape and is 5 eye widths wide and 8 eye widths high (Tolleth, 1987). Adult palpebral fissures are 8 to 11mm high and 28 to 50mm in width and are ideally separated by one horizontal palpebral width across the bridge of the nose (Chen, 2001). The margin of the upper eyelid hangs over the upper limbus of the cornea by 1 to 2 mm with its highest point between the pupil and the medial limbus. The pupil itself is positioned supero-medially of the centre of the iris. The upper eyelid crease, is formed where the anterior expansions of the levator aponeurosis muscle joins the skin (Galatoire, 2007). In Asians, the eyelid crease is often absent because the orbital septum is inserted lower down on the levator aponeurosis (Doxanas, 1984). Differences between Asian and other eyelid characteristics affect prosthesis design which must account for them in terms of inter-palpebral size, lid contour and blinking efficiency. The highest point of the lower eyelid is 5 to 7mm from the medial canthal angle where the lower punctum is located while its lowest point rests just lateral to the pupil at the inferior limbus. The eyelids typically slope upwards laterally, with the lateral canthus 2 mm higher than the medial canthus. Laterally positioned “laughter lines” are horizontal skin folds that are due to the action of the orbicularis oculi muscle. These folds become immobile ‘crow’s feet’ with aging accompanied by thinning of the dermis (Chen, 2001).

1.2.2 The anophthalmic socket

Knowledge about the anatomical features of the anophthalmic socket is critical to understanding how prosthetic eyes fit and perform. The anophthalmic socket varies considerably between individuals and its condition and form is influenced by the cause of eye loss, surgical technique, implant type and size, how long it has accommodated a prosthetic eye and age. Figure 1.1 shows the main features present in an anophthalmic socket with orbital implant and ocular prosthesis in place.
1.2.3 Eyelids

The eyelids are important structures to consider in any research into prosthetic eye wear as they retain the prosthesis in the socket and distribute tears during the action of blinking. The eyelids also provide a seal that prevents socket fluids from escaping past the prosthesis during wear.

The thinnest skin of the body is found in the eyelids which are given their form by the tarsi which are composed of dense fibrous tissue. The vertical height of the tarsus is 10 to 12mm in the upper eyelid and 4mm in the lower (Lemke & Della Rocca, 1990). The inner surface of the tarsus is lined with tarsal conjunctiva while the medial and lateral canthal ligaments anchor the tarsi (and eyelids) horizontally to the orbital rims (Chen, 2001). Horizontal tension to keep the eyelids pressed to the globe is provided by the tarso-ligmentous band which may become lax in the lower eyelid due to aging (and/or pressure from a prosthetic eye) leading to ectropion.

The orbicularis oculi muscle is the main eyelid protractor for the upper eyelid while the levator aponeurosis muscle is the main retractor. In upward gaze, contraction of both the levator and frontalis muscle occurs. The levator inserts on to the anterior surface of the upper tarsal plate, creating the upper eyelid.
crease. The horns of the levator aponeurosis anchor to the periosteum medially and laterally. When gaz-
ing down, the orbicularis muscle plays no active part and partial closure of the palpable aperture is due
to relaxation of the levator alone. The lower eyelid is depressed when gazing down due to the action of
the capsule-palpebral fascia which arises from the inferior rectus and inferior oblique and tarsal muscles
(Chen, 2001).

People blink about 12 times per minute (King & Michels, 1957; Carney & Hill, 1982) but this rate varies
between individuals and in different circumstances such as when anxious or in a noisy room. A dry atmo-
sphere does not appear to alter the blink rate. A complete blink takes about 1/3 of a second to complete
during which the eye-ball flickers upwards and inwards and back again. When people flinch reflexively
in response to danger the head moves backward and the orbicularis and its accessory muscles contract
causing the lids to squeeze shut. Blinking closure occurs when the levator aponeurosis relaxes just prior
to contraction of the palpable portion of the orbicularis oculi (McMonnies & Lowe, 2007). The wearing
comfort of prosthetic eyes may be affected by lagophthalmos which is not uncommon. A prosthesis that
is too large for the socket (either because the socket has contracted over time, or the prosthesis was made
large to match the companion eye), may promote lagophthalmos. In these cases the socket may become
dry and blinking will not wash away mucus and environmental debris from the inter-palpebral zone.

1.2.4 Extra-ocular muscles

The extra-ocular muscles are differentiated from the intra-ocular muscles, which operate on the inside of
the globe. When an eyeball is removed the extra-ocular muscles are harnessed for prosthetic eye motil-
ity in conjunction with an orbital implant. An appreciation of the anatomy of the extra-ocular muscles is
important for prosthetic eye research because the muscles are a major component of the anophthalmic
socket. They influence the fit of the prosthesis and their movements may play a role in the distribution
and flow of socket secretions. The muscles and the movements they generate in the prosthesis create the
potential for shear stresses that irritate the conjunctiva and result in excessive mucoid discharge.

Five of the six extra-ocular muscles arise from the orbital apex, while the inferior oblique arises from the
anteromedial floor of the orbit just inside the orbital rim. The extra-ocular muscles are the superior, in-
ferior, medial and lateral recti, and the superior and inferior obliques. The tendon fibres of these muscles insert themselves into the superficial layers of the sclera and merge with it.

The movements of the eyeball revolve around the approximate centre of the sphere so that the eyeball is not displaced. There are three axes of movement: the vertical axis around which the pupil moves left to right, and the horizontal axis around which the pupil moves up or down, and the anterior/posterior axis around which the eyeball intorts and extorts. The superior and inferior recti and the obliques work synergistically when carrying out certain movements. When looking upwards the superior recti and the inferior oblique work together and when looking downwards the inferior recti and superior oblique work together. The medial and lateral recti also work synergistically.

The superior rectus passes forwards and laterally before piercing Tenon’s capsule and inserting into the sclera. The levator aponeurosis which raises and holds the upper eyelid, is situated above the superior rectus and the tendon of the superior oblique. Contraction of the superior rectus causes the eye to look upwards or rotates it medially. It also assists in raising the upper eyelid.

The inferior rectus is the shortest of four recti muscles. It passes laterally and forwards along the floor of the orbit before piercing Tenon’s capsule and inserting into the sclera. A fascial expansion of the sheath of the inferior rectus attaches to the lower lid. Contraction of the inferior rectus causes the eye to look downwards or rotates it laterally. It can also depress the lower lid by means of its fascial expansion.

The medial rectus is more powerful than the lateral rectus and is the strongest of the recti muscles. It passes along the medial wall of the orbit, through Tenon’s capsule and into the sclera. Contraction of the medial rectus causes the eye to turn medially.

The lateral rectus passes forwards along the lateral wall of the orbit before piercing Tenon’s capsule and inserting into the sclera. Contraction of the lateral rectus causes the eye to turn laterally.

The superior oblique muscle is the longest and thinnest of the extra-ocular muscles. It passes forwards between the roof of the orbit and its medial wall to the trochlea which is a U-shaped fibro-cartilage pulley, closed superiorly by fibrous tissue. The trochlea is attached to the frontal bone just behind the orbital margin. A superior-nasal notch seen in many prosthetic eyes is made to accommodate the trochlea. The superior oblique narrows into a tendon enclosed in a synovial sheath as it passes through the trochlea.
The pulley action allows the muscle to bend downwards and backwards, and then laterally through Tenon’s capsule where it spreads out fan-like to its place of attachment on the sclera. Contraction of the superior oblique causes the eye to look downwards (together with the inferior recti) or laterally, or rotates it internally.

The inferior oblique passes between the inferior rectus and the orbital floor and inserts into the globe under the lateral rectus at the posterior lateral area of the eyeball. Contraction of the inferior oblique causes the eye to look upwards (together with the superior recti) or laterally, or rotates it externally.

1.2.5 The conjunctiva

A healthy conjunctiva is crucial to the comfort of a prosthetic eye and it is a key structure to consider in any research into prosthetic eye wear. The conjunctiva cushions the prosthesis and its epithelial layers contain various cells and glands that are the source of mucus that when excessive, causes problems for the prosthetic eye wearer. For these reasons the detailed anatomy of the conjunctiva is discussed here.

The conjunctiva is a thin, transparent mucus membrane that clothes the natural eyeball and the inside of the eyelids forming the conjunctival sac. The average circumference of the sac is about 9.5cm and is determined by the width of the palpebral fissure. The anterior epithelium of the sac merges with the epithelium of the cornea at the limbus while the conjunctiva at the margin of the lid is a transition zone between the skin and the conjunctiva proper. At the margin, the conjunctiva continues onto the eyelid where it ends in a shallow groove (the subtarsal fold) where the ducts of the meibomian glands are situated.

While the conjunctiva is a single continuous mucous membrane it has three main regions with different characteristics (Figure 1.2). They are the palpebral, bulbar and fornical regions. The palpebral region attaches to the eyelids, the bulbar attaches to the eyeball and the fornix region is the intermediate part that connects the other regions and forms the fornix. The palpebral region may itself be subdivided into orbital, tarsal and marginal zones. The marginal zone contains the ducts of the meibomian glands and the puncta through which the conjunctival sac becomes continuous with the lacrimal passages that lead tears to the inferior meatus of the nose. The upper tarsal conjunctiva adheres closely to the tarsus throughout its entire extent and the lower adheres closely for only half the width of the tarsus. The tarsal conjunc-
The conjunctiva in the orbital zone lies loosely over the underlying Müller’s muscle which lies between the superior border of the tarsal plate and the upper fornix. It is folded horizontally, allowing for movement of the eyeball. When examined closely, the superior half of the orbital conjunctiva is found to contain a series of shallow grooves and plateaux. These are not true papillae but may become so when inflamed. For example, when giant papillary conjunctivitis (GPC) occurs in anophthalmic sockets.

**Figure 1.2** The anophthalmic socket without a prosthesis showing the regions of the conjunctival sac.

The bulbar conjunctiva lies loosely on the sclera which can be seen through it, and is in contact with the tendons of the recti muscles covered by the fascia bulbi (Tenon’s capsule). At about 3 mm from the cornea, Tenon’s capsule, sclera, and the conjunctiva become much more closely attached. At the point of union a slight ridge in the conjunctiva may be detected. The conjunctiva of the fornix forms a complete circular fold that is interrupted on the medial side by the plica semilunaris and the caruncle. It is divided into superior, medial, inferior, and lateral portions. The superior fornix extends about 8 to 10 mm above the limbus in a normal eye. The inferior fornix, 8 mm below the limbus and the lateral fornix, about 14 mm from the limbus or 5 mm from the lateral commissure (Figure 1.3). These measurements vary considerably in anophthalmic sockets.
Figure 1.3 The conjunctival sac of a normal eye showing the unextended depth of the fornices.

The conjunctival fornix adheres to loose, distensible fibrous tissue of the fascial expansions of the sheaths of the levator and recti muscles, enabling these muscles to deepen the fornix when they contract. The fibrous tissue contains the glands of Krause and the muscle of Müller and becomes continuous with the tarsus centrally. The medial and lateral regions of the superior fornix are in contact with the orbital fat. The transparent conjunctiva of the inferior fornix enables its rich network of blood vessels to be readily seen as well as the whitish aponeurotic expansion from the inferior rectus and inferior oblique muscles.

The different regions of the conjunctiva in a normal eye vary considerably in structure and limit certain pathological processes to defined areas. Like all other mucous membranes, the conjunctiva, consists of two layers: the substantia propria and the epithelium.

1.2.5.1 The substantia propria of the conjunctiva

The substantia propria has two layers; the adenoid layer and a fibrous layer. The adenoid layer is 50 to 70 µ in thickness and initially forms in the fornix at 3 to 4 months of age where it, together with a growing conjunctiva, produces the horizontal folds present in the fornical conjunctiva. Lymphocytes are embed-
ded in the adenoid layer in large numbers and when the layer stops at the sub tarsal fold the lymphocytes cease as well.

The fibrous layer underlies the thinner adenoid layer but is virtually absent over the tarsus with which it merges. It encapsulates the glands of Krause, the unstriped muscle of Müller and the vessels and nerves of the conjunctiva.

1.2.5.2 The epithelium of the conjunctiva

In the lower eyelid the epithelium of the tarsal conjunctiva has three or four (sometimes five) layers of cells over its entire area, unlike the epithelium of the upper eyelid where two layers of cells are usually found. When four layers are present, the cells in the superficial layer are cone shaped, the next layer has elongated wedge shaped cells, the layer beneath this contains polygonal cells and the basal cells are cubical.

At the conjunctival margin on the lids, the muco-cutaneous junction divides dry and moist areas where the marginal strips of tear fluid end sharply and where the openings of the meibomian glands are found. On the cutaneous side, the eleidin and keratin layers of the skin end quite sharply and give way to about five layers of non-keratinised squamous epithelium of the marginal conjunctiva. The most superficial cells are flattened but still retain their nuclei and the deepest layer contains high cylindrical cells followed by several layers of polyhedral cells. Moving posteriorly, the layers of squamous cells gradually reduce, to be replaced by columnar and cubicle cells and further back, goblet cells begin to appear and become plentiful just beyond the sub tarsal fold.

In the upper eyelid, the epithelium of the tarsal conjunctiva is composed of a superficial layer consisting of tall cylindrical cells with oval nuclei whose axes lie at right angles to the surface, and a deeper layer made up of cubical cells with oval nuclei whose axes lie parallel to the surface. Towards the fornix, a third layer of polyhedral cells arises between the other layers and at the fornix, the epithelium is distinguished from the palpebral conjunctival epithelium by having this third layer.
1.2.5.4 Goblet cells

Goblet cells are the main source of the mucus that may become excessive in anophthalmic sockets with prosthetic eyes. Goblet cells are unicellular mucous glands, present in all areas of the conjunctival sac with the greatest numbers populating the medial third (Figure 1.4). They are large, round oval cells with flattened nuclei near the base but become larger and more oval as they rise from where they are formed amongst be cylindrical cells of the deepest layer of the conjunctiva, to the surface. The cytoplasm of the goblet cell is almost entirely filled by a sac containing cylindrically shaped mucous granules which contain mucoproteins GP1, GP2 and GP3M, consisting of glycoproteins, especially sialomucins. When the goblet cells reach the surface of the conjunctiva the sac ruptures and the granules are released and spread across the surface of the conjunctiva where they readily attach themselves to the microvilli of the epithelial cells. Collectively, the goblet cells secrete about 2 to 3 µL of mucus per day per eye which is about 1/1000th of the total fluid produced. Goblet cells, and the mucins they secrete, greatly increase when the conjunctiva becomes inflamed (Liotet et al., 1985).

![Distribution of goblet cells on the conjunctiva with eyelids everted](image)

**Figure 1.4** Distribution of goblet cells in the conjunctiva of a natural eye.
1.2.5.5 Conjunctiva of the anophthalmic socket

The loss of the eyeball is accompanied by a rearrangement of the conjunctiva and lacrimal apparatus, a loss of support for the upper and lower lids and a loss of orbital volume. Furthermore, following the fitting of an ocular prosthesis, cytological features of the conjunctiva undergo a change, as does the nature of tears. After enucleation or evisceration, the loose conjunctival lining of the newly formed socket adjusts as it heals and there is an inevitable loss of conjunctiva area. The plica semilunaris becomes indistinguishable but although the caruncle retains its position, its lateral border is often drawn posteriorly into the socket after removal of the eyeball. The provision of a prosthetic eye restores the fornices, which may have temporarily foreshortened, and returns the eyelids to their original positions where they resume their normal function.

Kim et al. (2008) investigated the cytology of conjunctival changes in anophthalmic patients who wore an ocular prosthesis. They used impression cytology which is an easy and non-invasive technique that employs cellulose acetate filter paper to lift surface cells from the conjunctiva. They obtained specimens from the centre of the superior tarsal conjunctiva, the centre of the inferior tarsal conjunctiva, and the centre of the bulbar conjunctiva at a point corresponding with the lateral edge of the limbus had it been present. The specimens, taken from both the socket and the companion eye, were examined by optical microscopy which was used to determine epithelial cell morphology and the density of goblet cells. Nucleus to cytoplasm ratios of non-goblet epithelial cells were measured by a micrometer under a light microscope. At all conjunctival locations sampled, the anophthalmic socket contained significantly less goblet cell density than the companion eye and significantly greater nucleus to cytoplasm ratios, especially in the lower tarsal conjunctiva. Counterintuitively, according to Kim et al. (2008), specimens from patients who cleaned their prosthesis once a day showed significantly less goblet cell density and greater nucleus to cytoplasm ratios at the superior tarsal conjunctiva than those who cleaned less often. The results of Kim et al. (2008) did not agree with the earlier results of an investigation by Chang et al. (2005) which found no statistical difference in goblet cell density or epithelial cell morphology in 12 anophthalmic patients with giant papillary conjunctivitis.
1.2.6 The lacrimal apparatus

A prosthetic eye depends upon the lacrimal apparatus in much the same way as a natural eye does. The lacrimal apparatus is composed of a number of glands and ducts that transport tears into the conjunctival sac from where they spread across the surface of the eyeball. The tears lubricate the eye, preventing friction between the globe and the lids, and drying out of the cornea. Most tears originate in the lacrimal gland and its accessory glands and travel medially to the puncta located at the margin of the upper and lower lids. From there they move first into the lacrimal canaliculus, then to the lacrimal sac, then on to the naso-lacrimal duct which drains into the inferior meatus of the nose. Under normal circumstances just enough tears to replace evaporation are generated so very little fluid passes down the naso-lacrimal duct. Basic tears are supplemented by reflex tears caused by psychogenic factors (weeping) or by mechanical or chemical irritation. Excessive reflex tears that are not blinked away via the naso-lacrimal duct spill over the lower lid.

The lacrimal gland is continuous posteriorly and divided anteriorly into separate orbital and palpebral lobes by the lateral horn of the levator aponeurosis muscle. The larger orbital part is situated superiorly in its fossa on the frontal bone in the lateral area of the orbital roof where it is connected by trabeculae. The ducts from the orbital portion pass through the smaller inferiorly placed palpebral portion. The lacrimal gland has short branch tubules and consists of masses of lobules, each about the size of a pinhead and separated with fat cells. The acini are made up of two layers of cells surrounding a central canal. The basal layer is myoepithelial in character and is flat and contractile while the other cells form the true secreting cells which are cylindrical in shape and contain granules. After secreting for a time, these cells become shorter and the granules disappear. The acini secretions pass on through very small interlobular ducts to arrive at slightly larger ducts before they finally open via 10 to 12 excretory ducts into the superotemporal conjunctival fornix with one or two more opening into the lateral part of the lower fornix.

With the removal of the eyeball, the lacrimal gland loses some support from the displacement of the lateral rectus but is otherwise undisturbed, being held in its fossa by weak trabeculae and supported further by the levator palpebrae muscle. The 10 to 12 excretory ducts that open into the superotemporal conjunctival fornix and the couple in the lateral inferior fornix continue their normal tear production.
The lacrimal gland is a serous gland and its tears are supplemented by fluids from the accessory lacrimal glands of Krause and Wolfing, the mucus producing conjunctival goblet cells and the sebaceous tarsal glands. In the accessory lacrimal glands of the palpebral conjunctiva, the epithelial cells lining the ducts contain secretory granules. These granules have a different electron density from those found within the acinar secretory cells, suggesting that the ductal epithelial cells produce mucoid secretion as well as goblet cells in the conjunctiva. If the lacrimal gland is missing or its motor nerve supply is cut off, the eye remains moist but basic tear secretion is radically reduced.

The glands of Krause have the same structure as the lacrimal gland. They are a continuation downwards of the palpebral portion of the lacrimal gland and most (about 42 of them) are embedded in the connective tissue of the sub-conjunctiva of the upper fornix between the palpebral portion and the tarsus. A further 6 to 8 can be found in the lower fornix, also on the lateral side. Similar glands to the glands of Krause are found in the Caruncle. The glands of Wolfring or Ciaccio are larger than the glands of Krause. There are 2 to 5 situated above or in the upper tarsus between the extremities of the tarsal glands and the superior border. Two further glands are found in the inferior edge of the lower tarsus. The excretory ducts are lined by a basal layer of cuboidal cells and a superficial layer of cylindrical cells which are similar to the conjunctiva on which they open. Henle’s glands are probably not true glands but folds of mucous membrane cut transversely. They occur in the palpebral conjunctiva between the tarsal plates and both the superior and inferior fornices. They are lined by epithelium, which is similar to that of the surrounding conjunctiva.

Like other glands and ducts making up the lacrimal apparatus, when the eyeball is removed the glands of Krause in the superior fornix, the glands of Wolfring in the two tarsi and Henle’s glands in the orbital conjunctiva may be repositioned but remain functional.

1.2.7 Tears

Tears are essential for the health of the natural eye and serve many of the same functions in the anophthalmic socket such as lubricating the eyelids, cleansing the socket, wetting the prosthesis and protecting against bacteria.
1.2.7.1 Tear film

The pre-corneal film can be considered to be a triple layer structure with an aqueous centre, a thin lipid top layer produced by the tarsal glands of each eyelid and a bottom layer of mucoproteins from the conjunctival goblet cells. The normal pre-corneal tear film measures from 6 to 9 µm in thickness immediately after a blink, 20% less after five seconds 50% less after 30 seconds. The presence of the lipid layer on the surface of the pre-corneal tear film may be observed with a tear scope (Guillon & Godfrey, 2007). The lipid layer extends from the lid margins to cover the tear film and reduce evaporation. It is approximately 0.1 µm thick, varying considerably with the time of exposure and the size of the eye. It thins out gradually following a blink but is compressed and thickened again when the eyelids close. The lipid layer stays within the vicinity of the palpebral aperture and does not normally drain into the conjunctival sac with the rest of the tear film. Mucins from goblet cells in the conjunctiva are essential for tear film stability as they produce a hydrophilic interface with the aqueous layer of the pre-corneal tear film. At the same time, the deep, glycoprotein part of the mucin layer is hydrophobic enabling it to attach to the surface epithelial cell membrane of the cornea. This is critical to eye health and vision but the epithelial membrane is missing on a prosthetic eye and a triple layer pre-corneal tear structure may not form. Prosthesis lubrication and the role of surface deposits that form on prosthetic eyes are investigated in Chapter 7. A meniscus of tear fluid, the marginal tear strip, is formed at the margins of both upper and lower lids where the tears gather on blinking, and flow medially towards the puncta of each lid. Few tears cross the cornea when the eye is open and if it stays open too long the film breaks up completely and dries. Tear break up time (TBUT) is the time it takes for the tear film to break up after the last blink and is a measure of tear film quality. Norn (1969) described the tear film break up time as ‘corneal wetting time’ and on average, TBUT takes about 30 seconds but it varies widely between individuals. A TBUT of less than 10 seconds is abnormal and indicative of meibomian gland dysfunction and or dry eye (Guillon & Godfrey, 2007).

1.2.7.2 Tear output

The daily volume of tears has been measured by a number of researchers who have come up with different
results. The consensus appears to be that the lacrimal secretion normally produced is between 1 gram as suggested by Schirmer (1903), and 15 to 30 g measured by Norn (1965). Schirmer’s tear secretion test is unsatisfactory as a precise quantitative test the tear secretion but is of considerable value in comparing the production of tears between eyes in the same person and between eyes of different persons as it can reveal very dry eyes. A less invasive test for tear volume is the phenol red thread test which utilises a cotton thread impregnated with a dye (phenol) that changes colour from yellow to red when it is wetted by the tears. The thread has a kink at one end which is hooked over the margin of the lower lid for 15 seconds. When it is removed the red portion is measured. Normal tear secretion measures about 21 mm while 11 mm and below is considered low volume (Guillon & Godfrey, 2007).

Allen et al. (1980) reported that the volume of basic tears in the anophthalmic socket was the same as in the companion eye and that, because of the absence of reflex tears in the socket, the overall tear volume was much less than in the companion eye. Reflex tears are mostly generated when the cornea is stimulated and when this source of stimulation is removed along with the eyeball, reflex tears no longer appear. The presence of the prosthetic eye also shields against external stimulation although tears induced by emotion or from a foreign body in the socket continue as before.

1.2.7.3 Tear distribution in a natural eye

A meniscus of tear fluid, the marginal tear strip, is formed at the margins of both upper and lower lids where the tears gather up against the exposed portion of the eyeball. The tears forming the inferior marginal strip run up the cornea for one or 2 mm due to the wettability of the conjunctiva and/or corneal surface. The tear meniscus is present on a prosthetic eye but has been shown to be lower than on the companion eye (Kim et al., 2011). Tears do not normally spread anteriorly past the openings of the meibomian glands and their lipid secretions which usually prevent them from spilling over the lid. The tears forming the superior marginal strip run down the cornea for one or 2 mm and end abruptly in a sharp line. When the upper eyelids are lifted away from the globe, tear fluid flows up towards the superior fornix. When the lower eyelids are lifted away from the globe, tear fluid flows into the inferior fornix. The marginal tear strips form again immediately the lids are allowed to return to their normal position. The tears
contained in both the upper and lower marginal tear strips are continuous with the reservoir of tears that forms at the lateral canthus. By means of this tear lake, the lacrimal fluid generated under the upper lid is able to access the lower tear strip. In the natural eye, the uniform thickness of the 3 layered pre-corneal tear film is caused by the spreading action of the palpebral conjunctiva over the cornea and the drawing out of reconstituted and fresh lipids from the tarsal glands at the margins when the lids open. Similarly, mucins are distributed over the cornea and conjunctiva by the movement of the eyelids which are in close contact with the epithelium. It is not known how the 3 layered pre-corneal tear film is distributed over the anterior surface of a prosthetic eye but it is likely not to form. Provisional work on this question is reported in Chapter 9.

The tear strips at the eyelid margins drain medially toward the so-called lacrimal lake, where they bathe the caruncle which lies between the medial canthus and the plica semilunaris. The tears moisten the caruncle but in normal circumstances do not pool because the lacrimal punctum of each papilla, resting against the sclera, draws tears into the canaliculus by capillary attraction, gravity and negative pressure. When the eyelids close they meet first at the lateral canthus and progressively drive the tears medially along the marginal tear strips towards the punctum, and then into the canaliculus. When blinking occurs, the muscular activity creates a milking or pump action that draws the tears through the puncta. A seal is maintained between the eyelids and the globe and no tears enter the fornices.

1.2.7.4 Tear distribution with a prosthetic eye

As with other unreferenced comments about the anophthalmic socket, this section is based on the clinical experience of the author. The presence of a prosthesis is necessary for basic tear distribution and drainage to resume although it may not operate as efficiently as previously. The efficacy of the lacrimal system in the anophthalmic socket (with structures intact) greatly depends upon the fit of the prosthesis. The ideal fit is where the prosthesis is in even contact with all areas of the palpebral conjunctiva and the remaining bulbar conjunctiva. The prosthesis extends into the fornices to the point where motility is not restricted. Because socket tissues are soft and pliable, this does not mean that the shape of the prosthesis must correspond exactly to the shape of the empty socket. Rather, the prosthesis should roundly and
smoothly mould the tissues and support them near their original positions while leaving only limited spaces for lacrimal fluids to pool. The even contact pressure against the orbital and tarsal conjunctiva will ensure that most of the tears that are produced will find their way to the marginal tear strips, most via the tear reservoir at the lateral canthus, but also via the medial canthus. Effective tear drainage around a prosthetic eye also relies upon the anterior surface having the same curvature as the original globe to ensure that a proper seal exists between Marx’s line on the eyelids and the surface of the prosthesis. Marx’s line is a very distinct line of cells along the marginal zone and it is the frictional contact zone between the eyelids and the surface of the globe (Donald et al., 2003). It is situated posteriorly to the meibomian gland orifices and is 0.1mm +/- .09 mm wide. The integrity of the seal has implications for the tear meniscus and the proper functioning of the puncta which should turn inwards naturally until they dip into the tear strip adjacent to the surface of the prosthesis. Because the volume of basic tears is not large, the tear flow mechanism appears to function satisfactorily in most cases, although tear pooling may slow down the movement of tears through the socket/prosthesis system.

1.2.7.5 Function of tears

In the normal eye the tear fluids with their antibacterial and lubricating properties are essential for the health and optical properties of the cornea. The tears transport atmospheric oxygen and ions to the cornea and flush away environmental debris. Lysozyme is an enzyme that provides a degree of protection against certain gram positive bacteria while other antibacterial substances in tears with more potency than lysozyme may be also be present. Lactoferrin is plentiful in tears and may have an anti-inflammatory function which is effective in attacking the cell membrane of gram negative bacteria. The antibody proteins, IgA and IgG are commonly found in tears and other immunoglobulins may also be present. The secretory phospholipase A2 is not bactericidal against gram negative bacteria (E. coli, salmonella typhimurium and P.aeruginosa) but has enough concentration in the tear film to kill gram positive bacteria (monocytogenes and staphylococcus aureus) (Guillon & Godfrey, 2007).
1.2.7.6 Function of mucus

The role of mucus in anophthalmic sockets does not appear to have been studied before and while it can be expected to lubricate the prosthesis and maintain the health of the conjunctiva, it is unlikely that it behaves the same as observed in the natural eye. An investigation of socket fluids, including mucus is recommended in the future research section in Chapter 9.

Mucus is composed mainly of mucins (a family of large, heavily glycosylated proteins) and inorganic salts suspended in water. It covers many epithelial surfaces and is secreted into fluids such as saliva and tears (Bowen, 2012). The lacrimal mucus is made up of several types of glycoproteins which originate in the lacrimal glands, the epithelial cells and the goblet cells where high molecular weight glycoproteins or true mucus is produced. Glycoproteins have an immunological role (immunoglobulins, transferrin); they transport metals (transferrin, ceruloplasmin), ions, or other molecules (albumin), or are oxidative (ceruloplasmin). Glycocalyx is a surfactant and together with the true mucus, has an immunological role. The viscosity of the true mucus limits the spread of microorganisms which must have specialised mechanisms to survive and develop in the mucus substrate. The mucus also cleans the ocular surface by trapping exfoliated epithelial cells, miscellaneous surface debris, and bacteria. Blinking causes the mucus network to collapse into single threads in the fornices where they move along to the medial canthus and out onto the skin surface (Adams, 1979). Mucus has a lubricating function which facilitates movement of the eye and eyelids (Liolet, 1985) and finally mucus acts as a sponge that enables aqueous tears to remain in contact with the epithelium.

The excessive production of mucoid discharge associated with prosthetic eye wear is the key problem addressed in this thesis

1.3 Dry eye, tear protein deposits and papillary conjunctivitis associated with contact lenses and prosthetic eyes

Contact lenses and prosthetic eyes come into contact with the conjunctiva, share similar eyelid action, bathe in the same ocular fluids and accumulate surface deposits. Because of these similarities a number of problems associated with wearing contact lenses have implications for prosthetic eyes including dry
eye, tear protein deposits and papillary conjunctivitis.

Contact lens intolerance is often associated with dry eye which is defined as ‘a disorder of the tear film caused either by a tear deficiency or excessive tear evaporation that causes damage to the inter-palpebral ocular surface’ (Lemp, 1995). Tear deficiency is most often caused by reduced tear production and excessive tear evaporation caused by meibomian gland disease. Healthy tears are central to the successful wearing of contact lenses, which when introduced to the eye, nearly always result in an unstable tear film leading to discomfort if not managed properly. Many contact lens wearers suffer from dry eye or an inadequate tear film resulting in scratchy, gritty, watery, burning, or itchy eyes (Lalitha, 2007). As suggested in section 1.2.7.3, it is not known if a pre-corneal tear film forms over prosthetic eyes or not, but the adequacy of tears in anophthalmic sockets is a requirement for the wearing comfort of prosthetic eyes.

Tear protein deposition on contact lenses has been well researched while deposit build-up on prosthetic eyes is investigated for the first time in this thesis. Surface deposits on contact lenses are not always associated with contact lens-induced papillary conjunctivitis (CLPC) (Gellatly et al., 1988) as disposable lens may cause these symptoms while extended wear rigid gas permeable (RGP) lenses seldom develop CLPC (Grant et al., 1989). Lever et al. (1995) concluded that lens bound protein was not the primary cause of lens discomfort or intolerance when they found no correlation between total protein deposited and patient comfort. These results contradicted the results of Wardlaw and Sarver (1986) which suggested that discomfort was associated with deposits even when the deposits were not conspicuous. Wardlaw and Sarver (1986) observed that lenses with the most deposits were the ones more frequently associated with discomfort although the discomfort may have also been the result of lens dehydration. Deposition on contact lenses is discussed further in Chapter 7 along with deposit build-up on prosthetic eyes.

CLPC or giant papillary conjunctivitis (GPC) associated with contact lens wear was first reported by Spring (1974). Donshik (2003) found that 85% of reusable soft contact lens resulted in CLPC compared with only 15% of RGP lenses. CLPC may develop spontaneously after many years of successful contact lens wear and often occurs in one eye and not the other. The symptoms of CLPC usually come before papillary conjunctivitis is observed and there is a poor correlation between symptoms and observed enlarged papillae. The symptoms of CLPC or GPC are excess mucus production, itching, reduced contact lens tolerance and blurred vision due to mucus smearing and deposition. The signs are only apparent on
the upper tarsal conjunctiva and begin with hyperaemia and fine papillae which become larger (0.3 to 1 mm diameter) and larger (GPC > 1 mm diameter) with oedema and excess mucus lying between the papillae and fibrosis at the papillary tips. This mucus is mild at first and accumulates at the medial canthus during sleep. It may be accompanied by itchiness on lens removal. As the CLPC progresses towards GPC the mucus becomes more and more severe causing the eyelids to stick together. This increase in mucus severity is accompanied by a loss of translucency of the conjunctiva and more general conjunctiva inflammation. The cause of CLPC is a combination of an immune response to antigenic protein deposits and physical trauma to the conjunctiva adjacent to the surface and edge of the lens (Donshik, 1994). GPC occurs more frequently in allergy sufferers and is also seen with vernal keratoconjunctivitis in the absence of a contact lens and in ocular prosthetic wear. CLPC will resolve once contact lenses are removed but where this is impractical most cases will respond to improved contact lens hygiene and condition (Donshik, 2003) which targets eliminating or reducing deposits and improving the physical interface of the lens with the conjunctiva.

Studies of giant papillary conjunctivitis (GPC) associated with prosthetic eye wear have concluded that prolonged wear of prosthetic eyes is associated with GPC (Srinivasan et al., 1979) and that GPC is an allergic disease of the eye associated with increased numbers of mast cells, eosinophils and lymphocytes in the conjunctiva (Bozkurt et al., 2007).

1.4 Eye loss

In addition to changes to appearance and routine bought about by maintaining a prosthetic eye, the loss of an eye is accompanied by a reduction of the visual field and a loss of depth perception. These changes and the concerns of anophthalmic patients at the time of eye loss and after at least two years’ of prosthetic eye experience are investigated in Chapter 2. This section on eye loss describes monocular vision which all non-blind anophthalmic patients experience, the types of sockets requiring prosthetic restoration, eye removal surgery, including the placement of orbital implants and finally the manufacture of prosthetic eyes.
1.4.1 Monocular vision

The loss of cues to depth perception as a result of loss of binocularity is important at distances less than 7m to 10m but especially at distances less than 1m. Binocular cues to depth perception that are lost are: retinal disparity where objects are projected on to each eye at different angles; convergence, where the two eyes focus on the same object producing kinaesthetic sensations in the extra-ocular muscles; shadow stereopsis, where images of shadows are fused stereoscopically. Cues to depth perception that are retained with monocular vision include: motion parallax (superimposing visual images by moving the head from side to side), relative size (static and dynamic objects become smaller with distance), aerial perspective (distant objects are duller and bluer than close objects and have lower contrast), accommodation (focusing on objects closer than 2m produces kinaesthetic sensations in the ciliary muscles of the iris), interposition (a near object covers part of a distant object), curvilinear perspective (parallel lines become curved at the outer extremes of the visual field), texture gradient (finer details can be seen more clearly on close objects), light and shadow (reflections help determine an object’s shape and spatial position), image blurring (objects in focus blur at the extremes of the visual field) (Chen, 2001).

Acquired monocular vision reduces the horizontal visual field by 10 to 20%. This results in anophthalmic people needing to turn their heads more frequently than binocular people in order to make up for the lost portion of the field. In a visually guided grasping experiment, anophthalmic subjects produced more head movements than binocular subjects who had one eye covered suggesting that anophthalmic people utilised motion parallax to aid manual prehension (Ihrig et al., 2007). Nicholas et al. (1996) investigated contrast sensitivity in the remaining eye of anophthalmic subjects. They found that the earlier in development that eye loss occurred, the greater the range of enhanced contrast sensitivity of the remaining eye.

Additional concerns associated with acquired monocular vision are: safeguarding the remaining eye, the need to employ driving aids such as special mirrors, facial appearance, and prosthetic eye maintenance (Neuro Optometric Rehabilitation Association, 2012).
1.4.2 Eye removal

The procedures for removing the eyeball and reconstructing the socket to receive a prosthetic eye are included in the thesis so that the different kinds of post-operative structures can be understood. Patients presenting for a prosthetic eye(s) may have been born without an eyeball (anophthalmia), or with an undeveloped eyeball (microphthalmia). Their eye(s) may have been blinded and scarred due to injury and may perhaps have become phthisical. They may have had their eyeball/s removed surgically. There are three procedures for removing the eyeball: enucleation, evisceration and exenteration. Exenteration involves the removal of all orbital tissue, including the eyeball and its supporting structures. Exenteration requires an orbital prosthesis rather than an ocular prosthesis and is outside the scope of this thesis because mucoid discharge is not a problem for these patients.

1.4.2.1 Enucleation

Enucleation is a surgical procedure whereby the globe is removed leaving behind the conjunctiva, Tenon’s capsule, extra-ocular muscles and the stump of the optic nerve. A procedure described by Chen (2001) is summarised below.

The conjunctiva is dissected from the limbus with a 360° incision which then allows the Tenon’s layer to be lifted gently from the globe exposing the extra-orbital muscles. Starting with the medial rectus, each muscle is dissected from the globe which is now only attached to the orbital apex by the optic nerve. To make access to the optic nerve easier and to facilitate handling, silk sutures are fixed to the muscle stumps on the globe. These sutures enable the globe to be pulled forward and turned slightly outwards. This manoeuvre allows medial access for a curved hemostat to clamp the optic nerve about 4 mm behind the Tenon’s capsule. The optic nerve is held steady with the hemostat while curved scissors, again using a medial approach, are used to sever the optic nerve and its encasing orbital tissue. The globe is now free to be lifted out of the socket leaving the Tenon’s capsule, the free ends of the muscles and the clamped orbital stump to be inspected. An 18mm to 20mm diameter wrapped spherical implant is now placed in the socket. The four recti muscles are brought forward and secured to the implant wrapping. The Tenon’s layer is then closed over the implant and the conjunctiva is draped over the Tenon’s layer and
sutured in place (Chen, 2001).

1.4.2.2 Evisceration

The evisceration procedure involves the removal of the intra-ocular contents of the eye including all accessible uveal tissues, the retina, the vitreous, and the lens. The cornea may or may not be removed and an implant may or may not be inserted. A description of an evisceration procedure with excised cornea described by Chen (2001) follows:

A 360° conjunctival incision is made around the cornea and the Tenon’s capsule is undermined back to the insertions of the extra orbital muscles. This is followed by a second, 300° limbal incision that leaves the cornea attached at its inferior sector. The corneal pedicle is grasped with forceps and held while the ciliary body and the iris root are excised from the sclera. The entire orbital contents are scooped, scraped or sucked out and any residue of uveal pigment is denatured with 100% ethanol. Working from inside the scleral shell, one or two radial slits per diagonal quadrant are made in the sclera. These slits relax the scleral shell and allow it to expand to accommodate an orbital implant which is then inserted into the scleral cavity. The size of the implant is usually no larger than 18 mm because a larger implant may result in less motility as the limits of the length-tension relationship of the extra-orbital muscles is reached. The corneal pedicle is excised and discarded and the edges of the scleral wound are overlapped and secured with mattress stitches. Next, the Tenon’s layer is drawn forward and sutured and finally, the conjunctiva is closed (Chen, 2001).

1.4.2.3 Enucleation versus evisceration

A 2003 survey of 456 ophthalmologists in the United Kingdom found that 718 enucleations and 699 eviscerations were performed in that year (Viswanathan et al., 2007). The evisceration procedure is simpler and less invasive than enucleation and appears to provide better motility of the prosthesis and better long term stability of the anophthalmic socket (Chen, 2001). However, modern enucleation procedures rival the results of evisceration (Deacon, 2008) and are preferred because they provides better histological...
diagnosis, more space for larger implants, better cosmesis, lower risk of extrusion and sympathetic ophthalmia (Viswanathan et al., 2007). Ocular prosthetists favour evisceration over enucleation (Timothy et al., 2003).

1.4.3 Intra-orbital implants and post-surgical conformers

Before discussing the making and fitting of prosthetic eyes it is necessary to consider intra-orbital implants and post-surgical conformers. As described in the procedures for enucleation and evisceration, intra-orbital implants are placed in the cavity created when the eyeball is removed and buried beneath the tissues. Post-surgical conformers are commonly placed in the socket immediately after surgery and precede the fitting of the prosthetic eye.

1.4.3.1 Intra-orbital Implants

Before 1884 when an English doctor, Phillip Henry Mules implanted a glass sphere into the scleral cavity of an eye following evisceration, the prosthetic eye was the only component involved in the restoration of the eye. The implant restored lost orbital volume and gave the overlying prosthetic eye more movement (Handley, 2006).

The volume of the eyeball is approximately 6 to 7 mL depending on the size of the eye. Ideally, this volume should be replaced by the cosmetic prosthesis and the orbital implant. The ideal implant is one that is sufficiently large to keep the ocular prosthesis as light as possible but not so large as to put pressure on the conjunctival wound, or allow insufficient room for the prosthetic eye, which ordinarily requires at least 5 mm thickness at the centre. The ideal implant is also one that never migrates or extrudes through the overlying conjunctiva (Chen, 2001).

Implants are either non-integrated or integrated. Non-integrated implants (usually spherical and made of poly (methyl methacrylate) (PMMA) or silicone) are not directly attached to the extra ocular muscles. Integrated implants are directly attached to the extra ocular muscles. Early integrated implants, such as Castro Viejo implants, Allen implants, Iowa implants and Universal implants, had holes or channels to
accommodate the extra ocular muscles. Many anophthalmic sockets still contain these implants but the rate of migration and extrusion has been unacceptable and the search for better materials and designs has continued. In 1989, a patented integrated orbital implant called the ‘Bioeye’ was approved by the United States Food and Drug Administration (Enotes, 2012). This new ‘coral’ implant was made from hydroxyapatite (a material derived from ocean coral) which has an interconnected porous matrix with a chemical structure similar to bone. This implant undergoes fibrovascular ingrowth by the patient’s own tissue. The strongest claim for the hydroxyapatite implant when it was introduced was that if drilled, the resulting hole would epithelialise and seal itself against infection. A peg placed in the hole provided direct mechanical linkage between a prosthetic eye and the implant. The pegged implant was very popular for a time because it provided excellent motility (Ashworth et al., 1996) but this technique has fallen out of favour due to the need for additional surgery, complications due to pegging and the fact that satisfactory prosthesis motility can be achieved without pegging (Viswanathan et al., 2007).

Orbital implants that are currently in use are: hydroxyapatite, porous polyethylene, bio ceramic, wrapped and unwrapped PMMA sphere, and simple silicon sphere. Various implant wrapping materials such as donor sclera, preserved human fascia lata, polyglactin 910 mesh, vicryl mesh, preserved human and bovine pericardium, allow direct suturing to the implant while porous polyethylene (Medpor) may be used without a wrapping and sutured directly. The performance of these various implants is very hard to quantify because of different medical histories of patients, the size of the implant needed, the presence of infection at time of surgery, different surgical techniques and different follow up times (Chen, 2001). The survey of 456 ophthalmologists in the United Kingdom carried out in 2003 by Viswanathan et al. (2007) found that 92% of ophthalmologists in the UK inserted an orbital implant after enucleation, 43% after evisceration for endophthalmitis cases and 69% after evisceration for non-endophthalmitis cases. PMMA implants were the most popular (used by 41.5% of ophthalmologists) followed by high-density porous polyethylene (26.5%), hydroxyapatite (15.7%), natural coral (12.3%) and others (alumina or glass) (3.45%). Fifty seven per cent (57%) of implants were wrapped when placed in the orbit. Vicryl mesh (32%) was the most commonly used wrap followed by donor sclera (29%), salvaged sclera (22%), Mersilene mesh (13%) and others (5%). In 2003, motility pegging of implants was only used by 7% of UK ophthalmologists. A report on orbital implants in enucleation surgery by the American Academy of Ophthalmology (2003) concluded that there was no difference in implant or prosthesis motility between
porous intra-orbital implants and donor sclera-covered nonporous spheres or between integrated and non-integrated implants. The Academy also commented on the great variability of reported exposure rates for porous implants. Some surgeons reported a low incidence of exposure rates, similar to that for non-porous implants while others documented significantly higher exposure rates with porous implants. In the UK 14% of ophthalmologists reported cases of exposure after either enucleation or evisceration, 4% reported extrusion after enucleation and 3% after evisceration (Viswanathan et al., 2007).

No research has been carried out to determine whether complication free surgical methods, implant types or wrapping materials are associated with conjunctival inflammation or excessive discharge with prosthetic eye wear. However, conjunctival inflammation and excessive discharge accompany implant exposure or extrusion, undissolved sutures, unhealed tissue and infection. These complications are included in the comprehensive list of causes of discharge discussed in Chapter 3. While the extent to which the design of a prosthetic eye influences motility is under investigated, Shields et al. (1994) have commented that poorly fitting prosthetic eyes with flat irregular posterior surfaces caused conjunctival thinning leading to erosion by pressure necrosis.

### 1.4.3.2 Post-surgical conformers

A soft silicon or rigid PMMA clear, conformer (with holes to facilitate the flow of socket secretions) is inserted after both enucleation and evisceration procedures. Advocates for the conformer suggest that it protects the sutured wound and maintains the fornices (Avisar et al., 2011). However to achieve this, a conformer would need to stretch out the conjunctival folds which may place unnecessary tension on the wound edge. Clearly, the fornices are not maintained by loose fitting conformers and their use is questionable. The conformer shields the raw wound and maintains some lid support but the edges of the holes often irritate the conjunctiva causing inflammation and excessive mucoid discharge. Other causes of mucoid discharge are the main focus of this thesis. Post-surgical conformers should be replaced with a prosthetic eye as soon as possible after the tissues have healed and the swelling subsided. This is usually about five or six weeks following enucleation. During this time some contracture of the socket may occur (whether a conformer is present or not) as the conjunctiva adapts to its new situation. However
the conjunctiva is relatively pliable and able to be remoulded during the fitting of the ocular prosthesis. A variation of the post-surgical conformer is the cosmetic conformer which is a normal conformer with pupil, iris and scleral colouring. Patients appear to prefer the cosmetic conformer to the standard clear conformer because the cosmetic conformer has a more acceptable appearance (Avisar et al., 2011; Patel et al., 1997).

1.5 Prosthetic eyes

The absence or disfigurement of an eyeball upsets the symmetry of the face and the proper functioning of the eyelids which cannot open and close properly or blink away stagnant tears and environmental debris. A well fitted prosthetic eye not only delivers good cosmesis but fills the socket so that tears cannot pool and supports the eyelids in their natural position enabling them to carry out their function of cleaning and lubricating. For anophthalmic children, the wearing of a prosthetic eye also stimulates the growth of hard and soft orbital tissues on the affected side. Without a prosthesis, development of the affected side may fall behind and result in an asymmetric face (Dixit et al., 2005).

1.5.1 Making and fitting a custom moulded prosthetic eye

An understanding of the materials, design and surface finish used in the manufacture and fitting of prosthetic eyes is necessary for the thesis because they are factors that influence the response of the socket to the presence of the prosthesis. A number of techniques for manufacturing and fitting a custom fit PMMA ocular prosthesis have been developed. The method summarised here is employed by the author but techniques using a range of pre-manufactured components are more common. This technique involves 4 one-hour clinical sessions interspersed with laboratory processing.

At the first clinical session, an impression is taken of the socket using polyvinyl siloxane or some other suitable material. The impression is removed from the socket after it has set and cast in a plaster-of-Paris mould. The visible diameter of the iris of the other eye is measured with callipers and transferred to a PMMA button which is trimmed to the correct size on a small lathe. While on the lathe a shallow depres-
tion is made for the pupil using a drill bit ground flat on the end. The iris colours are matched directly to the patient’s natural eye and applied to the button using fine grade artists’ oil paints and the smallest of sable hair brushes. When the paint dries, a clear PMMA cornea is processed over the top of the iris and an iris/corneal button is produced.

During the second session this iris/corneal button is imbedded into a wax shape made from the impression of the socket. The ‘wax eye’ is inserted in the eye socket and moulded repeatedly until the correct direction of gaze, size and lid contour is achieved. After the clinical session, the iris/corneal button is keyed so that it will attach to the side of a two part mould of dental plaster. The first part of the mould is made by settling the wax eye into soft plaster in the lower half of a specially designed metal flask. When the plaster has set, it is coated with a separating solution before a second mix of plaster is poured over the wax eye to form the top half of the mould. When the second mix of plaster has set, the wax is removed and the cavity filled with white PMMA which is then polymerised by immersing the mould in water for at least 30 minutes at 72°C.

The third session involves trimming the artificial cornea back so that a second layer of “stroma” can be added to the iris to give depth and so that the pupil and limbic edges can be softened. To complete the sclera, PMMA powder in yellows, blues and browns is then applied before fine veins, teased from red cotton thread, are laid in. A clear veneer of PMMA is then processed over the entire anterior surface of the prosthesis locking in the iris colours and veins. Finally, the prosthesis is polished with a buff to a high standard of finish. Different polishing standards and their effect on prosthetic eye wettability and rate of surface deposition is investigated in Chapter 7.

At the final session the polished prosthetic eye is fitted and instructions are given for removing and reinserting the prosthesis and for its on-going maintenance. The majority of prosthetic eyes are successfully completed after the fourth session but if the appearance and/or function is not satisfactory, further fittings and sometimes, further surgery is required to achieve an optimum result.

1.5.2 The difference between stock and custom fit prosthetic eyes

The chief advantage of PMMA prosthetic eyes is that they can be custom moulded and coloured for indi-
vidual patients. This greatly improves their prospects for receiving a comfortable and aesthetically pleasing prosthesis with optimum motility. Unlike custom prosthetic eyes, stock eyes, whether made from glass or PMMA, are pre-made and come in a range of colours and sizes and have a right and left standard shape which is deeply concave at the back. The hollow back accommodates a variety of implant shapes and sizes but may allow socket secretions to pool and stagnate in the non-fitting spaces. The colour, fit, size and direction of gaze of a stock prosthetic eye are arbitrary but the prosthesis can be successful if there is large selection to choose from. The ability to modify the size and shape of a stock prosthetic eye during fitting greatly enhances their success.

The greatest advantage of stock prosthetic eyes is that they are inexpensive to manufacture and, provided the selection is large enough, do not need to be fitted or adjusted by an ocular prosthetist. This is an important consideration in countries whose populations do not have access to custom moulded prosthetic eyes because of cost. Few western countries use stock prosthetic eyes but provide either custom moulded prosthetic eyes or partially pre-manufactured eyes with, for example, pre-painted iris/corneal units that are fitted to a moulded base.

1.5.3 Prosthetic eye motility

Motility of the prosthetic eye is made possible by rectus muscles working in conjunction with the orbital implant. Prosthetic eyes fitted over implants without a motility coupling device have about 64% of normal horizontal excursions and 45% of normal horizontal saccades and pursuit movements (Chen, 2001). (Fig. 5)
The horizontal lateral movement of the prosthesis is normally greater than horizontal medial movement while upward and downward movement is limited. A fulsome implant is better for motility because the prosthesis will gain more purchase from a wider foundation than a smaller one. Prosthesis design features that influence motility are the anterior curvature and the fornical extensions. A flat anterior curvature may meet eyelid resistance making turning harder to achieve. The critical fit for optimising movement of the prosthesis is between the periphery of the prosthesis and the fornical conjunctiva. This fit supports the central position of the prosthesis but allows relaxed conjunctival folds to straighten out during prosthetic eye movement.

1.6 Aims of the thesis

The motivation for the studies reported in this thesis and the two broad aims were to investigate mucoid discharge associated with prosthetic eye wear and to help address the gaps in the literature by reporting findings that impact on current clinical practice.

The author has practiced as an ocular prosthetist for more than 30 years. A regular complaint of patients
throughout this period has been excessive mucoid discharge associated with their prostheses. Very little has been published about this problem and no evidence-based treatment protocol has been developed to deal with it. The approach taken in this thesis has been to design and carry out a systematic set of individual investigations that would guide the research towards an understanding of the causes of the problems and potential solutions.

The specific aims of the individual investigations were:

To identify the concerns of experienced prosthetic eye wearers and investigate whether these had changed since they lost their eye. *This investigation will rank the level of concern that wearers have about mucoid discharge associated with their prosthetic eyes.*

To describe the biosocial profile of New Zealand prosthetic eye wearers. *This study will provide demographic information and determine the prevalence and severity of discharge in the anophthalmic population.*

To better understand the causes and treatments of mucoid discharge associated with prosthetic eye wear. *The information provided by surveying prosthetic eye wearers, ocularist websites and the available literature will identify gaps in knowledge about mucoid discharge.*

To develop tools to measure the condition of ocular prostheses and the socket’s response to prosthetic eye wear. *The development of these measurement tools will be necessary for the planned research into discharge to continue.*

To investigate the anophthalmic socket’s inflammatory response to prosthetic eye wear. *This investigation will use the research tools to investigate potential links between conjunctival inflammation, deposits on prosthetic eye surfaces and discharge.*

To investigate the nature of deposition on prosthetic eyes and the implications for conjunctival inflammation and discharge. *This investigation will incorporate contact lens experience and experiments designed to explore how deposits build up on prosthetic eyes, their effect on surface wettability and how different standards of surface polish affect the rate of deposit build-up and surface wettability.*

To compile an evidence based protocol for managing non-specific mucoid discharge associated with
This protocol will be based on the investigations carried out in this thesis.

1.7 Thesis organisation

This thesis conforms to the University of Auckland PhD regulations for a thesis with publications.

This introductory Chapter provides a brief background to the prosthetic eye field and identifies the problems to be addressed by this thesis. Chapters 2 to 7 (inclusive) describe individual investigations and outcomes that build upon each other towards the establishment of an evidence based protocol for managing non-specific mucoid discharge associated with prosthetic eye wear.

Chapters 2 is preparatory in that it identifies the concerns of anophthalmic patients.

Chapter 3 profiles the anophthalmic population of New Zealand.

Chapter 4 reviews the literature on discharge and investigates associations between wearing conditions and discharge severity.

Chapter 5 develops measuring tools required for continuing the research.

Chapter 6 uses the newly developed tools to investigate conjunctival inflammation and deposition on prosthetic eyes.

Chapter 7 examines the role of surface deposits and their effect on inflammation and discharge.

Chapters 2 to 7 each use the same format as follows:

A preface introducing the work of the chapter.

A published paper or submitted manuscript in its published or submitted form.

Additional unpublished results

Contribution and significance of the Chapter

Next steps
Chapter 8 presents a model of the response of the socket to prosthetic eye wear and an evidence based protocol for managing mucoid discharge associated with prosthetic eye wear.

Chapter 9 identifies directions for future research.

Chapter 10 lists the references used in the thesis.
Chapter 2
Concerns of anophthalmic patients wearing artificial eyes

2.1 Preface

The aim of the research described in this chapter was to identify the concerns of experienced prosthetic eye wearers and to investigate whether these had changed since they lost their eye.

The survey questionnaire used in the study incorporated visual analogue scales to rank levels of concern about various issues, including mucoid discharge. It was the first time a survey to investigate the concerns of experienced prosthetic eye wearers had been carried out. The survey was an appropriate start to the thesis project because it introduced the investigation into mucoid discharge associated with prosthetic eye wear from the patient’s perspective. The study was published as an original article in the Journal of Clinical and Experimental Ophthalmology:

2.2 Published Paper: Concerns of anophthalmic patients wearing artifical eyes


The study is presented here in its published form.
Concerns of anophthalmic patients wearing artificial eyes

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ABSTRACT

Background: To identify the concerns of experienced artificial eye wearers and investigate whether these had changed since they lost their eye.

Design: A retrospective study of private practice patients.

Participants: Sixty-three experienced artificial eye wearers.

Methods: An anonymous questionnaire was posted to participants. Paired Wilcoxon tests were used to investigate changes to concern levels over time. Ordinal logistic regression was used to investigate associations of demographic variables with concern levels.

Main Outcome Measures: Changes in level of concern over time.

Results: At the time of initial eye loss, participants were mainly concerned about the health of their remaining eye, coping with monocularity and receiving good advice. Between initial eye loss and the present, reductions in concern occurred with judging distance, peripheral vision, appearance, receiving good advice, comfort, retention, colour and movement of the artificial eye, fullness of orbit, loss of balance and postoperative pain. Patients whose jobs involved the public were more concerned about appearance and reduced visual range than those in other occupations. Participants’ chief present-day concerns were health of the remaining eye and watering, crusting and discharge. All results above had a probability <0.05.

Conclusions: The study emphasized patients’ concerns about the health of their remaining eye and their need for good advice at time of eye loss. Knowledge that their initial concerns about judging distance, reduced peripheral vision and appearance all decrease over time may help clinicians in counselling these patients. Watering, crusting and discharge was the chief present-day concern after health of the remaining eye.

Key words: anophthalmia, artificial eye, ocular prosthesis, quality of life.

INTRODUCTION

The loss of an eye is a major event that impacts on a person’s self image. The resultant monocular vision requires adaptations to perception because of the loss of binocular cues to depth and the reduction in visual field on the affected side. The changes in routine associated with wearing and maintaining an artificial eye add to the factors that affect anophthalmic patients’ quality of life.

The literature on artificial eyes is primarily focused on issues that confront surgical teams and patients immediately before and after the loss of their natural eye. There is extensive literature on surgical procedures and on the perceptual implications of monocular vision. A programme to help
people adapt to the changes brought about by the sudden imposition of monocular vision has been proposed and suggestions for fitting artificial eyes are easily found. But there are few published studies that describe how people adapt to artificial eye wear over time.

Of the few that can be found Rasmussen and Rasmussen identified that the most frequent complications associated with artificial eye wear are: secretion, lagophthalmos, enophthalmos, prosthesis instability and exophthalmos. Song et al. surveyed satisfaction of anophthalmic patients, and Nicodem and Ferreira have used a questionnaire to gauge the psychosocial profile of the patient with anophthalmia.

The long-term experience of artificial eye wearers has received little attention, and we could find no published research that examines the concerns of anophthalmic patients, nor how these concerns may change over time. This study aims to address this by identifying the concerns of experienced artificial eye wearers, determining whether their concerns changed over time and whether gender, age, occupation, time since losing the natural eye or time since having the existing artificial eye fitted might be associated with particular concerns.

METHODS

Recruitment

The database of the New Zealand Artificial Eye Service, a private health provider operating in the North Island of New Zealand, was queried to find people who were aged 18 years and over and who had at least 2-years experience wearing an artificial eye. Letters were sent to 278 individuals inviting them to return expressions of interest if they wished to participate in an extensive research project involving them in a number of interventions and assessments. Sixty-nine patients responded to this invitation and six subsequently dropped out. The remaining 63 were sent an anonymous questionnaire that they all completed and returned by post.

Questionnaire

The participants were aware that the questionnaire was the initial part of a wider investigation into factors affecting artificial eye wear. The method of recruitment, the questionnaire and the wider study had ethics approval from the University of Auckland Human Participants Ethics committee.

The questionnaire was divided into four sections: Section 1 requested demographic information including: gender, age, occupation, date of eye loss and date of fitting the present ocular prosthesis. Section 2 asked participants to use visual analogue scales (VAS) to mark their level of concern about each of eight general factors associated with artificial eye wear. A VAS was associated with each named factor. The named factors were drawn from the clinical experience of the authors. For each factor the participants were asked to recall how concerned they were when they initially lost their eye and also their present-day level of concern. The left end of each VAS scale was labelled ‘not concerned’, and the right end was labelled ‘very concerned’. Following the eight named concerns participants were invited to add any additional general concerns they had about artificial eye wear. The format was such that a VAS was associated with each additional concern. The section ended with free text space and an invitation to provide additional comments.

Section 3 had the same structure as section 2 with a VAS associated with each concern. The questions pertained to patients’ specific concerns about their artificial eye. Again there was a space after the named concerns for participants to add any additional artificial eye concerns and to indicate their level of concern with a VAS.

Section 4 asked participants whether they experienced watering, crusting and discharge (yes or no). It also invited them to consider which of the following three items concerned them the most: (i) watering, crusting and discharge; (ii) judging distance; or (iii) appearance. This section invited participants to make further comments about their experiences with these issues if they wished.

Statistical analysis

The participants’ levels of concern for the items in sections 2 and 3 of the questionnaire were obtained from the VAS as a number from 0.0 to 10.0. Paired Wilcoxon tests were used to investigate whether levels of concern changed from the time of the initial loss of their natural eye to the present time.

Ordinal logistic regression was used to investigate the factors that could be associated with the present levels of concern. For all outcomes other than ‘pain from the operation’ and ‘phantom sight sensation’ the levels of concern were grouped into three ordinal categories. The three categories were VAS readings: (i) less than 3; (ii) from 3 to less than 7; and (iii) 7 or greater. The probability of low concern was modelled. Because of the limited distribution of VAS ratings for ‘pain from the operation’ and ‘phantom sight sensation’ these outcomes were treated as binary: either absent (VAS rating = 0) or present (VAS...
Concerns of anophthalmic patients

rating > 0). Age, gender, occupation, time since eye was lost and the time since present artificial eye was fitted were included as the explanatory variables. Each concern was analysed separately. Occupations were classified into two groups for the purpose of this test. The public group \((n = 33)\) involved patients whose occupations involved direct face-to-face communication with the public. The non-public group \((n = 27)\) did not work directly with the public.

RESULTS

Study population

See Table 1. The participants in the study were not markedly different from the population from which they were drawn although with a higher ratio of women. The median age of participants was 65, and the youngest participant was 41.

Concerns of anophthalmic patients

Concerns of anophthalmic patients when they first lost their eye

Participants' initial concerns are shown in column 2 of Table 2. Their main initial general concerns were: the health of the remaining eye (median level of concern 7.0), ability to judge distance (6.8), receiving good advice (6.6), reduced peripheral vision (6.2) and concerns about appearance (5.6). Their main initial specific concerns about artificial eyes were: retention (median level of concern 5.8), direction of gaze relative to the good eye (5.7), comfort (5.3), movement (5.3) and fullness of orbit relative to the good eye (5.3).

Current concerns of anophthalmic patients after more than 2-year experience wearing an artificial eye

The chief present-day general concern for anophthalmic participants (column 3 of Table 2) was health of the remaining eye (median level of concern 6.7). This was followed by concerns about receiving good advice (3.3), reduced peripheral vision (3.1) and ability to judge distance (2.2). Change to appearance (1.7) was next, and loss of balance (1.3), phantom sight vision (0.8) and pain from the operation (0.5) were of little concern for the majority of participants.

The chief present-day specific concern about artificial eyes was watering, crusting and discharge (4.8) followed by concerns about direction of gaze (4.7), size relative to the good eye (4.3), fullness of the orbit and eyelid contour (4.3). Comfort (3.0), movement (2.6) and concerns about colour (2.0) were less concerning, and most participants were not troubled by artificial eye retention (1.7).

Change in levels of concern over time

Changes in level of concern over time are shown in columns 4 and 5 of Table 2. For all variables, where there was evidence of a real change the levels of concern decreased. The health of the remaining eye was the top concern initially and again at the present time. A change over time was not demonstrated for concern over the health of the remaining eye, phantom sight vision, direction of gaze relative to the good eye, size relative to the good eye, eye lid contour relative to good eye and watering, crusting and discharge.

Table 1. Key features of the group of patients invited to participate (anophthalmic patients >18 years with at least 2-years experience wearing an artificial eye) compared with the group of participants (the sample)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Patients invited to participate ((n = 278))</th>
<th>Study participants ((n = 63))</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>62%</td>
<td>56%</td>
</tr>
<tr>
<td>Female</td>
<td>38%</td>
<td>44%</td>
</tr>
<tr>
<td>Median age</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>61 years (range 9–89)</td>
<td>66 years (range 41-83)</td>
</tr>
<tr>
<td>Female</td>
<td>59 years (range 19–95)</td>
<td>64 years (range 41-83)</td>
</tr>
<tr>
<td>Median age at eye loss</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>22 years (range 1–82)</td>
<td>26 years (range 1–76)</td>
</tr>
<tr>
<td>Female</td>
<td>56 years (range 1–91)</td>
<td>30 years (range 1–71)</td>
</tr>
<tr>
<td>Anophthalmic side</td>
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<tr>
<td>Left</td>
<td>45%</td>
<td>51%</td>
</tr>
<tr>
<td>Right</td>
<td>55%</td>
<td>47%</td>
</tr>
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<td>Both</td>
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<td>Reason for eye loss</td>
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<tr>
<td>Accident</td>
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<td>Congenital</td>
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<td>Medical</td>
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<td>41%</td>
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<tr>
<td>Median time since prosthesis fitted</td>
<td>1.92 years</td>
<td>1.67 years</td>
</tr>
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</table>

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Concerns of anophthalmic patients wearing artificial eyes

Figure 1 illustrates the dynamics of the change in levels of concern over time. The initial concerns are arranged with the highest levels on the left and the lowest on the right.

Other concerns identified by participants

Individual participants identified a number of concerns in addition to the concerns named in the questionnaire by the researchers. These are shown in Table 3.

Watering, crusting and discharge

Almost all of the participants (93%) reported experiencing watering crusting and discharge with 60% of these indicating that this occurred on a daily basis.

Participants' comments

The large percentage of participants (66%) who volunteered comments indicated that the questionnaire tapped into significant areas of concern. Forty-six per
Concerns of anophthalmic patients

Chapter 2  Concerns of anophthalmic patients wearing artificial eyes

Table 3. Concerns of anophthalmic patients additional to those already itemized in the questionnaire

<table>
<thead>
<tr>
<th>General concerns</th>
<th>Artificial eye concerns</th>
</tr>
</thead>
<tbody>
<tr>
<td>Future appearance because of aging</td>
<td>Removing and inserting</td>
</tr>
<tr>
<td>Lower lid laxity</td>
<td>Loss of damage</td>
</tr>
<tr>
<td>People staring at the prosthesis</td>
<td>Fixed pupil size</td>
</tr>
<tr>
<td>Communicating with people on the blind side</td>
<td>Rotating prosthesis when rubbing</td>
</tr>
<tr>
<td>Ability to earn a living</td>
<td></td>
</tr>
<tr>
<td>Ability to drive</td>
<td></td>
</tr>
<tr>
<td>Adjusting to use the opposite eye for sighting</td>
<td></td>
</tr>
</tbody>
</table>

Table 4. Associations of demographic variables with levels of current concern

<table>
<thead>
<tr>
<th>Current concern</th>
<th>Explanatory variable</th>
<th>Odds ratio† and Wald 95% confidence limits</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reduced side vision</td>
<td>Gender (female vs. male)</td>
<td>2.4 (0.72–7.8)</td>
<td>0.16</td>
</tr>
<tr>
<td></td>
<td>Age</td>
<td>1.0 (0.89–1.1)</td>
<td>0.94</td>
</tr>
<tr>
<td></td>
<td>Occupation (non-public vs. public)</td>
<td>4.0 (1.2–13.7)</td>
<td>0.03</td>
</tr>
<tr>
<td></td>
<td>Time since natural eye lost</td>
<td>0.99 (0.96–1.0)</td>
<td>0.27</td>
</tr>
<tr>
<td></td>
<td>Time since artificial eye fitted</td>
<td>1.0 (0.91–1.1)</td>
<td>0.73</td>
</tr>
<tr>
<td>Retention of artificial eye</td>
<td>Gender (female vs. male)</td>
<td>1.2 (0.34–4.1)</td>
<td>0.80</td>
</tr>
<tr>
<td></td>
<td>Age</td>
<td>0.91 (0.81–1.0)</td>
<td>0.13</td>
</tr>
<tr>
<td></td>
<td>Occupation (non-public vs. public)</td>
<td>0.90 (0.25–3.2)</td>
<td>0.87</td>
</tr>
<tr>
<td></td>
<td>Time since natural eye lost</td>
<td>0.98 (0.95–1.0)</td>
<td>0.22</td>
</tr>
<tr>
<td></td>
<td>Time since artificial eye fitted</td>
<td>1.2 (1.0–1.3)</td>
<td>0.01</td>
</tr>
<tr>
<td>Watering, crusting and discharge</td>
<td>Gender (female vs. male)</td>
<td>0.60 (0.20–1.8)</td>
<td>0.36</td>
</tr>
<tr>
<td></td>
<td>Age</td>
<td>0.91 (0.81–1.0)</td>
<td>0.10</td>
</tr>
<tr>
<td></td>
<td>Occupation (non-public vs. public)</td>
<td>1.3 (0.43–4.0)</td>
<td>0.64</td>
</tr>
<tr>
<td></td>
<td>Time since natural eye lost</td>
<td>0.98 (0.96–1.0)</td>
<td>0.23</td>
</tr>
<tr>
<td></td>
<td>Time since artificial eye fitted</td>
<td>1.1 (1.0–1.3)</td>
<td>0.03</td>
</tr>
<tr>
<td>Change to appearance</td>
<td>Gender (female vs. male)</td>
<td>0.51 (0.16–1.6)</td>
<td>0.26</td>
</tr>
<tr>
<td></td>
<td>Age</td>
<td>0.97 (0.86–1.1)</td>
<td>0.58</td>
</tr>
<tr>
<td></td>
<td>Occupation (non-public vs. public)</td>
<td>3.3 (0.98–11.3)</td>
<td>0.05</td>
</tr>
<tr>
<td></td>
<td>Time since natural eye lost</td>
<td>0.99 (0.97–1.0)</td>
<td>0.70</td>
</tr>
<tr>
<td></td>
<td>Time since artificial eye fitted</td>
<td>1.1 (0.94–1.2)</td>
<td>0.35</td>
</tr>
</tbody>
</table>

†Modelling the probability of no concern, that is, an odds ratio of >1 means higher odds of no concern.

The database of the New Zealand Artificial Eye Service from which the study population was drawn may not be representative of the over 18 years of age anophthalmic population in New Zealand. Notably, participants were an older group resident in the upper North Island. Also, the recency of manufacture of the current artificial eye (median age 1.92 years) suggests that patients were well maintained, which is not necessarily the case for people in the wider community. Further limitations of the study include the likelihood that it attracted older participants who arguably had more time and interest to participate. The age group expected to be in active employment were quite well represented with 42% of participants under the normal retirement age of 65 years. The low response rate from those initially invited to participate in investigations of artificial eye wear and from which the sample population was drawn may have resulted in individuals with particularly high

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or low levels of satisfaction with their prosthesis being more likely to participate. The study did not link the cause of eye loss to particular concerns, and it may be that prosthesis wearers experience different concerns or concern levels depending on whether eye loss was congenital or because of accident or medical reasons. A survey of patients from a range of public as well as other private sources could address this question.

The questionnaire has allowed experienced wearers of artificial eyes to provide insights into concerns that are relevant for new anophthalmic patients and the clinicians who care for them. These insights encourage health-care teams to be alert to answer carefully patients’ questions about their remaining eye and to be knowledgeable about the perceptual impact of monocular vision. The evidence that the anophthalmic patient’s initial concerns decrease over time may be of assistance to clinicians when counseling patients. New patients may also take heart from the study of Song et al.,5 which reported an overall rate of satisfaction with initial artificial eyes of 71.8%. Participants’ voluntary comments highlighted the main concern factors and enriched the data. The health of the remaining eye was their chief concern throughout, and this reinforces the wisdom of advising patients to undergo regular clinical examinations of their remaining eye at periods appropriate for each particular patient. Protection of that eye with impact resistant non-prescription or prescription safety lenses 6 together with an appropriately safe frame design may also provide peace of mind for patients.

The chief current concern for participants after health of the remaining eye was watering, crusting and discharge. This result was accentuated by the high proportion of participants experiencing discharge (93%) and the large number of comments volunteered about the discharge problem. From this evidence the authors conclude that further research into the nature and management of watering, crusting and discharge is warranted.

The analysis of associations of demographic variables with current levels of concern showed that anophthalmic patients in public occupations were more concerned about their appearance than patients in non-public occupations. This result might be expected. The analysis also showed that they had greater concerns about reduced peripheral vision. This merits further investigation as it seems that anophthalmic patients may feel more uncomfortable with their limited visual range in public settings than in other situations. Length of time since the present artificial eye was fitted was associated with decreased levels of concern about retention and watering, crusting and discharge. The reason these concerns changed in this manner may have been because problems with the earlier artificial eye were resolved with the replacement prosthesis.

The least initial level of concern was phantom sight vision. This is a common phenomenon for patients when they first lose their natural eye,6 but it appears to worry them less than the other concerns they are dealing with at the time.

Aside from watering, crusting and discharge, the artificial eye concerns that changed the least over time were concerns about direction of gaze, size and eye lid contour. These concerns largely relate to surgical and technical details of the anophthalmic socket and were more concerning for present-day artificial eye wearers than concerns about the characteristics of their prostheses.

The study highlights the importance to anophthalmic patients of the health of their remaining eye and their need for good advice at the time of eye loss. Anophthalmic patients’ initial concerns about ability to judge distance, reduced peripheral vision and change to appearance all decrease over time. Patients whose occupations involved face-to-face contact with the public were more concerned about their appearance and reduced visual range than those whose jobs did not involve the public. Watering, crusting and discharge warrants further study as this problem is a pervasive and inconvenient condition associated with artificial eye wear – it was the main current concern for anophthalmic patients after health of the remaining eye.

REFERENCES

2.3 Additional material (unpublished)

2.3.1 Questionnaire sent to 278 anophthalmic patients.

The questionnaire used in the investigation ‘Concerns of anophthalmic patients wearing artificial eyes’ is shown in Figure 2.1. It was tested by seven anophthalmic patients before being sent to 278 anophthalmic patients of the New Zealand Artificial eye Service. The questionnaire was part of my research for a MSc degree and was later accepted as work done towards the requirements for a PhD.
QUESTIONNAIRE

This anonymous survey is being conducted by Keith Pine under the supervision of the University of Auckland, Dept of Optometry and Vision Science as part of the research work towards a MSc degree. The survey is being offered to people who are experienced wearers of artificial eyes.

Your help is very much appreciated.

<table>
<thead>
<tr>
<th>Gender</th>
<th>Male</th>
<th>Female</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Occupation (Previous occupation if retired)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>When was your eye lost?</td>
<td></td>
<td>(month / year)</td>
</tr>
<tr>
<td>When was your present artificial eye fitted?</td>
<td></td>
<td>(month / year)</td>
</tr>
</tbody>
</table>

For each statement below please mark the line with a vertical pen-stroke | or a tick ✓ to indicate your level of concern on a scale from 1 (not concerned) to 10 (very concerned). There are no right or wrong answers. The first short table is an example.

HOW CONCERNED WERE YOU ABOUT THESE FACTORS….. WHEN YOU FIRST LOST YOUR EYE? DURING THE LAST FEW WEEKS?

| | Not concerned | Very concerned |
| | 1 2 3 4 5 6 7 8 9 10 | |
| Example | | |
| Example concern | | |

HOW CONCERNED WERE YOU ABOUT THESE FACTORS….. WHEN YOU FIRST LOST YOUR EYE? DURING THE LAST FEW WEEKS?

| | Not concerned | Very concerned |
| | 1 2 3 4 5 6 7 8 9 10 | |
| General concerns | | |
| Ability to judge distance | | |
| Reduced side vision | | |
| Loss of balance | | |
| Change to your appearance | | |
| Getting good advice | | |
| Pain from the operation | | |
| Phantom sight sensation | | |
| Health of the remaining eye | | |
| Other general concerns (Please name) | | |
| 1. | | |
| 2. | | |
| 3. | | |

Comments

____________________________________________________________________

____________________________________________________________________

More questions overleaf

Figure 2.1 continues next page.
## Concerns of anophthalmic patients wearing artificial eyes

**Figure 2.1** Copy of questionnaire that was sent to 278 anophthalmic patients.

<table>
<thead>
<tr>
<th>Artificial eye concerns</th>
<th>WHEN YOU FIRST LOST YOUR EYE?</th>
<th>DURING THE LAST FEW WEEKS?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comfort</td>
<td>Not concerned</td>
<td>Very concerned</td>
</tr>
<tr>
<td>Retention (artificial eye stays in)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Watering, crusting and discharge</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Movement</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Colour relative to your good eye</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eyelid contour relative to your good eye</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fullness of orbit relative to your good eye</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Size relative to your good eye</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Direction of gaze relative to your good eye</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Other artificial eye concerns (name)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Do you experience watering, crusting and discharge with your artificial eye?  
Yes ☐ No ☐

If yes, how often does the discharge occur?  ………………………………………………………

Which of these factors currently concern you the most about wearing an artificial eye?

- Watering, crusting and discharge ☐    
- Appearance ☐    
- Judging distance ☐

Comments:

_________________________________________________________________________________
_________________________________________________________________________________
_________________________________________________________________________________
_________________________________________________________________________________

Please continue on the back if necessary

**THANK YOU FOR COMPLETING THIS QUESTIONNAIRE AND HELPING US BETTER UNDERSTAND THE ISSUES ASSOCIATED WITH WEARING ARTIFICIAL EYES.**
2.3.2 Analysis of free comments provided by patients

In addition to answering specific questions, patients were requested to comment freely if they felt that they could provide more information on any particular subject. A total of 35 comments were received. The subjective comments enriched the data and added another dimension to the results. Table 2.1 categorises the comments into items of concern and presents them in descending order of number of comments from highest to lowest. The largest number of comments was about watering, crusting and discharge and supported the conclusions of the study that this group of symptoms was an important concern.
Table 2.1 Free comments made by anophthalmic patients about their concerns.

<table>
<thead>
<tr>
<th>Category</th>
<th>Free comments from questionnaire</th>
</tr>
</thead>
</table>
| Watering, crusting and discharge | 1. Discomfort. Sensitivity due to dry air, air conditioning etc.  
2. Suppurating, Stickiness, crusting.  
3. Discharge was a real problem – but again have learned to live with it.  
4. I have not been able to ascertain what causes crusting and discharge,  
5. I have from time to time experienced excessive itching and inflammation of the eye lids.  
6. Some days are better than others. There is always a light dusting of crustiness upon waking in the morning. I find splashing water over my face and eye, morning and evening helps to keep it clean. Any discharge is easy to remove but if not removed eye-lid becomes inflamed and infected needing antibiotic ointment which then needs the eye to be removed several times a day for several days. I have found that the less I remove the eye, the less trouble I have. Keeping it clean in situ works for me.  
7. One issue that does increase crustiness, discharge and discomfort is spending too much time in front of a computer.  
8. Eye waters and discharges more when I’m tired or run down  
9. Being around smoke or cigarette smoke aggravates the eye.  
10. Watering happens often during the day. Wind and tiredness has a huge impact on watering, crusting and discharge. Eyelid closes involuntarily when really tired. Eye very dry during this time.  
11. Stopped getting significant discharge when I changed jobs about 2.5 years ago. Worked in heavy industry.  
12. Watering, crusting and discharge seems to relate to tiredness, working night shifts, windy conditions and general health. Drooping of top lid also seems to be affected by the same.  
13. Rather than watering it is dryness that concerns me.  
14. The wind tends to dry my eye out which causes irritation and... |

Table 2.1 continues next page.
<table>
<thead>
<tr>
<th>Concerns of anophthalmic patients wearing artificial eyes</th>
</tr>
</thead>
<tbody>
<tr>
<td>dryness.</td>
</tr>
<tr>
<td>15. Heavy discharge with blocked sinuses and heavy cold or sometimes feels like grit under top lid towards the outside.</td>
</tr>
<tr>
<td>16. Most discharge after cleaning.</td>
</tr>
</tbody>
</table>

| Appearance     | 1. Socket has sunk and top and bottom eye-lid seems to be sagging. |
|                | 2. Appearance is important too with a currently droopy eyelid and raised brow. |
|                | 3. Shrinkage of eye socket. |
|                | 4. Very concerned about how the eye looks to other people. Do not want it to look artificial. |
|                | 5. Appearance becomes less important as one ages. |
|                | 6. I feel ashamed if people stare at me in wonder |
|                | 7. I have had the artificial eye for so long that only the appearance concerns me. |
|                | 8. Being teased and bullied at school as a consequence of appearance was a painful experience. |

| Perception     | 1. I do not drive on the motorway as cannot cope with traffic passing on both sides! So drive in slow moving areas. |
|                | 2. Judging distance was a big factor to begin with – over the years I have learned to cope with it – still have the odd problem. |
|                | 3. Judging distance at close up, ie reaching for a handed cup of tea and parking a car, in reverse in particular |
|                | 4. I find difficulty in walking down stairs/steps. Hard to judge distance unless holding on to rail. I am inclined to bump into them if I am turning right or moving to the right. |
|                | 5. Around small children and toys limits one. Judging distance is relative to the loss of sight, not wearing an artificial eye. It causes greater problems with driving in older age. Probably due to slowing down. |
|                | 6. I judge distance very well through experience. |

| Costs          | 1. Long term costs. |
|                | 2. No realistic compensation from ACC. |

Table 2.1 continues next page.
2.4 Contribution and significance

This was the first time that the concerns of experienced prosthetic eye wearers had been investigated. Participants identified mucoid discharge symptoms (watering, crusting and discharge) as the second most concerning issue for experienced prosthetic eye wearers after health of the remaining eye. This result confirmed the author’s clinical observation about the discharge problem but importantly, it also verified that research into mucoid discharge associated with prosthetic eye wear was a worthwhile project to undertake from the perspective of prosthetic eye wearers.

The results highlighted the importance of providing patients with good information and advice at the time of eye loss and patients’ continued need for reassurance about their remaining eye. Also, when counselling traumatised patients about their prospects for the future it is useful for carers to know that the early concerns of patients about appearance and coping with sudden perceptual changes are likely to decrease over time.

2.5 Next steps

In the discussion section of the published paper we commented that the database of the New Zealand Artificial Eye Service (2012) from which the study population was drawn may not be representative of the anophthalmic population of New Zealand. It would be useful therefore, to undertake a survey that had larger numbers of participants, a wider geographical spread and that included patients of all ages from both the private and public health systems. Furthermore, the incidence and severity of discharge in the wider anophthalmic population was unknown at the beginning of this research project. Also unknown
at this stage was the demographics of the anophthalmic population in New Zealand and the aetiology of eye loss. An investigation of these issues would inform future research in New Zealand and internationally because, aside from a study by Trawnik (1996) in Dallas, Texas, no literature could be found on the biosocial profile of anophthalmic people. The next step in this thesis therefore, would be to survey prosthetic eye wearers in New Zealand in order to confirm their concerns and to discover more about anophthalmic people in general, and the incidence and severity of discharge in particular.
3.1 Preface

While it was established in Chapter 2 that mucoid discharge was an important concern for anophthalmic patients it was not known if the wider population of prosthetic eye wearers shared the same concerns nor how prevalent or serious the discharge problem was. The size of the anophthalmic population itself was also unknown because of the relative scarcity and diversity of prosthetic eye wearers. The research described in this chapter used a questionnaire sent to all the anophthalmic patients in New Zealand who were able to be contacted. The responses came from all over this country and a wide cross section of the anophthalmic population was represented. In addition to investigating the incidence and severity of mucoid discharge the demographics and aetiology of eye loss was also examined. The manuscript presented here was published in the New Zealand Medical Journal.

3.2 Published paper: Biosocial profile of New Zealand prosthetic eye wearers

Abstract

Aim To describe the biosocial profile of New Zealand (NZ) artificial eye wearers and establish a basis for future research and international comparison.

Methods This retrospective study surveyed 431 NZ artificial eye wearers to investigate their ethnicity, gender, age, causes of eye loss, age of current prosthesis, ocular prosthetic maintenance regimes and the extent and severity of discharge associated with prosthesis wear.

Results Approximately 3000 people wear artificial eyes in NZ. Accidents were the main cause of eye loss prior to 1990 and medical conditions have been the main cause since. In the 1960s, the ratio of men to women losing an eye from accidents was 5:1, but during the past decade the ratio was 1.4:1. Socket discharge occurred at least twice daily for one-third of the study group.

Conclusions Approximately 1 in 1440 people wear artificial eyes in NZ. Decline of eye loss due to accidents is consistent with decreasing workplace and traffic accidents and may be due to improved medical management, workplace safety standards and safer roads. Mucoid discharge is prevalent in the anophthalmic population of NZ and an evidence based treatment protocol for discharge associated with prosthesis wear is needed. Research into this distressing condition is planned.

The prosthetic eye literature has a limited number of published studies describing artificial eye wear over time,1–3 however, with the exception of a study carried out in Dallas, Texas from 1973 to 1977 and repeated in 1990 to 1994,4 no information about the epidemiology of eye loss appears to be available. Furthermore, mucoid discharge is wearers’ second highest concern after health of the remaining eye,5 but the incidence and severity of this problem in the anophthalmic population is unknown.

This retrospective study is designed to address this lack of information about prosthetic eye wear in New Zealand and to establish a basis for future artificial eye research and international comparison. The study investigated artificial eye wearers’ ethnicity, gender, age, causes of eye loss, age of current prosthesis, ocular prosthetic maintenance regimes and the extent and severity of discharge associated with artificial eye wear.

Methods

Background—The New Zealand Artificial Eye Service is the only provider of artificial eyes that offers a local service in Northland, a region which has a mixed rural/urban population, roughly representative of New Zealand’s overall population. The estimate of the total size of the anophthalmic population of New Zealand was calculated by extrapolating the number of Northland domiciled patients on the New Zealand Artificial Eye Service database to the estimated residential population of New Zealand.6
Recruitment and study design—Ethics approval for a questionnaire designed to document factors associated with artificial eye wear was obtained from the Multi Regional Ethics Committee of the Ministry of Health. The New Zealand Artificial Eye Service, the Royal New Zealand Foundation of the Blind, the Accident Compensation Corporation and five District Health Boards agreed to search their databases for all patients who had lost one or two eyes and to post an anonymous questionnaire to them.

A total of 1373 questionnaires were mailed out. No record could be kept of ‘Gone No Address’ returns or if any patients received more than one letter. The Royal New Zealand Foundation of the Blind delivered the questionnaire to their members by email and no record was kept of the additional number of recipients.

The three sections of the questionnaire addressed different topics: Section 1 requested demographic information and information about how the artificial eye was cared for.

Data were gathered on: age, ethnicity, date of eye loss, why the eye was lost, date of fitting the present prosthesis and date of last professional re-polish, how often the prosthesis was removed for cleaning, the reason for adopting the particular cleaning regime, whether hands were washed before removing the artificial eye, whether the prosthesis was left out over-night, how easy it was to remove the prosthesis, and finally whether help was required to remove it.

Section 2 asked participants to describe the nature and frequency of any discharge they were currently experiencing. Responses to this question were obtained as a value from zero to ten using visual analogue scales (VAS) to measure each of the four discharge characteristics: colour, viscosity, volume and frequency. The visual analogue scales and the descriptors are shown in Figure 1.

The participants were then asked whether they felt that having their artificial eyes professionally re-polished improved discharge and if so, how long the improvement lasted. A further section contained an open invitation and space to comment on prosthetic eye wearing experience.

Figure 1. Visual analogue scales for self-measuring discharge characteristics.
Results

The 109 patients on the Northland database of the New Zealand Artificial Eye Service made up 0.07% of the 157,300 population of the Northland Regional Council. This percentage, extrapolated to the total population of New Zealand in 2010 (4,367,700) resulted in an estimated total of 3026 anophthalmic people.

A total of 431 artificial eye wearers (31% of 1373) returned the completed study questionnaire. An analysis of these returns by regional institution is shown in Table 1.

Table 1. Returns of the questionnaire by regional institution

<table>
<thead>
<tr>
<th>Institution</th>
<th>Questionnaires posted</th>
<th>Returned</th>
<th>Percentage (%) returned</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capital &amp; Coast District Health Board</td>
<td>50</td>
<td>25</td>
<td>50</td>
</tr>
<tr>
<td>Lakes District Health Board</td>
<td>53</td>
<td>15</td>
<td>28</td>
</tr>
<tr>
<td>Waikato District Health Board</td>
<td>90</td>
<td>20</td>
<td>22</td>
</tr>
<tr>
<td>Auckland District Health Board</td>
<td>380</td>
<td>96</td>
<td>25</td>
</tr>
<tr>
<td>Royal NZ Foundation of the Blind</td>
<td>Canvassed online</td>
<td>19</td>
<td>unknown</td>
</tr>
<tr>
<td>Accident Compensation Corporation</td>
<td>280</td>
<td>83</td>
<td>30</td>
</tr>
<tr>
<td>NZ Artificial Eye Service</td>
<td>420</td>
<td>146</td>
<td>35</td>
</tr>
<tr>
<td>Canterbury District Health Board</td>
<td>100</td>
<td>27</td>
<td>27</td>
</tr>
<tr>
<td><strong>Totals</strong></td>
<td><strong>1373</strong></td>
<td><strong>431</strong></td>
<td><strong>31</strong></td>
</tr>
</tbody>
</table>

Ethnicity—A comparison between ethnicities in the study population and the New Zealand population was made. Europeans were the only ethnicity to be over represented (79% of the study population compared with 70% of the NZ population). Māori people made up 13% of the study population compared with 14% of the NZ population. Pacific peoples (4% study, 7% NZ), Asian peoples (3% study, 9% NZ) and others (0% study, 1% NZ).

Gender—Of the 334 participants who provided personal details, 41% were women and 59% were men.

Age—Participants were represented across all ten age bands chosen for the study (Figure 2). Eighty-two percent (82%) were 40 years of age or over.
Eye loss—The reported causes of eye loss were: accident (50%), medical (43%) and congenital (7%).

Eye loss due to tumours of various kinds was the most prevalent medical cause followed by glaucoma, detached retina, cataract and then diabetes.

Workplace accidents were the most common type of accident followed by sporting/leisure accidents, home, motor vehicle, assault and lastly medical misadventure (Figure 3).
The highest proportion of eyes lost from any cause occurred between ages one and nine years inclusive (15% of all eyes lost). Between 10 and 69 years eye loss was evenly distributed over the decades (varied between 10% and 12% each decade).

Eye loss due to accident as a function of gender is shown in (Figure 4). For ages less than 40 years eye loss due to accident was significantly greater in men than women (P=0.002) but women and men over 40 lost eyes to accidents in similar numbers.

**Figure 4. Gender mix of eye loss due to accident**

![Graph showing gender mix of eye loss due to accident](image.png)

**Changing causes of eye loss**—Accidents were the main cause of eye loss before the 1990s but since then medical causes of eye loss have predominated (Figure 5).

Table 2 illustrates how the ratio of men to women whose eye loss was due to accident has varied over time.

**Table 2. Ratios of men to women whose eye loss was due to accident from 1960 to 2010**

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Ratio: men to women</td>
<td>5 : 1</td>
<td>2.3 : 1</td>
<td>1.8 : 1</td>
<td>2.4 : 1</td>
<td>1.4 : 1</td>
</tr>
</tbody>
</table>
Discharge associated with artificial eye wear—The average severity score (from 0–10 on the visual analogue scale) for discharge frequency was 5.55 (SD 2.8), discharge colour 5.33 (SD 2.6), discharge volume 3.68 (SD 2.19) and discharge viscosity 4.59 (SD 2.28) (Figure 6).

Figure 5. Cause of eye loss in New Zealand over time
Thirty-three percent of the study population marked a VAS score of ≥7 for frequency (discharge occurred at least twice daily) and 59.3% of the random comments about discharge were made by participants who scored ≥7.0 for discharge frequency. Ten percent of the study population marked a VAS score of ≥7 for discharge volume (moderately profuse), 32% for colour (creamy yellow) and 18% for viscosity (thick).

**Age of current artificial eye**—The majority of participants (64%) had worn their present prosthetic eye for four years or less, 21% for between 5 and 9 years, 8% between 10 and 19 years, and 8% for more than 20 years.

**Frequency of professional re-polishing**—51% of the participants had their artificial eyes re-polished every year, 9% more often than yearly and 40% less often.

**Artificial eye removal and cleaning regimes**—48% of people in the study population removed and cleaned their artificial eyes daily but 26% left their artificial eyes in place for more than a month. Twenty-six percent removed their prostheses overnight.

**Hand washing behaviour**—The majority of wearers (58%) always washed their hands before removing their artificial eye, 25% mostly washed their hands, 12% washed sometimes and 5% never washed their hands.

**Removal difficulty**—Eight per cent (8%) of wearers had difficulty removing their artificial eye including 6% who needed this to be done by others.

**Discussion**

While the 431 artificial eye wearers recruited to this study represented 31% of the 1373 letters that were mailed out they probably made up 14% of the total anophthalmic population in New Zealand which is estimated by the authors to be approximately 3000 or 1 anophthalmic person for every 1443 in the general population.

Thirty-six percent (36%) of study participants lost their eye(s) within the past eleven years indicating that individuals were more likely to participate if their experience of eye loss was more recent. This bias may have increased the number of participants whose current artificial eye was under 11 years old relative to those who lost their natural eyes more than 11 years ago. However, it is unlikely to have affected the main conclusions of the study.

Europeans who might be more comfortable than other ethnic groups completing the English language questionnaire may have biased ethnicity representation and accounted for the finding that Europeans were more highly represented in the study population than in the general population.

Another limitation of this study is that different surgical techniques, socket and eyelid problems, or unsuitable prostheses were not investigated. Discharge may be more severe in the presence of these problems, but there is no reason to suspect that such problems were more or less prevalent in our study population than in the general anophthalmic population. Future studies are planned to try to elucidate some of the mechanisms of increased socket discharge.

The literature on the characteristics of anophthalmic populations is sparse but some information can be found on related topics. For example, Chang et al⁸ describe...
aetiologies and clinical characteristics of corneal opacities leading patients to seek cosmetic treatments at the Department of Ophthalmology at Seoul National University Hospital. They examined 401 patients with corneal opacities and report characteristics of age and gender that were similar to the anophthalmic population in this study.

A notable exception was the considerably younger age when injury occurred in the Korean study. The Eye Injury Snapshot Data Summary, 2004–2008 from the USA also contained characteristics of age, gender and accident type that were reflected in this study although the ratios of accidents resulting in eye injury and eye loss are quite different. In particular, the most common place to injure an eye was in the home (44.1%) but relatively few eyes (16%) were actually lost through home injuries.

The causes and gender mix reported in a study of eye loss carried out in Dallas County, USA from 1990 to 1994 were broadly in line with this study except that the percentage of eye loss due to accident was higher (59.8% compared to 54%).

Comparisons with the literature are summarised in Table 3. While the studies are very diverse they suggest that gender mix (more young males) and causes of eye loss (more accidents) may be common to most present day anophthalmic populations.

Table 3. Comparisons of eye loss in New Zealand with related injuries in Korea and America

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Corneal opacities in Korea</th>
<th>Eye injury in the USA</th>
<th>Eye loss in Dallas County 1990–1994</th>
<th>Eye loss in New Zealand</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cause</td>
<td>Trauma: 50.6%</td>
<td>59.8%</td>
<td>54%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Medical: 43.9%</td>
<td>33.3%</td>
<td>46%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Congenital: 5.5%</td>
<td>6.9%</td>
<td>8%</td>
<td></td>
</tr>
<tr>
<td>Gender (all causes)</td>
<td>Men: 60.7%</td>
<td>64.2%</td>
<td>59%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Women: 39.3%</td>
<td>35.8%</td>
<td>41%</td>
<td></td>
</tr>
<tr>
<td>Gender (accident only)</td>
<td>Men</td>
<td>73%</td>
<td>65%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>27%</td>
<td>35%</td>
<td></td>
</tr>
<tr>
<td>Age when accident</td>
<td>0–15 yrs: 69.5%</td>
<td>0–18 yrs: 25.4%</td>
<td>0–19 yrs: 31%</td>
<td></td>
</tr>
<tr>
<td>occurred</td>
<td>15–55 yrs: 28.6%</td>
<td>18–45 yrs: 47.6%</td>
<td>20–49 yrs: 49%</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>46+ yrs: 26.9%</td>
<td>50+ yrs: 20%</td>
<td></td>
</tr>
<tr>
<td>Accident type</td>
<td>Home</td>
<td>44.1%</td>
<td>16%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sport/recreation</td>
<td>14.7%</td>
<td>25%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Workplace</td>
<td>15.6%</td>
<td>27%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Roads</td>
<td>11.4%</td>
<td>15%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>14.2%</td>
<td>18%</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>7.1% (gunshot)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Eye loss—Young men who lost their eyes because of accidents strongly altered the gender, age and cause of eye loss characteristics of the study population. This group was the reason that workplace and sporting/leisure accidents were the most prevalent. However, the dynamics of eye loss appear to be changing over time as eye loss due to accident has declined relative to medical causes and the gender mix of accident victims has changed with a decreasing ratio of men to women.

This study was not designed to uncover the reasons for these dynamics but the trend towards less accidents resulting in eye loss is consistent with the decrease of work...
related head and neck injuries between 2003 and 2010 reported by the NZ Accident Compensation Corporation7 and the decrease of traffic injuries from a peak of 23,385 in 1973 to 14,541 in 2009.10 Improved medical management of eye injury is likely to also play a part in the reduction of eye loss from accident.

**Discharge and artificial eye maintenance**—The observation that 59.3% of the random comments referring to discharge were made by participants who scored ≥7.0 on the 1-10 range of the visual analogue scale for discharge frequency suggests that these people were more motivated to write a comment about discharge than those with less severe scores. This in turn suggests that severity scores of ≥7.0 for frequency (discharge occurred at least twice daily) are likely to impact on the quality of life of prosthetic eye wearers.

It is disturbing therefore that one-third of the study population reported severity scores of ≥7.0 for discharge frequency and as many as 9% experienced severity scores of ≥7.0 for both volume and frequency. The high incidence and severity of this problem occurred even though access to professional prosthetic eye services was good. Unfortunately, a standardised treatment protocol for discharge associated with artificial eye wear is lacking11 and further research into the cause and treatment of this prevalent and distressing condition is needed.

**Conclusions**

This study has sought to address the lack of information about prosthetic eye wearers in New Zealand. We estimated that approximately 1 in every 1,440 people wear artificial eyes in this country and that most of the anophthalmic population lost their eyes through accident. Men under 40 years were the most ‘at risk’ group. The gender mix and cause of eye loss appears to be changing over time.

Accidents were the main cause of eye loss in the decades prior to 1990 and medical conditions have been the main cause since. The decline of accidents resulting in eye loss is consistent with decreasing workplace and traffic accidents in the general population and may be due to improved workplace safety standards, safer roads and better medical management. An additional finding of this study was that in spite of good healthcare provision, mucoid discharge is prevalent in the anophthalmic population of New Zealand with 33% experiencing discharge at least twice a day.

Further research is needed to establish an evidence based standardised treatment protocol for discharge associated with artificial eye wear.

**Competing interests:** Keith Pine owns and operates a private practice in ocular prosthetics, the NZ Artificial Eye Service.

**Author information:** Keith Pine, Ocular Prosthetist, Dept of Optometry and Vision Science, New Zealand National Eye Centre, The University of Auckland; Brian Sloan, Ophthalmologist, Dept of Ophthalmology, New Zealand National Eye Centre, The University of Auckland; Robert J Jacobs, Associate Professor, Dept of Optometry and Vision Science, New Zealand National Eye Centre, The University of Auckland

**Correspondence:** Assoc Prof Robert Jacobs, Department of Optometry and Vision Science, New Zealand National Eye Centre, The University of Auckland, Private Bag 92019, Auckland 1142, New Zealand. Email: r.jacobs@auckland.ac.nz
References:

3.3 Additional material (unpublished)

3.3.1 Survey questionnaire

The survey questionnaire (Figure 3.1) was not published in the paper due to space limitations. It is presented here as a supplement to the description in the methods section of the paper.
**QUESTIONNAIRE**

This survey is being conducted by Keith Pine as part of his PhD research project under the supervision of the University of Auckland, Dept of Optometry and Vision Science.

The survey is being offered to people who wear artificial eyes.

Your help is very much appreciated.

<table>
<thead>
<tr>
<th>Date of birth</th>
<th>Age when you lost your eye?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong><strong>/</strong></strong>/____</td>
<td>__________________________</td>
</tr>
</tbody>
</table>

Ethnicity (please tick)

- European
- Māori
- Pacific Peoples
- Asian
- Middle Eastern/Latin American/African
- Other (Please specify) ________________________________________________________________

How did you lose your eye(s) Accident □  Please describe if you wish __________________________

Medical □  Please describe if you wish __________________________

Congenital (birth defect) □  Please describe if you wish __________________________

When was/were your present artificial eye(s) fitted?   _______/________  (month / year)

When was/were your present artificial eye(s) last re-polished?  _______/________  (month / year)

How frequently do you have your artificial eye(s) re-polished?  __________________________

How often do you currently remove your artificial eye(s) for cleaning?  __________________________

Why do you remove your artificial eye this often?  __________________________

Do you wash your hands before removing your artificial eye(s)?

- Yes (always) □
- Yes (mostly) □
- Yes (sometimes) □
- No (never) □

Do you leave your artificial eye(s) out over night?  Yes □  No □

Is/are your artificial eye(s) easy to remove?  Yes □  No □

Do you remove your artificial eye(s) yourself or get help?  Self □  With help □
DISCHARGE

Please describe the nature and frequency of any discharge you currently experience by marking the line with a pen-stroke, thus: /. This will indicate your assessment of each discharge characteristic on a scale from 0 to 10. This first chart is an example.

**EXAMPLE of a how to use the chart to describe COLOUR of discharge**

<table>
<thead>
<tr>
<th>Clear</th>
<th>White</th>
<th>Cream</th>
<th>Yellow</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>8</td>
<td>9</td>
<td>10</td>
<td></td>
</tr>
</tbody>
</table>

Please complete the following charts.

**FREQUENCY OF DISCHARGE**

<table>
<thead>
<tr>
<th>Never</th>
<th>Monthly</th>
<th>Weekly</th>
<th>Twice weekly</th>
<th>Daily</th>
<th>Twice daily</th>
<th>Continuously</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>7</td>
<td>8</td>
<td>9</td>
<td>10</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**COLOUR OF DISCHARGE**

<table>
<thead>
<tr>
<th>Clear</th>
<th>White</th>
<th>Cream</th>
<th>Yellow</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>8</td>
<td>9</td>
<td>10</td>
<td></td>
</tr>
</tbody>
</table>

**VOLUME OF DISCHARGE**

<table>
<thead>
<tr>
<th>Minimal</th>
<th>Profuse</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

**VISCOSITY (stickiness/thickness) OF DISCHARGE**

<table>
<thead>
<tr>
<th>Runny</th>
<th>Stringy</th>
<th>Moderately thick</th>
<th>Very thick</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>8</td>
<td>9</td>
<td>10</td>
<td></td>
</tr>
</tbody>
</table>

Does having your artificial eye(s) professionally polished improve discharge? Yes ☐ No ☐

If yes, how long does the improvement last? ________________________________________

What seems to make your discharge worse?
________________________________________________________________________________
________________________________________________________________________________

What seems to make your discharge better?
________________________________________________________________________________
________________________________________________________________________________

Figure 3.1 continues next page
CONCERNS OF ARTIFICIAL EYE WEARERS

For each statement below please mark the line with a pen-stroke, thus: / This will indicate your level of concern on a scale from 0 (not concerned) to 10 (very concerned).

<table>
<thead>
<tr>
<th>HOW CONCERNED ARE YOU ABOUT THESE FACTORS?</th>
<th>Not concerned</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Judging distance</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reduced side vision</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Your appearance</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mucoid discharge</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Health of your remaining eye</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ability to earn a living</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Comments: Adam

EXPRESSION OF INTEREST IN THE REST OF THE STUDY

☐ (✓) I am not interested in participating in the rest of the study. (If you tick this box you do not need to fill in your name and contact details below. Thank you for your help).

☐ (✓) I am interested in the other parts of the study and possibly becoming a participant. Please send me more information and telephone me to discuss the project and answer my questions. (If you tick this box please fill in your address details below so we can contact you).

Name: __________________________________________

Address: ________________________________________

________________________________________________

Telephone: ______________________ Mobile: ___________

E-mail: _________________________________________

Parent’s or guardian’s signature (If participant is under 16 years of age):

________________________________________________

Figure 3.1 Questionnaire sent to 1373 anophthalmic patients throughout New Zealand. 431 patients (31%) returned the completed questionnaire.
3.3.2 Investigation of the concerns of prosthetic eye wearers

It was established in Chapter 2 that mucoid discharge was an important concern for anophthalmic patients but it was not known if the wider population of prosthetic eye wearers shared the same concerns as patients of the New Zealand Artificial Eye Service from which the study population was drawn. This investigation into the concerns of anophthalmic people had larger numbers of participants, a wider geographical spread and included patients of all ages from both the private and public health systems.

3.3.2.1 Introduction

The survey questionnaire described in Chapter 2 was completed by 63 private patients of the New Zealand Artificial Eye Service. An analysis of the data revealed that mucoid discharge associated with prosthetic eye wear was the anophthalmic patient’s second most concerning issue after the health of the remaining eye. This result confirmed the author’s clinical observation of patients’ concerns about discharge but not the concerns of prosthetic eye wearers in the wider population. The aim of this study was to investigate the concerns of a larger, more widespread population of prosthetic eye wearers and to compare the results of the two surveys.

3.3.2.2 Methods

The survey questionnaire (Figure 1) was sent to 1373 prosthetic eye wearers in New Zealand. Included in the survey questionnaire was a question about the level of concern prosthetic eye wearers had about judging distance, reduced side vision, appearance, mucoid discharge, health of the remaining eye and ability to earn a living. The answers were marked on visual analogue scales which measured levels of concern from 0 to 10 where 0 was not concerned and 10 was very concerned. In the first survey the scale was between 1 and 10 where 1 was not concerned and 10 was very concerned. The first scale was adjusted for the purposes of comparing the differences between the two surveys.

3.3.2.3 Results

Four hundred and thirty one (431) prosthetic eye wearers from throughout New Zealand completed and returned the survey questionnaire (Figure 3.1). The map in Figure 3.2 illustrates the distribution of
anophthalmic patients who completed the questionnaire. Concerns about ability to earn a living were negligible (Mean 3.17, SD = 1.0).

Figure 3.2 Map of New Zealand showing the distribution of anophthalmic patients who completed the questionnaire. The responses received from each geographic region are numbered.

The results of this survey compared with the results of the patient survey described in Chapter 2 are shown in Table 3.1 and Figure 3.3. The increase in concern levels between the second survey and the first for reduced side vision and appearance altered the ranking of concerns. Whereas mucoid discharge was the second highest concern after health of the remaining eye in the first survey, the second survey showed no difference between concerns about appearance, reduced side vision and mucoid discharge (P>0.05) as the second equal highest concern levels after health of the remaining eye.
**Table 3.1** A comparison of results between the first and second surveys on the concerns of anophthalmic patients.

<table>
<thead>
<tr>
<th>Concern</th>
<th>1&lt;sup&gt;st&lt;/sup&gt; survey mean level</th>
<th>2&lt;sup&gt;nd&lt;/sup&gt; survey mean level</th>
<th>Difference of means</th>
<th>95% CI of difference</th>
<th>T-test</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Judging distance</td>
<td>2.8</td>
<td>4.1</td>
<td>1.3</td>
<td>0.2852 to 1.9239</td>
<td>0.008</td>
<td></td>
</tr>
<tr>
<td>Reduced side vision</td>
<td>3.1</td>
<td>4.8</td>
<td>1.7</td>
<td>0.7483 to 2.3465</td>
<td>0.0002</td>
<td></td>
</tr>
<tr>
<td>Appearance</td>
<td>2.4</td>
<td>4.4</td>
<td>2.0</td>
<td>1.0226 to 2.8233</td>
<td>0.0001</td>
<td></td>
</tr>
<tr>
<td>Mucoid discharge</td>
<td>4.4</td>
<td>4.7</td>
<td>0.3</td>
<td>-0.6257 to 1.0166</td>
<td>0.64</td>
<td></td>
</tr>
<tr>
<td>Health of remaining eye</td>
<td>5.3</td>
<td>6.6</td>
<td>1.3</td>
<td>0.3978 to 2.2027</td>
<td>0.005</td>
<td></td>
</tr>
</tbody>
</table>

**Figure 3.3** Comparison of mean concern levels in the first and second surveys.

When levels of concern were averaged across the two surveys the ranking of concerns was health of the remaining eye, mucoid discharge, reduced side vision, judging distance and appearance (Figures 3.3 & 3.4).
3.3.2.4 Discussion

The study population of the second survey appeared to be representative of the anophthalmic population of New Zealand due to the wide geographic spread and number of responses to the questionnaire (Figure 3.2).

The second survey questioned participants about the five main concern factors identified in the first survey plus a question (not asked in the first survey) about participant’s ability to earn a living. With the exception of concerns about mucoid discharge which remained the same, all the other concern factors increased compared to the first survey. Mucoid discharge was still an important concern in the second survey as it ranked second equal with reduced side vision and appearance. Furthermore, when the two surveys were combined (Figure 3.4), concerns about mucoid discharge were the second highest after health of the remaining eye. The results of the second survey were therefore consistent with those obtained in the smaller study of 63 private patients described in Chapter 2. Health of the remaining eye was the chief concern for both studies and mucoid discharge was the second highest concern. The increased level of concerns about reduced side vision and appearance in the second survey indicate that these concerns are important and ways of mitigating their impacts should continue to be sought after by clinicians.
3.4 Contribution and significance

Mucoid discharge was found to be prevalent in the anophthalmic population with 33% experiencing discharge at least twice a day. The majority of these people (59.3%) were motivated to write comments about discharge which suggested that their quality of life was affected by their discharging sockets. The study also highlighted a report by Osborn & Hettler (2007) who surveyed members of the American Society of Ocularists in 2007 and concluded that a standardised set of protocols for managing mucoid discharge was lacking. They called for further studies to be carried out.

This study was important in a wider context because it established a baseline for future prosthetic eye research in New Zealand and internationally, making it possible for researchers to compare changing demographics of anophthalmic populations and the aetiology of eye loss over time and between countries. The results of the study provided insights into the changing dynamics between medical and accidental causes of eye loss and gender mix. These changes are likely to be linked to the decline of workplace and road accidents in the general population due to improved workplace safety standards, safer roads and better medical management. The estimation of the number of people who wear artificial eyes in New Zealand (3,000) was a useful statistic because the information is valuable for the health services catering to this small, well dispersed group. The study was consistent with the finding of the smaller survey reported in Chapter 2 and supported its conclusions that mucoid discharge was a major concern for prosthetic eye wearers.

3.5 Next steps

This chapter determined the scale of the discharge problem, linked discharge with prosthetic eye wearers’ quality of life and highlighted Osborn & Hettler’s (2007) conclusion that a standardised set of protocols for managing mucoid discharge was lacking.

The next step of this systematic set of investigations into mucoid discharge was to subject the data from the survey in this chapter to further analysis to determine whether relationships existed between anophthalmic patients’ demographics, personal prosthetic eye maintenance regimens, professional re-polishing
and discharge experience. Also a comprehensive review of the literature and of ocular prosthetists’ views was needed to identify gaps in knowledge about mucoid discharge and its management. These steps are taken in the next chapter.
Chapter 4
A survey of prosthetic eye wearers to investigate mucoid discharge

4.1 Preface

The investigation in the previous chapter provided demographic information about the anophthalmic population in New Zealand and determined the prevalence and severity of discharge. It obtained data from a questionnaire that was completed by 431 prosthetic eye wearers. This chapter aimed to better understand the causes and treatments of mucoid discharge associated with prosthetic eye wear by further analysing the information from the survey used in the Chapter 3. Additional information from ocularist websites and the available literature was reviewed in order to identify gaps in knowledge about mucoid discharge and its management.

4.2 Published paper: A survey of prosthetic eye wearers to investigate mucoid discharge


The study presented here was published in the Clinical Ophthalmology Journal.
A survey of prosthetic eye wearers to investigate mucoid discharge

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Background: This study aimed to better understand the causes and treatments of mucoid discharge associated with prosthetic eye wear by reviewing the literature and surveying anophthalmic patients.

Methods: An anonymous questionnaire was completed by 429 prosthetic eye wearers who used visual analog scales to self-measure their discharge experience for four discharge characteristics: frequency, color, volume, and viscosity. These characteristics were analyzed with age, ethnicity, years wearing a prosthesis, eye loss cause, removal and cleaning regimes, hand-washing behavior, age of current prosthesis, and professional repolishing regimes as explanatory variables. Eighteen ocularists’ Web sites containing comments on the cause and treatment of discharge were surveyed.

Results: Associations were found between discharge frequency and cleaning regimes with more frequent cleaning accompanying more frequent discharge. Color was associated with years of wearing and age, with more years of wearing and older people having less colored discharge. Volume was associated with cleaning regimes with more frequent cleaners having more volume. Viscosity was associated with cleaning regimes and years of wearing with more frequent cleaning and shorter wearing time accompanying more viscous discharge. No associations were found between discharge characteristics and ethnicity, eye loss cause, hand washing, age of current prosthesis, or repolishing regimes. Forty-seven percent of ocularists’ Web sites advised that discharge was caused by surface deposits on the prosthesis, 29% by excessive handling of the prosthesis, and 24% by other causes.

Conclusions: A standardized treatment protocol for managing discharge is lacking. More frequent prosthesis removal and cleaning was associated with more severe discharge, but the direction of cause and effect has not been established. Professional repolishing regimes had limited impact on discharge experience. Further research into the socket’s response to prosthetic eye wear, including the physical, chemical, and biological elements of the conjunctiva, the socket fluids, and the deposits that cover the prosthetic eye is recommended.

Keywords: anophthalmia, prosthetic eye, secretions, discharge, deposits

Mucoid discharge associated with prosthetic eye wear is a common occurrence that impacts on the quality of life of people who have lost an eye. Pine et al1 report that discharge is the second most important concern for experienced prosthetic eye wearers after health of their remaining eye and affects 93% of wearers – 60% of these on a daily basis.

The literature does not provide a complete understanding of the nature and causes of discharge associated with prosthetic eye wear. This is reflected in the range of opinions offered by ocularists’ Web sites and the lack of a standardized treatment...
protocol for this distressing condition. This study attempts to provide a better understanding of discharge by examining aspects of prosthetic eye wear that are likely to be associated with discharge. It investigates the influence on discharge of hand washing before handling the prosthesis, removal and cleaning regimes, repolishing frequency, and the effect on discharge of wearers’ age and wearers’ ethnicity.

**Methods**

A survey of 18 ocularist websites found to provide advice about mucoid discharge and/or prosthetic eye cleaning regimes was carried out. Ethics approval to send a questionnaire to prosthetic eye wearers in New Zealand was obtained from the Multi-region Ethics Committee of the Ministry of Health, New Zealand. The New Zealand Artificial Eye Service, the Royal New Zealand Foundation of the Blind, the Accident Compensation Corporation, and five District Health Boards agreed to search their databases and post the anonymous questionnaire to their anophthalmic patients.

A total of 1373 letters with the questionnaires were mailed out. No record could be kept of “Gone No Address” returns or if any patients received more than one letter. The questionnaire was divided into two sections: Section 1 requested demographic information and information about how the prosthetic eye was cared for. Data were gathered on age, ethnicity, date of eye loss, why the eye was lost, date of fitting the present prosthesis and date of last professional repolish, how often the prosthesis was removed for cleaning, the reason for adopting the particular cleaning regime, whether hands were washed before removing the prosthetic eye, whether the prosthesis was left out overnight, how easy could the prosthesis be removed, and whether help was required to remove it. Section 2 asked participants to describe the nature and frequency of any discharge they were currently experiencing using the visual analog scales shown in Figure 1. There was a scale for each of the four discharge characteristics: color, viscosity, volume, and frequency. Each scale was continuous with 0 at the left end and 10 at the right end. The descriptors placed above the scale assisted participants to mark a position along the scale that best described their experience with the particular discharge characteristic. Numbers and descriptors towards the right end of each scale reflected greater severity of discharge experience. For example, on the viscosity scale

### Figure 1: Visual analog scales for self-measuring four discharge characteristics.

<table>
<thead>
<tr>
<th>Frequency of discharge</th>
<th>Never</th>
<th>Monthly</th>
<th>Weekly</th>
<th>Twice-weekly</th>
<th>Daily</th>
<th>Twice-daily</th>
<th>Continuous</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Color of discharge</th>
<th>Clear</th>
<th>White</th>
<th>Cream</th>
<th>Yellow</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Volume of discharge</th>
<th>Minimal</th>
<th>Profuse</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Viscosity (stickiness/thickness) of discharge</th>
<th>Runny</th>
<th>Stringy</th>
<th>Moderately thick</th>
<th>Very thick</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>
“runny” corresponded with 0–1, “stringy” at 3–4 suggests the formation of mucus strands, “moderately thick” was placed at 6–7, and “very thick” at 9–10 reflected the most severe experience.

The participants were then asked whether they felt that having their prosthetic eyes professionally repolished improved discharge and if so, how long the improvement lasted.

**Statistical analysis**

To investigate factors related to the frequency, volume, color, and viscosity of discharge, a general linear model was used (one for each outcome) with explanatory variables of age, ethnicity (European/other, Maori/Pacific, Asian), years wearing a prosthesis, reason for eye loss (accident, medical, congenital), frequency cleaned (at least once per week [1], less than once a week but at least once a month [2], less than once a month but at least once a year [3], never [4]), frequency of professional repolish (entered as more frequently than yearly [1], every one to two years [2], less than every two years but sometimes [3], never [4]), hand washing before removing (coded as no [0], yes sometimes [1], yes mostly [2], yes always [3]), and age of current prosthesis. As many participants did not record the frequency of professional repolishing, the analyses were first run including this variable but it was removed when not shown to be associated with any discharge characteristic.

**Results**

Forty-seven percent of ocularists’ websites advised that mucoid discharge was caused by surface deposits that build up on the prosthetic eye, 29% that it was caused by excessive handling of the prosthesis, and 24% gave other causes, such as dust and dirt in the socket.

The recommended cleaning regime for 47% of the sites was to not remove the prosthesis unless it was uncomfortable or discharging. Thirty-five percent recommended that the prosthetic eye should be left alone and only removed by the ocularist yearly or every 6 months. A further 18% recommended a set routine for removal and cleaning that varied between daily and twice monthly (Table 1).

Of the 1373 questionnaires mailed to New Zealand prosthetic eye wearers, 429 (31%) were completed and returned.

**Prosthetic eye removal and cleaning regimes**

Of the wearers who completed this section of the questionnaire, 35% removed and cleaned their prosthetic eyes daily, 15% less frequently than daily but up to and including weekly, 8% between weekly and monthly, 14% monthly, and 27% less frequently than monthly.

Participants’ reasons for their particular cleaning regime included excessive discharge, discomfort, hygiene, because they were advised to, and habit. The most common reasons cited were excessive discharge or discomfort and hygiene, although hygiene was less important for those removing their prostheses less frequently than monthly.

### Variables associated with discharge measures

Frequency of repolish was not shown to be associated with any of the measures of discharge so was not included in the analyses reported due to the number of responders not answering this question (Figure 2, Table 2).

#### Frequency of discharge

There was strong evidence of an association of frequency of cleaning with frequency of discharge ($P < 0.0001$) with those cleaning less often reporting a lower frequency of discharge. No other variables could be shown to be associated with frequency of discharge.

#### Color of discharge

There was strong evidence of an association between period of prosthetic eye wear and color of discharge ($P = 0.006$) with those who had had their prosthetic eye longer reporting a less colored discharge. There was also evidence of an association of age with discharge color with older people reporting a less colored discharge. No other variables could be shown to be associated with the color of discharge.

#### Volume of discharge

There was strong evidence of an association of frequency of cleaning with volume of discharge ($P = 0.002$) with those cleaning less often reporting a lower volume of discharge.

---

**Table 1** Summary of advice relating to discharge published on ocularists’ websites

<table>
<thead>
<tr>
<th>Percentage</th>
<th>Cause of discharge (n = 17)</th>
</tr>
</thead>
<tbody>
<tr>
<td>47%</td>
<td>Build-up of deposits</td>
</tr>
<tr>
<td>29%</td>
<td>Handling the prosthesis</td>
</tr>
<tr>
<td>24%</td>
<td>Other</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Percentage</th>
<th>Recommended cleaning regime (n = 17)</th>
</tr>
</thead>
<tbody>
<tr>
<td>47%</td>
<td>Do not remove unless uncomfortable or discharging</td>
</tr>
<tr>
<td>35%</td>
<td>Leave in and do not handle</td>
</tr>
<tr>
<td>18%</td>
<td>Set regime – daily to twice monthly</td>
</tr>
</tbody>
</table>
No other variables could be shown to be associated with volume of discharge.

Viscosity of discharge

There was evidence of an association of frequency of cleaning with viscosity of discharge \((P = 0.02)\) with those cleaning less often having a lower viscosity of discharge score. There was also evidence of longer periods of prosthetic eye wear being associated with viscosity with longer time having a lower viscosity score. No other variables could be shown to be associated with viscosity of discharge.

Professional repolishing regimes

Fifty-one percent of the participants had their prosthetic eyes repolished every year, 9% more often than yearly, and 40% less often. When asked directly “Does having your prosthetic eye(s) professionally repolished improve discharge? (Yes or No),” 44% of wearers reported no improvement. When asked directly, “If yes, how long does the improvement last,” 18% said that the improvement lasted less than 1 month, 20% that the improvement lasted between 1 and 6 months, and 5% that the improvement lasted longer than 6 months. Fourteen percent were unsure (Figure 3).

Discussion

The survey of ocularists’ Web sites revealed that the cause of discharge has not been settled. The largest group believed that the main cause was the buildup of surface deposits on prosthetic eyes, but the sites appear to contradict this with a majority (82%) recommending that prosthetic eyes (with deposits) (a) never be removed and cleaned or (b) only be removed and cleaned if causing discomfort or discharge. Osborn and Hettler surveyed members of the American Society of Ocularists in 2007 and found that 31% recommended to patients that they remove and clean their prosthesis “whenever the socket felt irritated,” 25% recommended monthly removal, and 22% recommended that their prosthesis be removed “whenever it is dirty.” They noted that further studies need to be conducted so a consensus can be achieved by ocularists and a standardized set of treatment protocols developed.

The website of the UK National Health Service (NHS) National Prosthetic Eye Service advises patients to remove and clean their prosthetic eyes at least once every 30 days, but daily cleaning or several times daily cleaning is also recommended if there is a lot of discharge. Their recommended cleaning method is to rub the prosthesis gently with the fingers using warm water and mild nonscented soap. The NHS website suggests that cleaning the prosthetic eye removes the main cause of discharge, which is a buildup of dirt and dust from the environment. This advice may be compared with the opinion of LeGrand that a “properly designed, perfectly polished prosthesis is all that is required for total comfort with no excess secretions. Such a prosthesis need...
only be removed once each year for professional cleaning to remove natural deposits and restore its polished surface.”

These two differing recommendations appear to be based on different assumptions. The UK recommendation suggests that cleaning is most important in managing discharge. LeGrand states that the most important factors in managing discharge are proper design (undefined in his paper) and finish of the surface of the prosthesis.

The literature has paid limited attention to the problem of discharge. Vasquez and Linberg22 and Kim et al23 found that there were bacteriologic and cytologic differences between anophthalmic and natural sockets but that these differences were not found to be associated with symptoms of discharge. In 1983, Jones and Collin24 classified the causes of discharging sockets. They associated acute discharge with viral or bacterial conjunctivitis. Chronic discharge with recurrent symptoms often did not respond to topical antibiotics so causes other than infection were implicated. Their classification achieved its aim of allowing more accurate diagnosis of infections but left open the question of effective treatment for ongoing discharge problems.

Allen et al25 found that patients with noteworthy problems had only half as much basic tear secretion in their anophthalmic sockets as those without problems. They suggested that aqueous or oily prosthetic lubricants might be of value. Fett et al26 evaluated the need for additional lubrication in 200 anophthalmic patients and found that 23% required supplementation. However, neither Allen nor Fett directly linked low basic tear production or the use of prosthetic lubrication with the discharge problem. Deposit formation on contact lens materials has been investigated,27,28 but that work has not yet been extended to prosthetic eyes.

Table 3 presents a summary of the putative causes of discharge noted in the above literature together with patients’ comments about discharge taken from a survey of 63 anophthalmic patients in 2009.1 A limitation of this study was that many of the causes noted in Table 3 (for example, socket and eyelid problems or unsuitable prostheses) were not investigated. Discharge was likely to be more severe in the presence of these problems.

Vasquez and Linberg22 did not investigate hand-washing behavior, but hand washing may have been a factor in their additional finding that patients who frequently manipulated their prosthesis had a significantly higher proportion of Gram-negative bacteria in the conjunctiva of their sockets. Whether wearers hand washed or not and in line with Vasquez and Linberg, this study found no evidence of an association of hand washing with discharge experience.
The finding that more frequent removal and cleaning was associated with more discharge does not indicate the direction of the effect as wearers who experience discharge are likely to clean their prosthesis more frequently than those who have no discharge. This is borne out with frequent cleaners citing discharge as the reason they cleaned more often than infrequent cleaners. Clearly, having an uncomfortable and/or discharging socket is motivation to remove and clean the prosthetic eye frequently. However, this behavior could mask the problem for a number of wearers if frequent cleaning was contributing to the discharge in the first place. Evidence about the cause of discharge may be found by investigating the physical interface between the prosthesis and the conjunctiva. Present at this interface are the physical, chemical, and biological elements of the conjunctiva, the socket fluids, and the deposits that cover the prosthetic eye.

Table 3 Putative causes of mucoid discharge summarized from ocularists’ websites, formal literature, and subjective comments from patients in a previous study

<table>
<thead>
<tr>
<th>Specific causes</th>
<th>Non-specific causes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Viral or bacterial infections</td>
<td>Physical irritation from prosthesis</td>
</tr>
<tr>
<td>Environmental allergens</td>
<td>Size, surface finish, surface deposits, weight,</td>
</tr>
<tr>
<td>Irritants in the socket</td>
<td>material and manufacturing process, etc</td>
</tr>
<tr>
<td>Eye stress</td>
<td>Protein, dirt, etc</td>
</tr>
<tr>
<td>Drying conditions</td>
<td>Contamination from fingers and eyelids</td>
</tr>
<tr>
<td>Clinical intervention</td>
<td>Defective tear production and drainage</td>
</tr>
<tr>
<td>Damaging behavior</td>
<td>Infective focus (dacryocystitis)</td>
</tr>
<tr>
<td></td>
<td>Excessive rubbing of prosthesis, etc</td>
</tr>
<tr>
<td>Deposits on prosthesis</td>
<td>Anatomical limitations</td>
</tr>
<tr>
<td>Shape and fit of prosthesis</td>
<td>Poor lid closure, grafted tissue, scarring, etc</td>
</tr>
<tr>
<td>Removal regime</td>
<td>Medical conditions</td>
</tr>
<tr>
<td>Cleaning agents</td>
<td>Unwell, side effects from drugs</td>
</tr>
<tr>
<td>Socket hygiene</td>
<td>Orbital implant</td>
</tr>
<tr>
<td>Lacrimal system</td>
<td>Extrusion, conjunctival inclusion cysts, granuloma</td>
</tr>
<tr>
<td>Anatomical limitations</td>
<td>Cytological features</td>
</tr>
<tr>
<td></td>
<td>Squamous metaplasia</td>
</tr>
<tr>
<td></td>
<td>Patient demographics</td>
</tr>
<tr>
<td></td>
<td>Age, life style, etc</td>
</tr>
</tbody>
</table>

![Figure 3](image-url) The duration of the effect on discharge experience of professional repolishing.

The association between longer periods of prosthetic eye wear and less colored and viscous discharge may indicate that the socket accommodates prosthetic eyes better over time. However, period of wear was not shown to affect frequency and volume of discharge, which are more important characteristics for wearing comfort. The finding that older people are likely to have discharge with less color may be of value to future researchers investigating discharge.

Annual repolishing of prosthetic eyes is recommended by a large majority of ocularists, and 60% of wearers undertook repolishing at least this often. It was surprising to find that wearers in this study thought that professional repolishing did not have any significant effect on their discharge experience because it is commonly assumed that a clean smooth surface on the prosthetic eye is paramount. When asked directly whether repolishing improved discharge, 62% of wearers reported no improvement or that any improvement lasted less than 1 month. This result suggests that professional repolishing may play only a minor part in reducing discharge...
discharge and that personal removal and cleaning regimes are more important.

There appears to be no consensus among practitioners for treatment of mucoid discharge associated with prosthetic eye wear, and there remains a large and underinvestigated group of patients with nonspecific discharge for which many causes of discharge have been postulated. Further research is warranted because prosthetic eye wearers ranked discharge as the second most important concern after health of their remaining eye.1 We have taken initial steps to investigate the discharge issue with this retrospective study and have found as expected that more severe discharge was associated with frequent removal and cleaning. Personal removal and cleaning regimes appear to be more important than professional repolishing, which appeared to have limited impact on discharge experience. Further research into the socket’s response to prosthetic eye wear, including the physical, chemical, and biological elements of the conjunctiva, the socket fluids, and the deposits that cover the prosthetic eye is recommended.

Disclosure
The authors report no conflicts of interest in this work.

References
4.3 Additional material (unpublished)

4.3.1 Full summary of opinions about mucoid discharge provided by ocularist websites

Information about the cause of mucoid discharge and prosthetic eye cleaning regimes provided on ocular prosthetists’ web-sites was analysed in Table 1 of the above paper. A fuller description of the information (accessed 29th April 2012) is shown below.

Website: www.artificialeyeclinic.com

Information provided about cause of discharge: “Regular removal keeps the socket mildly irritated. Usually there is a significant build-up of salt and protein deposits on the eye in one year’s time. Polishing removes these potentially irritating deposits.”

Recommended cleaning regime: “No need to remove between annual visits to ocularist.”

Recommended cleaning agent: No comment.

Recommended cleaning method: No comment.

Website: artificialeyes.com.au

Information provided about cause of discharge: “You should have your acrylic prosthetic eye cleaned and polished by your Cos-Medic Ocularist every six to twelve months as secretions will build up over the surface and penetrate into the eye causing discomfort and excessive discharge.”

Recommended cleaning regime: “Annual or 6 monthly visits to ocularist.”

Recommended cleaning agent: No comment.

Recommended cleaning method: No comment.
Information provided about cause of discharge: “The artificial eye, being of an alien nature to the human tissue, causes a discharge in the socket. This in turn necessitates the removal and cleaning of the eye for reasons of comfort, hygiene and cosmetic appearance.”

Recommended cleaning regime: “The amount of discharge determines removal frequency.”

Recommended cleaning agent: “Warm water and mild soap.”

Recommended cleaning method: No comment.

Information provided about cause of discharge: “Acrylic plastic has intermolecular spaces large enough for the passage of water molecules. While the plastic eye is being bathed in the tear film, it takes up water very slowly. The water moves continually through the plastic carrying with it minute quantities of substances with small enough molecules to pass through the spaces. Very probably viruses and some bacteria can get into the eye. Very good evidence indicates that proteins collect in the plastic and that these cause irritation in the eye socket.”

Recommended cleaning regime: “No two people react the same way to the prosthesis. You should discover by trial how long you can go between cleanings. Wear the eye as long as it does not have material stuck to its front surface and it is comfortable. In simple terms, “Don’t bother it unless it bothers you.” Only a few persons need to remove the eyes once each day for cleaning. Fewer yet remove and wash them morning and evening. Perhaps only one in many thousands find it necessary to take the eye out during sleep, replacing it in the morning.”

Recommended cleaning agent: “Mild soap and hot water.”

Recommended cleaning method: “Rub it vigorously with pressure from the tips of your soapy fingers. The water used can be as hot as the hands can stand.”
Information provided about cause of discharge: “Your meibomian and lacrimal glands, and the mucus membrane release fluid. This combination of liquid causes a protein deposit to gradually accumulate on the prosthetic surface. This build up can irritate the underlying tissue.”

Recommended cleaning regime: “This is dependent upon your ability to completely close the eyelids, if you have any allergies, and your personal hygiene care of the prosthesis. Some patients have to remove it daily, others once a week, a month or annually. We will evaluate your tolerance level after the prosthesis is worn for a time period.”

Recommended cleaning agent: No comment.

Recommended cleaning method: No comment.

Information provided about cause of discharge: “Remove the prosthesis only as necessary. Too much handling can cause irritation and excessive secretions.”

Recommended cleaning regime: “Remove only as necessary.”

Recommended cleaning agent: “For heavier mucus deposits, soak the eye prosthesis several hours or overnight in 3% hydrogen peroxide in a small container using enough hydrogen peroxide to cover the prosthesis. After soaking, rinse the prosthesis in water. Place the prosthesis back in the container and add one half teaspoon of baking soda with cold water: soak an additional 30 minutes. This neutralizes the hydrogen peroxide.”

Recommended cleaning method: “Wipe the surface of the prosthesis with a damp Kleenex to remove any residual protein deposits: rinse well with water or soft contact lens saline solution and reinsert.”
Information provided about cause of discharge: “LEAVE IT IN AND LEAVE IT ALONE. Those words pretty much sum things up. The reason for this is the more that you disrupt the tissues and tear film the more irritation you cause yourself through excess mucus and discomfort.”

Recommended cleaning regime: “Leave it in and leave it alone.”

Recommended cleaning agent: “Mild soap.” Recommended cleaning method: “Use a soft cloth.”

Information provided about cause of discharge:

Recommended cleaning regime: “Once or twice a month.”

Recommended cleaning agent: “Soak in 3% solution of hydrogen peroxide.”

Recommended cleaning method: “If deposits are seen, scrub with a wet cotton ball.”

Information provided about cause of discharge: “There is protein in your tears. As the tears evaporate, they leave a coating of protein on the eye prosthesis. This build-up eventually causes a reaction on the underside of the lids, leading to irritation.”

Recommended cleaning regime: “When necessary.”

Recommended cleaning agent: “Mild soap and water.”

Recommended cleaning method: “To help reduce protein build-up, periodically soak your eye for a few minutes in contact lense solution, then give it a good hard rub with a wet tissue.”
Information provided about cause of discharge: “Avoid removing your prosthesis. Too much handling can cause irritation to your socket and produce excessive secretions.”

Recommended cleaning regime: “Monthly.”

Recommended cleaning agent: “Baby shampoo.”

Recommended cleaning method: “Use a wet wash cloth.”

Information provided about cause of discharge: “If not cleaned correctly this protein will collect upon the surface of the artificial eye as a crystalline coating and will eventually make the artificial eye feel gritty. The socket lining and the inner surface of the eyelids may become inflamed and sore in extreme cases.”

Recommended cleaning regime: “Varies from a few days to a couple of months.”

Recommended cleaning agent: “Hard contact lens cleaner. Soap or detergent is not recommended.”

Recommended cleaning method: “Rub gently.”

Information provided about cause of discharge: “Protein accumulated on the polished surface. An older prosthesis may absorb secretions from the socket and cause a continual discharge and irritation.”

Recommended cleaning regime: “Every 1 or 2 months.”

Recommended cleaning agent: “Soak the eye in warm, soapy water for a few minutes. This softens any protein build up that may have accumulated on the polished surface.”

Recommended cleaning method: “Using a soft cloth, firmly rub the eye to remove this deposit. Rinse well in clean water to remove all traces of the soap then reinsert back into the eye socket.”
Website: [www.ocularpro.com](http://www.ocularpro.com)*

Information provided about cause of discharge: “Mucous secretion deposits on the surface.”

Recommended cleaning regime: As long as the eye is comfortable it should not be removed. Repolish 6 monthly.

Recommended cleaning agent: Hard contact lens cleaning solution.

Recommended cleaning method: Rub vigorously with fingertips.

*www.oculopro.com revised its site between August 2011 and April 2012. No comments about mucoid discharge are provided on the revised site.

Website: [www.seocularists.com](http://www.seocularists.com)

Information provided about cause of discharge: “Build up of protein sediment.”

Recommended cleaning regime: “If comfortable do not remove. Repolish 6 monthly.”

Recommended cleaning agent: “Mild soap or baby shampoo.”

Recommended cleaning method: “Rub with fingers or soft cloth.”

Website: [www.strausseye.com](http://www.strausseye.com)

Information provided about cause of discharge: “Protein build up.”

Recommended cleaning regime: “The prosthesis should be professionally cleaned at least once a year to remove protein build-up.”

Recommended cleaning agent: “If the prosthesis is removed it should be washed prior to re-insertion with a mild soap, such as Ivory or Johnsons’ Baby Shampoo.”

Recommended cleaning method: No comment.
Website: artificialevecare.com

Information provided about cause of discharge: “Body acids in the socket and UV light causes the acrylic to break down at molecular level becoming duller causing discomfort.”

Recommended cleaning regime: “6 weekly.”

Recommended cleaning agent: “Use antibacterial soap or dish detergent.”

Recommended cleaning method: No comment.

Website: www.siniora.gr/faqs.htm

Information provided about cause of discharge: “An ill-fitting protheses can lead to scratching and irritation of the conjunctiva, resulting in increased mucus discharge.”

Recommended cleaning regime: “Personal preference but otherwise because of foreign body, excessive discharge, to heal infection or before surgery.”

Recommended cleaning agent: “Contact lens solution.”

Recommended cleaning method: “Wipe with soft tissues.”

Website: www.bfwh.nhs.uk

Information provided about cause of discharge: “It is normal to have a certain amount of discharge in your socket. This varies from one person to the next. It can be worse in very cold weather or for instance if you are not well. You can also get a build up of dirt or dust in your socket. This again can vary a lot. If you work in a dirty or dusty atmosphere you are likely to suffer more discharge than someone who works in a cleaner atmosphere.”

Recommended cleaning regime: “There are no set rules about this. If you have a lot of discharge from your socket you may need to clean it several times a day. For most people, once a day seems about right.”
It is up to you to decide, however we recommend that the eye is removed for cleaning at least once every thirty days.”

Recommended cleaning agent: “Use warm water and mild, non-scented soap to wash your artificial eye.”

Recommended cleaning method: :Rub the eye gently with your fingers but make sure you do not scratch or drop it. Rinse the eye thoroughly using sterile water before you refit it. Make sure you rinse all the soap off.”
4.4 Contribution and significance

The research in this chapter described the range of possible causes of mucoid discharge associated with prosthetic eye wear by providing a comprehensive summary of putative causes. The finding that there was no consensus about the potential cause of nonspecific discharge and that current opinions about the management of discharge were varied and contradictory was important because it confirmed the need for the investigations planned in the thesis. The evidence from the survey results, that more severe discharge was associated with frequent removal and cleaning was also important for planned investigations in the thesis, even though the direction of cause and effect was not established at this time. The additional finding from the survey results that professional re-polishing appeared to have limited impact on discharge experience was counter to normal clinical practice and raised questions about the maintenance of prosthetic eyes.

4.5 Next steps

The association between prosthetic eye cleaning frequency and more severe discharge found in this chapter suggested that the interface between the prosthesis and the conjunctiva needed to be examined more closely. To undertake this examination, tools needed to be developed to measure the socket’s inflammatory response to prosthetic eye wear (investigated in Chapter 6) and to measure deposits that build up on prosthetic eye surfaces (investigated in Chapter 7).

The next step was to design and develop these measuring tools and to test their inter-rater and test/retest reliability. This process is described in the next chapter.
Chapter 5
Measuring tools for prosthetic eye research

5.1 Preface

The association between more severe discharge and more frequent prosthetic eye cleaning found in Chapter 4 suggested that the interface between the prosthesis and the conjunctiva needed to be examined more closely. Present at this interface are the conjunctiva, the prosthetic eye, the socket fluids and the deposits that build up on prosthetic eye surfaces. In order to investigate the potential influence of these elements on mucoid discharge, ways of measuring conjunctival inflammation and surface deposits on prosthetic eyes needed to be developed. Photographic grading scales are used extensively in optometry and ophthalmology and this approach was adopted for the design of the measuring tools that were developed in this chapter.

The idea for staining deposits with dental plaque disclosing solution described in this chapter was a consequence of the interdisciplinary make up of the project team which consisted of an ophthalmologist, optometrist and the author, an ocular prosthetist with a dental technology background. A number of staining agents currently used in ophthalmic practice were examined prior to finding that dental disclosing solution (containing Rose Bengal ingredients) was effective for staining deposits and readily available in liquid form. The paper presented here was published by the Clinical and Experimental Optometry Journal.

5.2 Published paper: The development of measurement tools for prosthetic eye research


The study is presented here in its published form.
The development of measurement tools for prosthetic eye research

Background: The aim was to develop tools to measure the condition of ocular prostheses and the socket’s response to prosthetic eyewear.

Methods: A novel staining technique for displaying deposits on prosthetic eyes was developed. Equal interval perceptual grading scales for measuring inferior palpebral conjunctival inflammation, and anterior and posterior stained surface deposits on prosthetic eyes were developed from 800 photographs of 43 volunteers. The photographs for each scale were chosen by the authors. A group of four ophthalmologists, three optometrists and three senior students was consulted about selection criteria and asked to position the photographs along a 1.5 m rule to determine equal intervals. Photographs judged not to represent exactly equal perceptual intervals were exchanged with others from the original pool. The final scales (a five-photograph scale for inflammation and two 11 photograph scales for deposits) were assessed for inter-rater reliability and test-retest reliability by groups of senior optometry students.

Results: Standard deviations for inter-rater reliability tests were 0.52 scale units for the inflammation scale, 0.99 for the anterior surface deposits scale and 1.03 for the posterior surface deposits scale. The standard deviation of the test-retest differences for inflammation was 0.6 scale units and for both anterior and posterior surface deposits it was 0.71.

Conclusions: A novel technique for displaying and measuring the intensity and extent of deposit formation on prosthetic eye surfaces has been described. The two equal interval perceptual grading scales that have been developed to quantify the extent of deposit formation together with the equal interval perceptual scale for grading severity of palpebral conjunctival inflammation will for the first time allow the effects of prosthetic eye wear to be evaluated. Further research to validate the scale for palpebral conjunctival inflammation in a clinical setting is recommended. The technique for staining deposits on prosthetic eyes is recommended for clinical practice.

Key words: conjunctiva, deposits, grading scales, inflammation, prosthetic eyes

The literature on prosthetic eyes is not well developed. Available information is focused on early issues surrounding eye removal, such as surgical procedures, the effects on patients’ visual perception and the emotional impact of eye loss. A small number of researchers have investigated the anophthalmic socket’s response to prosthetic eye wear but aside from a link between giant papillary conjunctivitis and prolonged prosthetic eye use, wearing behaviour has not been found to have any effect on conjunctival cytological features or the flora of the socket. Two recent studies have investigated potential links between prosthetic eye removal and cleaning regimes and inflammation in anophthalmic sockets. Chang...
and colleagues used an independent ophthalmic pathologist to estimate inflammation on a 0–3 scale, while Kim and colleagues used a four-point verbally descriptive scale for bulbar conjunctival inflammation and the four-level verbally descriptive scale for tarsal conjunctival inflammation of Saini, Rajwanshi and Dhar. Both investigations failed to find any significant link between inflammation and care regime; however, it is possible that these scales were too coarse for small changes in inflammation to be noticed.

Bailey and colleagues recommended using finer than four-point grading scales and Chong, Simpson and Fong showed that scales using reference photographs had better repeatability than verbally descriptive scales.

No finely spaced photographic grading scales designed specifically for the investigation of anophthalmic sockets appear to have been developed, although many scales exist for other purposes. Hurst, Mitchell and Douthwaite created a photographic grading system for contact lens deposits, but to investigate prosthetic eyes an alternative method for displaying and measuring deposits needs to be developed. The nature and dynamics of deposition on prosthetic eyes is very different from deposition on contact lenses. Deposits revealed by the staining solution used in this study form over all prosthetic eye surfaces except perhaps for the inter-palpebral zone. Because the body of a prosthetic eye is opaque, only very thick deposits are visible unless they are stained. Contact lens deposits on the other hand exist in the inter-palpebral zone and can easily be seen because the material on which they form is transparent.

This study describes a technique for displaying deposits on prosthetic eyes. It aimed to develop and confirm reliability of three photographic grading scales to aid prosthetic eye research: one for grading conjunctival inflammation in anophthalmic sockets and one each for stained deposits on the anterior and posterior surfaces of prosthetic eyes. The study included consultation with experienced ophthalmologists and optometrists and used perceptual and physical attributes when developing the scales similar to that described and recommended by Schulze, Jones and Simpson.

### METHODS

#### Data collection

Every two to four weeks over a three-month period, 43 volunteers had their anophthalmic sockets photographed with lower lids everted using a cotton bud (Table 1). The deposits on their prosthetic eyes were stained with a solution of 5 g of GC Corporation’s plaque disclosing gel dissolved in 30 ml of OcuPure saline solution. The prosthetic eyes were immersed in the solution at 20°C (68°F) for a period of 2 min. After removing and blotting with tissue paper, the prosthetic eyes were photographed front and back against a black background, which included standard grey and colour scales to ensure the consistency of the photographic settings throughout the project. All the photographs of sockets and prosthetic eyes (800 in total) were printed 12 cm × 8 cm with a colour laser printer in a single session using a single batch of satin-finish photographic paper. The study had ethics approval from the University of Auckland Human Participants Ethics committee and the research...
adhered to the tenets of the Declaration of Helsinki.

**Development of grading scales and judgement criteria**

Thirty photographs depicting a full range of severities for each condition of conjunctival inflammation, anterior surface deposits and posterior surface deposits were chosen by consensus among the authors. A provisional five-photograph inflammation scale and two provisional 11 photograph deposits scales were developed. The larger numbers of photographs in the two deposits scales were needed to incorporate both the pink and blue characteristics of the stained deposits within the same scale. Deposits that appeared lightly stained were pink, whereas those that were more heavily stained appeared blue.

The provisional scales were presented to a consultation group, comprised of four ophthalmologists, three optometrists and three senior optometry students. The consultation group was formally interviewed about the provisional scales and the judgement criteria they were likely to use in estimating severity of inflammation and deposit formation. For the conjunctival inflammation scale, the consultation group said that they focused primarily on the appearance of the 10 mm wide band across the inferior palpebral conjunctiva adjacent to the lid margin. They considered vasodilation of conjunctival blood vessels, apparent roughness of the conjunctival surface (for example, papillae) and the visible presence of any oedema.

For the deposits scales, the consultation group noted the extent of the stained deposits within the same scale. Deposits that appeared lightly stained were pink, whereas those that were more heavily stained appeared blue.

The members of the consultation group were then asked independently to place the photographs from the provisional scales along a 1.5 m rule in positions that represented their judgments of the relative severity of the factor being assessed, beginning with the least severe at 0 m and the most severe at 1.5 m. The photographs were assembled on a white table top and the lighting conditions (nominal correlated colour temperature 6,500 K, nominal colour rendering index greater than 90, illuminance greater than 500 lux) were kept identical for each session. This placement process identified images that were not consistent with an equal interval scale. These photographs were removed by the experimenters and replaced with others from the pool judged more likely to be placed at equal intervals. The members of the consultation group then repeated the placement task. The final outcome of this iterative process was the set of photographs shown in Figures 1, 2 and 3 that represent the best possible uniform scales.

**Inter-rater reliability of the scales**

**SCALE FOR CONJUNCTIVAL INFLAMMATION**

Four to six photographs of the anophthalmic sockets of 43 patients were taken at different times to provide images that covered a wide range of severity of inflammation. The resulting 218 photographs were individually coded and placed at the centre of a neutral grey Microsoft PowerPoint slide, which contained the grading scale to be tested. The slides were divided into four batches and presented in random order to 40 final year optometry students, who had at least three years of clinical training under supervision. A rest period with a short comical video followed the completion of each batch to reduce fatigue. The students were asked to grade the severity of conjunctival inflammation shown in each photograph to the nearest 0.1 unit by interpolation within the photographic scale as proposed by Bailey and colleagues. For each photograph, the difference between individual severity assessments and the average of all assessments were plotted to determine the bias and the estimated limits of agreement.

**SCALES FOR ANTERIOR AND POSTERIOR SURFACE-STAINED DEPOSITS ON PROSTHETIC EYES**

The process for determining the test-retest reliability of the scales for deposits was the same as used for the inflammation scale except that only 18 final year students participated.

**RESULTS**

**Inter-rater reliability of the scales**

In Figures 4, 5 and 6, the differences between the individual grader’s assessments of severity for each photograph are shown as a function of the average of all the assessments for that photograph. The 95 per cent confidence limits of the differences are marked on the plots. The standard deviation of the differences for conjunctival inflammation (Figure 4) was 0.32. For deposits on the anterior surface (Figure 5), it was 0.99 and for posterior surface deposits (Figure 6) it was 1.03.

**Test-retest reliability of the scales**

In Figures 7, 8 and 9, the differences between each grader’s test and retest scores for each scale is shown as a function of the average of the individual grader’s test-retest scores. The 95 per cent confidence limits of the differences are marked...
Artificial eye research tools  Pine, Sloan and Jacobs

Figure 1. Grading scale for lower palpebral conjunctival inflammation in anophthalmic sockets

Figure 2. Grading scale for stained deposits on the anterior surface of prosthetic eyes

Figure 3. Grading scale for stained deposits on the posterior surface of prosthetic eyes
Figure 4. Inter-rater differences for the grading of inferior palpebral conjunctival inflammation. For each photograph, the difference between individual assessments and the average of all assessments was plotted. The mean of the differences was -0.01 and the standard deviation of the differences was 0.52.

Figure 5. Inter-rater differences for the grading of deposits on the anterior surface of prosthetic eyes. For each photograph, the difference between individual assessments and the average of all assessments was plotted. The mean of the differences was 0.0 and the standard deviation of the differences was 0.99.

Figure 6. Inter-rater differences for the grading of deposit severity on the posterior surfaces of artificial eyes. For each photograph, the difference between individual assessments and the average of all assessments was plotted. The mean of the differences was 0.0 and the standard deviation of the differences was 1.03.

Figure 7. Test-retest reliability of the conjunctival inflammation grading scale. The differences between each grader’s test and retest scores were plotted against the average of their test-retest scores. The mean of the differences was -0.03 and the standard deviation of the differences was 0.57.
The standard deviation of the test-retest differences for conjunctival inflammation (Figure 7) was 0.57 (concordance correlation coefficient = 0.808, 95 per cent confidence interval 0.800–0.816). For anterior surface deposits (Figure 8), the standard deviation of test-retest differences was 0.71 (concordance correlation coefficient = 0.786, 95 per cent confidence interval 0.771–0.801) and for posterior surface deposits (Figure 9), it was 0.71 (concordance correlation coefficient = 0.777, 95 per cent confidence interval 0.761–0.791).

**DISCUSSION**

Deposits form at the interface between the prosthetic eye surface and the conjunctiva and their effect on mucous discharge, socket comfort and socket health cannot be fully investigated unless tools to measure changes and outcomes have been created. The technique for staining deposits and the equal interval grading scales for measuring their intensity and extent developed here address this need and are key to further investigations into prosthetic eye wear.

The scale for measuring conjunctival inflammation is likely to be useful for clinical practice as it allows clinicians to monitor the level of conjunctival inflammation in anophthalmic sockets. While the scales for measuring deposits on prosthetic eyes may have limited use in clinical practice, the staining method is a valuable means of detecting and recording blemishes on the prosthesis. The plaque-disclosing gel used in this study is commonly used by dentists to demonstrate proper brushing and inter-dental cleaning techniques and could be used in the same way to educate prosthetic eye wearers about effective cleaning techniques. The grading scales for the deposits and the staining technique may have further applications in areas of research involving biofilm colonisation of synthetic materials.

In line with Efron, Morgan and Jagpa’s suggestion to avoid ‘display bias’ between test and retest sessions was observed by having the sessions at the same venue. Difficulties in scheduling the same observers into the same venue prevented the second session being run on a later date. It is possible that despite the short breaks between batches of tests and the tailoring of the pace of presentations to the needs of the group, observer fatigue may have influenced the results. The effect of fatigue would likely be to increase the variability of results and reduce the reliability of the scales. The half-hour rest period between test and retest sessions may have allowed graders to remember their previous scores but this is doubtful because of the large number of photographs and the randomness of the order of presentation.

The size of the steps in the scales was somewhat arbitrary, although based on the authors’ clinical experience. To allow...
the scales to have the opportunity of detecting finer gradations of change, we followed the recommendation of Bailey and colleagues8 and asked our observers to grade to the nearest 0.1 unit on the photographic scales. Ultimately, this study has demonstrated that the scales’ steps appear to have the correct order of magnitude in terms of inter-rater and test-retest reliability. Strong correlations between the test and retest scores were also observed in this study.

To assess whether the grading scale differences created for this study are likely to perform comparably with scales created for grading contact lens complications, we compared our results with those provided by Efron, Morgan and Katsara.10 They compared the reliability data of four different grading systems for bulbar conjunctival redness. While the palpebral conjunctival inflammation scale in this study is not limited to redness, the reliability data fall within the ranges calculated for these other grading systems. The comparison is shown in Table 3.

The ability to confidently detect change occurs with a grade change of 1.02 scale units for the conjunctival inflammation scale, 1.94 scale units for the anterior deposits scale and 2.04 units for the posterior deposits scale. The close agreement between the graders’ abilities to detect change (with 95 per cent confidence) and every second step in the two scales for deposits provides researchers with a tool for measuring deposits that measures statistically significant differences.

### Table 3. Comparison of grading reliability data from four different grading systems for bulbar conjunctival redness compared in the study of Efron, Morgan and Katsara and the palpebral conjunctival inflammation scale developed in this study.

<table>
<thead>
<tr>
<th>Reliability</th>
<th>Efron</th>
<th>Annunziaton</th>
<th>CCLRU</th>
<th>Vistakon</th>
<th>This study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>0.55</td>
<td>0.58</td>
<td>0.53</td>
<td>0.59</td>
<td>0.40</td>
</tr>
<tr>
<td>Upper 95 per cent confidence limit</td>
<td>0.82</td>
<td>0.81</td>
<td>0.84</td>
<td>0.84</td>
<td>0.51</td>
</tr>
<tr>
<td>Lower 95 per cent confidence limit</td>
<td>0.28</td>
<td>0.36</td>
<td>0.34</td>
<td>0.34</td>
<td>0.29</td>
</tr>
</tbody>
</table>

### CONCLUSIONS

A novel and valuable technique for displaying and measuring the intensity and extent of deposit formation on prosthetic eye surfaces has been described. The two equal interval perceptual grading scales that have been developed to quantify the extent of deposit formation together with the equal interval perceptual scale for grading severity of palpebral conjunctival inflammation will for the first time allow the effects of prosthetic eye wear to be evaluated. The palpebral conjunctival inflammation scale and the technique for staining deposit formation on prosthetic eyes are recommended for use in clinical practice.

### GRANTS AND FINANCIAL ASSISTANCE

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### REFERENCES


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5.3 Additional material (unpublished)

5.3.1 Cleaning prosthetic eyes

The method of staining the deposits on prosthetic eyes described in this chapter enabled surface deposits to be revealed for the first time. The staining technique and the grading scales for measuring the intensity and extent of surface deposits were developed in order to further the research into mucoid discharge associated with prosthetic eye wear. However, these tools may also be used to measure the effectiveness of different methods for cleaning prosthetic eyes assuming that the stain itself did not change the nature of the deposits. The observations reported here suggest that a well conducted investigation in the future using the tools developed in this chapter, may provide useful information for the care of prosthetic eyes. This topic is included in the recommendations for future research in Chapter 9.

During the course of the investigations reported in this thesis, the surface deposits on over 530 prosthetic eyes were stained with dental plaque disclosing solution and in each case the stained deposits were cleaned off before the prosthesis was returned to the patient. The experience of cleaning stained, visible deposits enabled the effectiveness of different cleaning methods to be judged and provided qualitative evidence for recommending that prosthetic eyes be cleaned by firmly wiping all surfaces with a paper towel wetted with cold water. This cleaning method was simple and its use ensured that all surface deposits were removed effectively.

Several other cleaning methods were tested but were either less effective or as effective but more complicated. When tissue paper wetted with cold water was used it broke up before sufficient wiping pressure could be applied. Industrial strength paper towels wetted with cold water appeared to be more abrasive and could potentially dull the surface polish of the prosthesis. A cloth or flannel wetted with cold water was just as effective as a wetted paper towel but perhaps not as hygienic if it was shared with others. Warm water did not affect cleaning effectiveness and nor did the use of soap. Cleaning with the fingers under running water (without cloth or paper) was only partially effective whether or not soap was used.

A further observation was that rubbing the surfaces with a dry tissue, cloth or paper towel did not remove the stained deposits but brought them to a high polish. If the deposits had not been revealed by staining
it could easily be assumed that the polished surfaces were perfectly clean.

5.4 Contribution and significance

The novel staining technique for displaying the intensity and extent of deposit formation on prosthetic eye surfaces is important because previously, deposits could only be seen when they built up considerable layers and dulled the surface polish. The ability to reveal newly formed deposits through staining has implications for the way prosthetic eyes are inspected and cleaned in clinical practice. The successful development of the equal interval photographic grading scales for measuring the extent and intensity of deposit build-up on prosthetic eyes will not only enable the next steps in this thesis to be carried out, but will provide a measurement standard for other researchers. The equal interval photographic grading scales for measuring palpebral conjunctival inflammation extends the range of scales used in optometry and ophthalmology and provides a useful tool for ocular prosthetists to record inflammation in the anophthalmic socket.

5.5 Next steps

The measuring tools developed in this chapter enabled conjunctival inflammation in anophthalmic sockets and deposit build-up on prosthetic eye surfaces to be systematically recorded for the first time. These tools were essential for conducting the next set of investigations required for the thesis. They would enable the socket’s inflammatory response to prosthetic eye wear to be examined (Chapter 6) and the build-up of deposits on prosthetic eye surfaces to be described (Chapter 7).
Chapter 6
The response of the anophthalmic socket to prosthetic eye wear

6.1 Preface

The next logical step in this set of investigations into discharge associated with prosthetic eye wear was to undertake a detailed quantitative analysis of the response of the anophthalmic socket to the presence of the prosthesis. To do this the investigation reported in this chapter utilised the grading scales for conjunctival inflammation and surface deposits developed in Chapter 5.

The first experiment used the scales to compare the severity of inflammation in anophthalmic sockets and their companion eyes. The difference between the two severity measures enabled inflammation caused by the prosthesis to be separated from other inflammation causes. The difference measure was then used to determine the influence of tear volume, mucoid discharge, the weight, shape, wearing time and frequency of cleaning on prosthesis induced inflammation. The work presented here was published by the Journal of Clinical and Experimental Optometry.

6.2 Published Paper: The response of the anophthalmic socket to prosthetic eye wear


The study is presented here in its published form.
The response of the anophthalmic socket to prosthetic eye wear

**Purpose:** The aim of this study was to investigate the inflammatory response of the anophthalmic socket to prosthetic eye wear.

**Methods:** One hundred and two prosthetic eye wearers were recruited for this observational study. Photographic grading scales were used to measure the severity of conjunctival inflammation and the extent and intensity of stained deposits on the prosthetic eyes. Tear volume was measured with the phenol red thread test. For mucoid discharge, visual analogue scales were used to assess frequency of occurrence, colour, volume and viscosity. For the prostheses, assessments were made of weight, shape, wearing time and frequency of cleaning.

**Results:** Anophthalmic sockets had more severe conjunctival inflammation than their companion eyes ($p=0.0001$). The difference in inflammation between the companion eye and the anophthalmic socket was associated with discharge volume ($p=0.01$) and discharge viscosity ($p=0.007$) with greater difference in inflammation being associated with higher levels of discharge volume and viscosity. A greater difference in inflammation was also associated with less surface deposition ($p=0.009$). No evidence of associations was found between difference in conjunctival inflammation and the other variables.

**Conclusions:** Recently developed grading scales for measuring inflammation in anophthalmic sockets and deposits on prosthetic eyes were used for the first time in this study. It is recommended that in clinical practice, inflammation grades for both socket and companion eye conjunctiva be compared, when determining if prosthesis-induced inflammation is present. The finding that more discharge was associated with more conjunctival inflammation is logical but the finding that less inflammation was associated with more deposits is counter-intuitive to those familiar with the contact lens literature. The apparently benign nature of at least some deposits on the prostheses raises questions about the maintenance of prosthetic eyes. We conclude that the simple presence of deposits is unlikely to be linked with inflammation of the conjunctiva in wearers of prostheses, who like those in this study, cleaned their prostheses regularly but not frequently.

Keywords: anophthalmic socket, conjunctiva, inflammation, deposits, prosthetic eye

Two recent studies by Chang and colleagues and Kim and colleagues have investigated links between prosthetic eye removal, cleaning regimes and conjunctival inflammation in anophthalmic sockets. Chang and colleagues used an independent ophthalmic pathologist to estimate inflammation on a 0–3 scale, while Kim and colleagues used a verbally descriptive biomicroscope-based grading of bulbar conjunctival inflammation to describe degrees of conjunctival injection and oedema, together with the criteria used by Saint, Rajwansi and Dhar for tarsal conjunctival inflammation (Table 1).

Both investigations failed to find any significant link between inflammation and care regime; however, it is possible that the scales they used were too coarse for small changes in inflammation to be noticed. Bailey and colleagues recommended using finer than four-point grading scales and Chong, Simpson and Fong showed that scales using reference photographs have better repeatability than verbally descriptive scales. Pine and colleagues developed a novel technique for staining deposits on prosthetic eyes and followed the recommendations of Bailey and colleagues and Chong, Simpson and Fong by creating a photographic grading scale with fine divisions for measuring conjunctival inflammation in anophthalmic sockets. Pine and colleagues also created similar scales for measuring the extent and intensity of stained deposits on prosthetic eye surfaces.

This study employs these measuring tools for the first time. It uses them to compare conjunctival inflammation in the anophthalmic socket with the companion eye and to investigate associations between inflammation and some of the factors associated with prosthetic eye wear. The factors included were tear volume, mucoid discharge and for the prosthetic eye, its weight, shape, wearing time, surface deposits and frequency of cleaning.

**METHODS**

The New Zealand Artificial Eye Service, the Royal New Zealand Foundation of the Blind, the Accident Compensation Corporation and five District Health Boards agreed to...
An open-eye phenol red thread test was used to assess tear volume on both eyes. The ‘Zone-quick’ sterile standardised phenol red threads were provided by Showa Yakuhin Kako Company Limited of Tokyo, Japan. The lower lid of each eye (chosen randomly) was gently pulled down and the folded 3.0 mm end of the thread was placed onto the palpebral conjunctiva at a point one-third medially of the lateral canthus. After 15 seconds the thread was removed and the wetted stained portion was immediately measured in millimetres.

To grade conjunctival inflammation, the lower lids of the anophthalmic socket and the companion eye were everted over a cotton bud to fully expose the lower tarsal conjunctivae. Separate digital photographs were taken using standardised camera settings (Table 2). The photographs were coded to de-identify the participant but to allow tracking. Each photograph was copied onto the centre of separate PowerPoint (Microsoft, Redmond, WA, USA) slides. Each PowerPoint slide contained a copy of a previously developed five-photograph grading scale on a grey background (Figure 2). The severity of conjunctival inflammation of the photograph in the centre of each slide was graded independently by three experienced clinicians (an ophthalmologist, an optometrist and an ocular prosthetist). The graders were instructed to use interpolated grades to the nearest 0.1, when assessing inflammation on a 0–4 scale.
The severity score for the conjunctival inflammation of the anophthalmic socket of each subject was compared to the score for the companion (control) eye. The differences between socket and companion eye inflammation severity grades were used in further analyses.

To grade the extent and intensity of surface deposits on prosthetic eyes, a staining solution was made by dispersing 5.0 g of GC Corporation plaque disclosing gel (Table 3) in 30 ml of 0.85 per cent saline solution. The prostheses were submerged in the solution at 20°C (68°F) for a period of two minutes. After removing and blotting with tissue paper, the prosthetic eyes were photographed front and back against a black background, which included a standard grey scale and colour scale to ensure the consistency of the photographic settings throughout the project (Figure 3). The prosthetic eyes were cleaned to remove the stained deposits and polished before being returned to participants.

Photographs of the stained prostheses were set up on Microsoft PowerPoint slides and graded by the same graders and in the same manner as the photographs of conjunctival inflammation described above using only the previously developed deposits grading scales6 (Figure 4). The average of the anterior and posterior scores was used to calculate the final grade.

A general linear model was used to investigate variables associated with the difference in conjunctival inflammation in the socket compared to the companion eye. Explanatory variables included were the shape and weight of the prosthetic eye, how long the participant had worn a prosthesis, frequency of cleaning, surface deposits on the prosthesis, difference in tear volume between the prosthetic and companion eye and measures of discharge. Volume and viscosity of discharge were selected to represent the discharge properties. A sample of 100 would have 80 per cent power to detect a correlation of 0.27 at the five per cent level of significance.

Concordance correlation9 and a paired t-test were used to investigate differences between conjunctival inflammation of the anophthalmic socket and the companion eye.

RESULTS

Six volunteers chosen for the study elected not to participate but the 102 participants who attended clinics lived in or near main urban areas (more than 30,000 population)10 of the North Island of New Zealand.

Table 3. GC Corporation plaque disclosing gel ingredients

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>70–75 per cent</td>
</tr>
<tr>
<td>Ethyl alcohol</td>
<td>18–20 per cent</td>
</tr>
<tr>
<td>Food red 105 (Rose Bengal)</td>
<td>4 per cent</td>
</tr>
<tr>
<td>D-sorbitol</td>
<td>3 per cent</td>
</tr>
<tr>
<td>Sodium carboxymethyl cellulose (CMC-Na)</td>
<td>2 per cent</td>
</tr>
<tr>
<td>Butyl p-hydroxybenzoate</td>
<td>&lt;1 per cent</td>
</tr>
<tr>
<td>Flavouring</td>
<td>&lt;1 per cent</td>
</tr>
<tr>
<td>Sodium salicylate</td>
<td>&lt;0.1 per cent</td>
</tr>
</tbody>
</table>
Sixty-three attended clinics at Auckland, 13 at Wellington, 11 at Tauranga, eight at Whangarei and seven at Rotorua. No ocular health issues were identified in the companion eye of any participant and no implant exposures or other signs of specific irritation were found in the anophthalmic sockets.

The severity of the lower palpebral conjunctival inflammation of the natural eye correlated with that of the anophthalmic socket (concordance correlation coefficient of 0.45, 95 per cent confidence interval 0.304 to 0.574); however, the difference between the two was significant (mean difference 0.58 ± 0.72, p = 0.0001).

Associations were found between the difference in inflammation (between socket and companion eye) and discharge volume (p = 0.01) and viscosity (p = 0.007), with more severe inflammation in the anophthalmic socket compared to the companion eye being associated with higher levels of discharge volume and viscosity. Difference in inflammation was also associated with surface deposition (p = 0.009) with more severe inflammation in the anophthalmic socket compared to the companion eye being associated with fewer deposits. We were unable to demonstrate an association between the difference in conjunctival inflammation and prosthetic eye maintenance, period of wear, prosthesis weight or shape or tear volume in this study. The estimates of the beta coefficients and their standard errors for all variables included in the analysis can be seen in Table 4.

**DISCUSSION**

The study was designed to attract prosthetic eye wearers that were well dispersed throughout the North Island of New Zealand. This was to ensure (as much as possible) that a wide variety of surgical procedures and prosthesis wearing conditions were represented.

Photographic grading scales with fine grading steps were used to measure conjunctival inflammation rather than the verbally descriptive coarser scales used by Kim and colleagues or the 0–3 scale used by Chang and colleagues. This study did not measure cytologic change but like the studies of Kim and colleagues and Chang and colleagues, it did compare conjunctival inflammation of the anophthalmic socket with the companion eye and tested the hypothesis that there was no association between inflammation and aspects of prosthesis wear, including cleaning frequency. All three studies found no statistically significant associations with cleaning regime, where a questionnaire was used to determine cleaning frequency; however, cleaning frequency may not be the best method for determining prosthetic eye ‘cleanness’ because it does not take into account cleaning effectiveness, which is a function of how well the prosthesis is cleaned. This study graded stained surface deposits, which is a method for measuring cleaning effectiveness. Such an objective assessment of the outcome of cleaning is a more direct way of assessing different prosthetic eye-care regimes.

The finding that inflammation in the anophthalmic socket is correlated to inflammation in the companion eye was expected as socket inflammation has many causes (including sympathetic responses) other than those related just to prosthetic eye wear. The majority of anophthalmic sockets (69 per cent) had a severity grade that was greater than for the companion eye, suggesting that this increase was caused by effects related to the presence of the prosthesis. The correlation between socket and companion eye inflammation together with the observation that 31 per cent of sockets have the same or less severe inflammation...
than the companion eye, suggest that both eyes should be graded when determining prosthetic-induced inflammation in clinical practice. In future studies the quantification of the inflammatory response might be improved with the use of recently introduced InflammaDry™ technology. This technology could be expected to provide an objective measure of conjunctival inflammation but its limitation might be that it is able to detect only the presence but not the degree of inflammation. InflammaDry is reported to work by detecting matrix metalloproteinase enzymes that are produced by stressed epithelial cells on the conjunctival surface. The InflammaDry product was not available for this study.

The finding that the volume and viscosity of discharge in anophthalmic sockets is associated with the difference in conjunctival inflammation is not surprising as the association is well documented in the contact lens literature. For example, the symptoms of contact lens-associated papillary conjunctivitis (CLPC) have been described as excess mucous production, itching, reduced contact lens tolerance and blurred vision due to mucus smearing and deposition. This mucus is mild at first and accumulates at the medial canthus during sleep. As the CLPC progresses toward giant papillary conjunctivitis (GPC), the mucus becomes thicker and more profuse, causing the eyelids to stick together. This increase in severity of mucus is accompanied by a loss of translucency of the conjunctiva and more general conjunctival inflammation. Deposit formation on contact lens materials has been investigated but this work has not yet extended to prosthetic eyes. Furthermore, deposits capable of being stained appear to build up in areas in continuous contact with the conjunctiva rather than in the inter-palpebral zone, which is the area occupied by contact lenses. Inter-palpebral zone deposits on prosthetic eyes are exposed to the air and the action of the eyelids and are likely to be the same or similar to contact lens deposits as described by McMonnies and Lowe, who reported that deposits on non-rotating contact lenses form in the inferior area or in a horizontal band across the centre of the lens, where they have been left to dry by inefficient blinking and/or lagophthalmos. Based on contact lens experience, any deposits left to dry in the inter-palpebral zone of prosthetic eyes are not beneficial to wearing comfort; however, deposits covering those surfaces that are in continuous contact with the conjunctiva may not be harmful.

The finding of an inverse relationship between severity of conjunctival inflammation of the anophthalmic socket and surface deposition on prosthetic eyes has not been previously reported. The evidence of an association between inflammation and mucoid discharge is important because discharge is a major concern for prosthetic eye wearers. These two findings together (inflammation with discharge and inflammation with fewer deposits) directly link the presence of deposits with less severe discharge; however, the correlation between more deposits and less discharge does not indicate the direction of cause and effect, as wearers who experience discharge are likely to have fewer deposits because they often clean their prostheses more frequently due to the discharge. What is apparent from the results is that the deposits themselves did not inflame the conjunctiva of the participants in this study who cleaned infrequently. This finding, while clinically counter-intuitive from the perspective of contact lens practitioners, may gain some support from the equally counter-intuitive finding of Kim and colleagues that the conjunctiva of anophthalmic sockets with prostheses that were cleaned once a day or more (removing deposits), showed more cytological changes than those that were cleaned less than once a day. Furthermore, 82 per cent of the websites of oculists recommend that prosthetic eyes never be cleaned, or only be cleaned if causing discomfort or discharge. Clearly, the retention of surface deposits through infrequent cleaning is not counter-intuitive to these practitioners. Finally, if surface deposits on prosthetic eyes were harmful, it might reasonably be assumed that treatment protocols for their management would be as well established as they are for contact lenses. This is not the case.

A caveat on this finding is that long-term continuous wearers of prosthetic eyes were not well represented in this study. Therefore, the finding leaves unanswered the question of how long deposits should remain on prosthetic eyes before they cause problems such as GPC.

Time of day may influence the inflammatory response of anophthalmic sockets, as accumulated debris can conceivably irritate the conjunctiva during sleep. This possible source of increased inflammation is unlikely to have been a great influence on the results because virtually all the participants in the study were examined at least two hours after waking.

The reasons why deposits did not inflame the conjunctiva of participants in this study who cleaned infrequently have not been addressed in this study; however, possible explanations for this include better wettability of prosthetic eye surfaces in the presence of deposits and better lubrication, if deposits contain mucins, as they do in contact lens deposits. The consequence of these possible properties of deposits would be that less compatibility of deposits with less severe discharge; however, the correlation between more deposits and less discharge does not indicate the direction of cause and effect, as wearers who experience discharge are likely to have fewer deposits because they often clean their prostheses more frequently due to the discharge. What is apparent from the results is that the deposits themselves did not inflame the conjunctiva of the participants in this study who cleaned infrequently. This finding, while clinically counter-intuitive from the perspective of contact lens practitioners, may gain some support from the equally counter-intuitive finding of Kim and colleagues that the conjunctiva of anophthalmic sockets with prostheses that were cleaned once a day or more (removing deposits), showed more cytological changes than those that were cleaned less than once a day. Furthermore, 82 per cent of the websites of oculists recommend that prosthetic eyes never be cleaned, or only be cleaned if causing discomfort or discharge. Clearly, the retention of surface deposits through infrequent cleaning is not counter-intuitive to these practitioners. Finally, if surface deposits on prosthetic eyes were harmful, it might reasonably be assumed that treatment protocols for their management would be as well established as they are for contact lenses. This is not the case.

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### Table 4. Association of variables with difference in conjunctival inflammation between socket and companion eye using the five-photograph 0–4 inflammation grading scale

<table>
<thead>
<tr>
<th>Variable</th>
<th>Inflammation difference per unit change</th>
<th>Standard error</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Years wearing a prosthesis</td>
<td>0.006</td>
<td>0.004</td>
<td>0.13</td>
</tr>
<tr>
<td>Shape of prosthesis *</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shape category 1 versus 4</td>
<td>0.53</td>
<td>0.33</td>
<td>0.27</td>
</tr>
<tr>
<td>Shape category 2 versus 4</td>
<td>0.22</td>
<td>0.34</td>
<td></td>
</tr>
<tr>
<td>Shape category 3 versus 4</td>
<td>0.39</td>
<td>0.32</td>
<td></td>
</tr>
<tr>
<td>Weight of prosthesis (g)</td>
<td>-0.09</td>
<td>0.08</td>
<td>0.26</td>
</tr>
<tr>
<td>Days between cleaning</td>
<td>0.001</td>
<td>0.001</td>
<td>0.11</td>
</tr>
<tr>
<td>Deposits grade (0–10 scale)</td>
<td>-0.08</td>
<td>0.03</td>
<td>0.009</td>
</tr>
<tr>
<td>Tears difference (mm)</td>
<td>0.006</td>
<td>0.007</td>
<td>0.45</td>
</tr>
<tr>
<td>Discharge volume (1–10)</td>
<td>0.22</td>
<td>0.08</td>
<td>0.01</td>
</tr>
<tr>
<td>Discharge viscosity (1–10)</td>
<td>0.22</td>
<td>0.08</td>
<td>0.007</td>
</tr>
</tbody>
</table>

* Shape of prosthesis was categorised according to the contour of the posterior surface.
frictional irritation of the conjunctiva occurs when deposits are present.

CONCLUSION

Recently developed grading scales for measuring inflammation in anophthalmic sockets and deposits on prosthetic eyes were used for the first time in this study. It is recommended that in clinical practice, inflammation grades for both socket and companion eye conjunctivae be compared when determining if prosthesis-induced inflammation is present. The finding that more discharge was associated with more conjunctival inflammation is logical but the finding that less inflammation was associated with more deposits is counter-intuitive to those familiar with the contact lens literature. The apparently benign nature of prosthesis deposits raises questions about the maintenance of prosthetic eyes. We conclude that deposits are likely not linked with inflammation of the conjunctiva for prosthesis wearers who, like those in this study, cleaned regularly but not frequently. Further research on the physical, chemical and biological nature of deposits on prosthetic eyes is planned.

REFERENCES

6.3 Additional material (unpublished)

6.3.1 Investigation of tear volume in anophthalmic sockets

6.3.1.2 Background

The experiment described in the submitted paper compared tear volume of the anophthalmic socket and conjunctival inflammation but found no correlation. This result was sufficient for the purposes of the investigation into the socket’s inflammatory response to prosthetic eye wear but the data on tear volume collected from the 102 participants produced a result which was different from the findings of a seminal paper on the subject (Allen et al., 1980). This short paper describes the result and discusses it in relation to Allen et al’s findings.

6.3.1.3 Method

An open-eye phenol red thread test was used to assess tear volume on both eyes. The lower lid of each eye (chosen randomly) was gently pulled down and the folded 3mm end of the thread was placed onto the palpebral conjunctiva at a point 1/3 medially of the lateral canthus. After 15 seconds the thread was removed and the wetted stained portion was immediately measured in millimetres.

6.3.1.4 Results

The tear volume of the natural eye estimated using the wetted length of the Phenol red thread tests correlated with the tear volume of the anophthalmic socket (Pearson’s coefficient r = 0.17) but the difference between the two was significant (2 sample t-test p=.001) with the anophthalmic socket (Mean 28.63mm SD 8.18) having a greater volume of tears than its companion eye (Mean 24.61, SD 8.37). The majority of anophthalmic sockets (60%) had more tear volume than the companion eye, 5.9% had the same volume and 34.1% had less volume.
6.3.1.5 Discussion

This is a different finding from Allen et al. (1980) referred to in section 1.2.7.2 of Chapter 1, who used Schirmer I and II tests for measuring tear volume and reported that 78% of anophthalmic sockets had less tears than their companion eye. The volume of basic tears in the anophthalmic socket was the same as in the companion eye but that, because of the absence of reflex tears in the socket, the overall tear volume was much less than in the companion eye. The finding in this study was the opposite of Allen et al’s result and calls into question their conclusion that: ‘Since the reflex tears supply most of the aqueous component of the tears the wearers of artificial eyes are left with an excessive proportion of the mucin and oily components with little aqueous to wash them away. The result is the thick mucoid residue that is so troublesome to many patients.’ If this was the main cause of discharge as suggested, an association between tear volume and conjunctival inflammation should have been found in the investigation in Chapter 6. No such association was found. On the other hand, a dry companion eye is likely to be accompanied by a dry anophthalmic socket – both needing relief from lubricating drops. Fett et al. (1984) evaluated the need for additional lubrication in 200 anophthalmic patients and found that 23% required supplementation. Their result suggests that 77% of patients had sufficient tears and this outcome appears to be closer to the finding in this study that 65.9% of participants had the same or more volume of tears in their socket than in their companion eye.

Tear volume is part of a broader question which needs to be explored in future research. The research question might be how tears function in the anophthalmic socket compared with the companion eye, how they lubricate the prosthesis and how they are influenced by surface deposits on the prosthetic eye. The results of this research could contribute towards the development of a model of the workings of the anophthalmic socket.

6.4 Contribution and significance

Key outcomes from this study were the success of the measuring tools in providing: firstly, a quantitative assessment of the effectiveness of cleaning prosthetic eyes, secondly for identifying a relationship
between deposits and discharge, and thirdly for identifying a relationship between deposits and conjunctival inflammation. A further important finding was that deposits, of themselves, did not appear to inflame the conjunctiva or cause discharge in people who do not clean their prostheses frequently. This finding is limited to the length of time participants in this particular study had allowed deposits to build up. It leaves unanswered the question of how long deposits should remain on the prosthetic eye before they cause giant papillary conjunctivitis or other problems (Bozkurt et al., 2007; Srinivasan et al., 1979).

6.5 Next steps

This study was unable to establish the direction of cause and effect of the association between more severe discharge and more frequent cleaning of prosthetic eyes found in Chapter 4, nor between discharge, inflammation and deposits found in this chapter. It is clear however, that deposits of themselves, do not appear to cause discharge. If deposits do not cause discharge, the cause must be: 1) mechanical irritation of the conjunctiva during removal and reinsertion of the prosthesis for cleaning due to added friction and/or deformation of the conjunctiva, 2) foreign material and/or bacteria introduced into the socket during removal and reinsertion of the prosthesis for cleaning, 3) direct contact with the conjunctiva of the raw surface of the prosthesis unmediated by deposits, or 4) destruction of homeostasis of the socket’s micro-environment. No research has been carried out to show the effect of mechanical irritation of the conjunctiva following removal and reinsertion of a prosthetic eye, but it seems unlikely that intermittent mechanical irritation would be enough to cause on-going discharge, even though it remains a possibility. Similarly, foreign material introduced into the socket when cleaning is an unlikely cause of on-going discharge because of its infrequency. Irritation from bacterial infection is a possible cause, but “no differences in bacterial flora were observed between symptomatic and asymptomatic patients suggesting that symptoms of irritation were not usually related to abnormal bacterial flora” (Vasquez & Lindberg, 1989).

The potential causes of discharge associated with frequent cleaning will be discussed more fully in Chapter 8. In the meantime, the next chapter explores the third possibility, which is that direct contact with the conjunctiva of the raw surface of the prosthesis unmediated by deposits is a cause of discharge. It approaches the issue by investigating the characteristics of deposits and rates of deposition on different
prosthetic eye surface finishes and finds a causal link for the associations between discharge, inflammation and deposits.
Chapter 7

Deposit build-up on prosthetic eyes and the implications for conjunctival inflammation and mucoid discharge

7.1 Preface

The work reported in Chapter 4 of this thesis found evidence for an association between more severe mucoid discharge and more frequent cleaning of the prosthetic eye. In Chapter 6, further evidence was found for associations between the presence of deposits on prosthetic eye surfaces and conjunctival inflammation and discharge. However, the direction of cause and effect of these associations was not established. This chapter aims to find a likely link for these associations by reviewing contact lens literature and investigating the effect of deposits on surface wettability. The chapter also examines how different prosthetic eye polishing standards influenced surface wettability and the rate of deposit build-up using both in-vivo and in-vitro experiments. The results of the in-vivo investigation are described in the paper published by the Clinical Ophthalmology Journal. The in-vitro investigation has been added as unpublished material in the section that follows.

7.2 Published paper: Deposit build-up on prosthetic eyes and the implications for conjunctival inflammation and mucoid discharge


The paper is presented here in its published form.
Deposit buildup on prosthetic eyes and implications for conjunctival inflammation and mucoid discharge

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Brian Sloan²
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¹Department of Optometry and Vision Science, ²New Zealand National Eye Centre, The University of Auckland, Auckland, New Zealand

Background: The aim of this study was to investigate deposit buildup on prosthetic eyes and the implications for conjunctival inflammation and discharge.

Methods: Forty-three prosthetic eye wearers participated in the study. Twenty-three had their prostheses polished normally before being worn continuously for 2 weeks. After this time, surface deposits were stained, photographed, and graded. The prostheses were then repolished to optical quality contact lens standard and worn for a further 2 weeks, when the deposits were again stained, photographed, and graded. Two participants had deposits on their prostheses stained, photographed, and graded on nine occasions at decreasing intervals ranging from 1 year to 1 day. Eighteen participants had the wetting angles on their prostheses measured with a goniometer before and after cleaning, after polishing normally, after polishing to optical quality contact lens standard, and after 10 minutes of wearing their optical quality contact lens polished prostheses. Concordance correlation, multiple regression, and paired t-tests were used for the statistical analysis.

Results: More surface deposits accumulated on prostheses polished normally than on those polished to an optical quality contact lens standard after 2 weeks of wear. The interpalpebral zone of most prostheses (observed without magnification) appeared to be clear of deposits. Removal of deposits significantly decreased surface wettability, but wettability returned after 10 minutes of wear. Optical quality contact lens polished produced more wettable surfaces and a slower rate of deposit accumulation than normal polishing.

Conclusion: We recommend that an optical quality contact lens standard be the minimum standard of finish for prosthetic eyes. This standard may assist the smooth action of the lids over the interpalpebral zone of the prosthesis and the cleansing action of tears. The presence of deposits in the retropalpebral zone may improve the lubricating properties of socket fluids which, in turn, may result in less frictional irritation of the conjunctiva and less mucoid discharge.

Keywords: prosthetic eye, deposits, wettability, conjunctival inflammation, mucoid discharge, cleaning regime

Introduction

Pine et al have used recently developed measuring tools¹ to demonstrate that the presence of surface deposits on prosthetic eyes is associated with less conjunctival inflammation and less severe mucoid discharge in anophthalmic sockets.² However, the causal direction of these associations was not established in this study. Furthermore, there appears to be no literature describing deposit buildup on prosthetic eyes, even though extensive literature describes deposit buildup on contact lenses. Prosthetic eyes are somewhat analogous to contact lenses, but are made from different materials and worn for very different reasons. Both devices come into contact with the conjunctiva,
share a similar eyelid action, are bathed in the same ocular fluids, and accumulate surface deposits. Because of these similarities, relevant information from contact lens investigations provides a useful background for this study. For example, the composition of deposits on contact lenses is likely to be similar to deposits on prosthetic eyes. Contact lens deposits include tear proteins, lipids (lipid deposit buildup may be both on the surface and inside the lens matrix\(^1\)), mucin, and contaminants, such as skin lipids, dirt, microorganisms, and metallic and nonmetallic debris.\(^5\)

The aims of this investigation were: to describe the formation of surface deposits on prosthetic eyes over time; to investigate rates of deposit buildup on prostheses with different standards of polish; and to understand the cause of the reported associations between deposits, conjunctival inflammation, and severity of mucoid discharge.\(^1\)

Materials and methods
Forty-three unilateral prosthetic eye wearers were entered into the study after they completed a questionnaire and agreed to participate in prosthetic eye research which had prior approval from the University of Auckland Human Participants Ethics Committee and the Multi-Region Ethics Committee of the New Zealand Ministry of Health. Participants were excluded from the study if they were aged younger than 18 years, had ocular health issues, or had not worn a prosthetic eye for at least 6 months.

Measuring surface deposits on prosthetic eyes
A staining solution was made by dispersing 5 g of plaque disclosing gel (a mix of mainly ethyl alcohol, food red 105, and water; GC Corporation, Tokyo, Japan) in 30 mL of 0.85% saline solution.\(^1\) The participants’ prostheses were submerged in the solution at 20°C (68°F) for a period of 2 minutes. After removing and blotting with tissue paper, the prosthetic eyes were photographed front and back against a black background which included a standard gray scale and a color scale to ensure the consistency of photographic settings throughout the study. Standardized camera settings were used.\(^2\) Photographs of the stained prostheses were coded to deidentify the participant but to allow tracking. Each photograph was copied onto the center of a Microsoft PowerPoint (Microsoft Corporation, Redmond, WA) slide which contained a previously developed 0–10 photographic grading scale by which the extent and intensity of deposit buildup could be measured.\(^1\) Separate anterior surface and posterior surface deposit scales allowed assessment of the severity of deposit buildup according to the extent and intensity of the stained deposits. The graders were the authors (an experienced ophthalmologist, optometrist, and ocular prosthetist) who used interpolated grades to the nearest 0.1 between 0 and 10 when assessing the deposits. The final grade for the stained deposits on each prosthetic eye was the average of the three graders’ anterior surface and posterior surface scores.

Polishing prosthetic eyes
The process for polishing prosthetic eyes in this study involved four steps. Firstly, the prosthesis was trimmed and the surfaces ground all over with a fine (120 grit) arbor band. Secondly, diatomaceous earth was applied to the surfaces with a wet calico polishing mop and/or a felt cone to remove the marks left by the arbor band. Thirdly, polishing compound for plastics final polish (Bego, Lincoln, RI) was applied with a dry calico polishing mop to achieve the normal polish grade. The Bego product is no longer in production but is similar to other commercially available denture polishing compounds. Fourthly, an optical quality contact lens polishing standard was obtained using aluminum oxide paste applied with a foam polyurethane rotating cone.

Deposit buildup on prosthetic eyes polished to normal and to optical quality contact lens standards
Twenty-three of the 43 participants enrolled in the study had their prostheses finished to a normal polishing standard before return to the socket where they were worn without removing and cleaning for 2 weeks. At the end of the 2-week period, the prostheses were removed and their surface deposits were graded according to the method for measuring surface deposits on prosthetic eyes described above. The prostheses were then cleaned and polished to an optical quality contact lens standard before being returned to the participants and worn continuously for a further 2 weeks. At this point, they were removed and their surface deposits were graded as before. Concordance correlation\(^7\) and paired t-tests were used to investigate differences after 2 weeks of continuous wear between the grade of deposit buildup on prosthetic eyes polished to normal standard and to optical quality contact lens standard.

Deposit buildup on prosthetic eyes worn continuously over time
Two of the 43 participants were chosen because their prostheses had not been removed and cleaned for 12 months. Their prostheses were removed and the surface deposits were measured according to the method for measuring
surface deposits on prosthetic eyes described above. The stained deposits were removed by wiping them firmly with a paper towel wetted with cold water before being returned to the participants for continued wear without removing or cleaning. This measuring process was repeated eight more times at decreasing intervals ranging from one month to one day. The extent and intensity of the stained deposits at each interval was plotted as a function of time, and regression analysis was used to describe the results further.

**Wettability of prosthetic eyes under different conditions of wear**

The final 18 of the 43 participants were requested to not remove or clean their prostheses for at least 24 hours. After this time, their prostheses were removed and gently blotted dry with tissue paper before being placed in a goniometer. Distilled water droplets were applied to the least convex area that could be found on each prosthesis (usually just on or above the superior limbus). This slightly convex area was adjusted to be as horizontal as possible. Wetting angles were assessed and the average of right and left angles made by each droplet of water was calculated for each prosthetic eye. High wetting angles indicated low wettability and vice versa.

The prostheses were wiped clean of deposits with a wetted paper towel and the wetting angles were measured again. They were measured a third time after the prostheses were polished to a normal standard (as described earlier in the methods used for polishing prosthetic eyes), and a fourth time after the prostheses were polished to an optical quality contact lens standard. The prosthetic eyes were then returned to the participants and ten of them wore their prostheses for 10 minutes before returning to have the wetting angles on their prosthetic eyes measured a fifth time. Multiple regression was the statistical method used to analyze the data.

**Results**

**Deposit buildup on normal and highly polished prosthetic eyes**

The rate of deposit buildup was greater on normally polished prostheses than on prostheses polished to optical quality contact lens standard. After 2 weeks of continuous wear, the normally polished prostheses had significantly more deposits (mean \(3.06 \pm 1.91\)) than prostheses polished to optical quality contact lens standard (mean \(2.26 \pm 2.00\), paired-samples \(t\)-test, mean difference \(-0.81 \pm 1.40\), 95% confidence intervals \(-1.48\) to \(-0.13\), \(P = 0.02\)). Two qualitative examples are shown in Figure 1.

**Wettability of prosthetic eyes under different conditions of wear**

Figure 2 shows deposit buildup over time. Regression analysis results (coefficient of determination \(R^2 = 0.98\), residual standard deviation = 0.4, \(P < 0.0001\)) are shown in Figure 3. The photographic series in Figure 4 illustrates the rate of buildup of deposits on the surface of the prosthetic eye worn by participant 2 in Figure 2. A notable characteristic of deposit formation indicated by the photographs is that the interpalpebral zone (observed without magnification) remained clear of stained deposits for considerable periods of continuous wear. However, it was observed that deposits could encroach onto this space after prolonged periods. An example of this is shown in Figure 5.
(P < 0.0001) and when they were polished to a normal standard (P < 0.0001). The increased wetting angles indicated that the wettability of prosthetic eye surfaces was reduced when deposits were removed and was reduced further still when the prostheses were polished to a normal standard.

However, the wetting angles of prosthetic eyes when first removed from the socket were not significantly different to the wetting angles of prostheses freshly polished to an optical quality contact lens standard (P = 0.117) or to wetting angles 10 minutes after the prosthetic eyes were placed back in their sockets (P = 1.0; Table 1 and Figure 6). These wetting angle measurements indicate that the wettability of the prosthetic eye surfaces was the same for prostheses worn continuously for at least 24 hours, for prostheses polished to an optical quality contact lens standard before wear, and for freshly polished prostheses after 10 minutes in the socket.

**Discussion**

Before the introduction of hydrogel (soft) and rigid gas permeable lenses, almost all contact lenses were made from poly-methyl methacrylate (PMMA), which is the same material used for manufacturing prosthetic eyes. Deposits on PMMA contact lenses are similar in form to deposits on soft lenses, but no comparisons between deposits on PMMA lenses and PMMA prosthetic eyes are available. Fowler et al. used scanning electron microscopy to investigate deposits on the anterior surfaces of PMMA contact lenses. They found that deposits on PMMA lenses were readily removed with a single cleaning and that PMMA lenses attracted fewer deposits.
than soft lenses. The layered coatings, films, or plaques of tear protein deposits described by Franklin et al.9 appear to be similar to the most prevalent type of deposits on prosthetic eyes. They mainly occupy the surfaces that are in continuous contact with the conjunctiva and can be seen in Figure 7, which depicts dry stained deposits on the temporal limbus of a left prosthetic eye worn continuously for 3 months (magnification 400×).

Two distinct zones of surface deposit buildup on prosthetic eyes were observed in this study. The first was the interpalpebral zone, where deposits are exposed to air and the action of the eyelids, and the second was the retropalpebral zone, where deposits are in continuous contact with the conjunctiva. These areas are clearly shown in Figure 1, prosthesis 2. While the interpalpebral zone appeared to be clear of deposits, microscopic analysis was not used in this study. If deposits are present in the interpalpebral zone, they are likely to be the same or similar to the deposits on contact lenses described by Fowler et al.8 and Franklin et al.9 Issues such as inefficient or incomplete blinking are likely to influence deposit buildup in the interpalpebral zone, but not on other areas of the prosthesis.

The normal polishing technique described in this study is the usual standard of finish for dentures and most prosthetic eyes (at least in New Zealand), while the optical quality contact lens polish is the technique commonly used for polishing hard contact lenses. Optical quality contact lens polish has been recommended for prosthetic eye polishing by LeGrand.10 The finding that prosthetic eyes polished to an optical quality contact lens standard accumulated deposits at slower rates than normally polished prosthetic eyes suggests that adherence of deposits depends on the relationship between surface matrix fineness and the size of protein molecules, and that the surface matrix of normally polished prosthetic eye surfaces enables protein molecules to adhere more readily than finer polishes. Surface matrix fineness also appears to be a factor influencing deposition on contact lenses. For example, Franklin et al. reported that one of the reasons that deposits take longer to build up on rigid gas permeable lenses than on hydrogel lenses is that rigid gas permeable polymers have lower matrix porosity.3

Table 1 Mean wetting angles of 18 prosthetic eyes after different interventions

<table>
<thead>
<tr>
<th>Surface</th>
<th>Intervention</th>
<th>Mean difference</th>
<th>Standard error</th>
<th>P-value</th>
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<tr>
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<td>Multiple regression</td>
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<td>After cleaning</td>
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<td>8.07</td>
<td>&lt;0.0001</td>
<td>−85.08 −39.02</td>
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<td>Normal polish</td>
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<td>&lt;0.0001</td>
<td>−64.99 −18.94</td>
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<td></td>
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<td></td>
<td>After 10 minutes of wear</td>
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<td>&lt;0.0001</td>
<td>39.02 85.08</td>
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<td>0.132</td>
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<td>17.82 64.31</td>
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<td>8.07</td>
<td>&lt;0.0001</td>
<td>41.6 87.66</td>
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<td>&lt;0.0001</td>
<td>198.94 65</td>
</tr>
<tr>
<td></td>
<td>After cleaning</td>
<td>−20.07</td>
<td>8.00</td>
<td>0.132</td>
<td>−42.9 2.75</td>
</tr>
<tr>
<td></td>
<td>Contact lens polish</td>
<td>21.99</td>
<td>8.16</td>
<td>0.110</td>
<td>−2.26 44.23</td>
</tr>
<tr>
<td></td>
<td>After 10 minutes of wear</td>
<td>44.55*</td>
<td>8.07</td>
<td>&lt;0.0001</td>
<td>21.52 67.58</td>
</tr>
<tr>
<td>Contact lens polish</td>
<td>Original condition</td>
<td>20.98</td>
<td>8.22</td>
<td>0.117</td>
<td>−2.46 44.43</td>
</tr>
<tr>
<td></td>
<td>After cleaning</td>
<td>−41.07*</td>
<td>8.15</td>
<td>&lt;0.0001</td>
<td>−64.31 −17.82</td>
</tr>
<tr>
<td></td>
<td>Normal polish</td>
<td>−20.98</td>
<td>8.15</td>
<td>0.110</td>
<td>−44.23 2.26</td>
</tr>
<tr>
<td></td>
<td>After 10 minutes of wear</td>
<td>23.56*</td>
<td>8.22</td>
<td>0.048</td>
<td>0.12 47.01</td>
</tr>
</tbody>
</table>

Notes: High wetting angles indicate low wettability and vice versa. A minus sign (−) denotes negative values. *Statistically significant; **difference between conjunctival inflammation in the anophthalmic socket and the companion eye.
Surface wettability is another factor that influences deposition on contact lenses, with increasing wettability having been shown to decrease deposition. A goniometer was used in this study for measuring wetting angles on prosthetic eyes. Wetting angle (or contact angle) analysis has become a widely accepted method by which to infer the wetting characteristics of contact lenses. It involves measuring the angle between a liquid and the lens surface at the three-phase boundary where a liquid, gas, and solid intersect. The findings that prosthetic eyes polished to an optical quality contact lens standard show more wettability than those polished to a normal standard, and that higher polished surfaces accumulate deposits at a slower rate, might be particularly important for the surface finish of the interpalpebral zone of the prosthesis. This is the zone where wetting and drying cycles occur and where the cleansing action of tears takes place. The interpalpebral zone needs to be as free from deposits as possible to avoid conjunctival battering during blinking. As the eyelids slide over the interpalpebral zone of a prosthetic eye containing deposits and debris, the area most likely to receive this battering is Marx’s line which has been shown to develop epitheliopathy in contact lens patients with dry eye symptoms. Clearly, deposits left in the interpalpebral zone of prosthetic eyes are not likely to be beneficial to wearing comfort and, consequently, it is recommended that prostheses polished to an optical quality contact lens standard be the minimum standard for prosthetic eye finishes. An optical quality contact lens standard of finish may also facilitate the lubricating function of tears in the retropalpebral zone when the prosthesis is first inserted into the socket and before the layered coatings, films, or plaques of tear protein deposits become established. The finding that wetting angles decreased (and wettability increased) significantly when deposits were present in the retropalpebral zone may be the reason why surface deposits are associated with less severe conjunctival inflammation in anophthalmic sockets and that more frequent cleaning of prosthetic eyes (deposit removal) is associated with more severe discharge. By increasing surface wettability, the deposits may improve the ability of socket fluids to lubricate the prosthesis. If mucins are present in prosthetic eye deposits, as they are in contact lens deposits, components of glycoproteins such as the surfactant glycocalyx may also facilitate the lubricating function. The consequence of these properties of deposits.
would be that less frictional irritation of the conjunctiva occurs when deposits are present.

The finding that wetting angles of prosthetic eye surfaces decreased after only ten minutes of wear (suggesting the presence of protein deposits) is consistent with a number of observations reported in the contact lens literature.\(^{16,18-20}\)

Limitations of the study include the short period of the 2-week experiment with different surface polishes (Figure 1) because this did not reveal how long the difference in deposit buildup rates for the two polishing standards might last. The investigation concerning the rate of deposit buildup on prosthetic eyes worn by two participants had limitations because of the small sample size. The reason for this small number was the invasive nature of the experiment coupled with the shortage of available participants who cleaned their prostheses less frequently than yearly.

**Conclusion**

Prosthetic eyes are somewhat analogous to contact lenses. Both devices come into contact with the conjunctiva, share a similar eyelid action, are bathed in the same ocular fluids, and accumulate surface deposits. Because of these similarities, relevant information from contact lens investigations has been included in this study. Two distinctive areas of deposit buildup are described. The first is the interpalpebral zone where deposits are exposed to the air and the action of the eyelids, and the second is the retropalpebral zone where deposits are in continuous contact with the conjunctiva. We recommend that an optical quality contact lens standard of finish (shown to have better wettability and a slower rate of deposit buildup) be the minimum standard of finish for prosthetic eyes. This standard may be important for the interpalpebral surface, where it assists the smooth action of the lids over the interpalpebral zone of the prosthesis and the cleansing action of tears. When deposits were removed by cleaning, surface wettability decreased significantly, suggesting that the presence of deposits in the retropalpebral zone improves the lubricating properties of socket fluids which, in turn, may result in less frictional irritation of the conjunctiva when the prosthesis moves. This finding provides evidence for a causal link between the presence of deposits and less conjunctival inflammation and discharge reported by Pine et al.\(^{7}\)

**Disclosure**

Some of the participants in this study were recruited from the New Zealand Artificial Eye Service, which is owned and operated by Keith Pine. The authors report no other conflicts of interest in this work.

**References**

7.3 Additional material (unpublished)

7.3.1 Deposit build-up and wettability of prosthetic eyes incubated in artificial tear solution.

7.3.1.1 Background

The in-vivo study described in the manuscript above was the first to investigate deposit build-up on prosthetic eyes. The investigations described in this section are laboratory studies that approach the topic from a different perspective using in-vitro experiments to explain some of the results and to broaden the evidence base for the major findings. In addition, it compares the characteristics of deposits on different contact lens materials with deposits on prosthetic eye material.

The specific aims of the laboratory studies were to: a) Investigate the amount of protein deposited on prosthetic eye material (poly methyl methacrylate (PMMA)) with different surface finishes immersed in protein only artificial tear solution (ATS) for different periods of time. b) Investigate the amount of protein deposited on PMMA with different surface finishes immersed in protein/lipid ATS for different periods of time. c) Compare the results of investigations a) and b) with the results of Bontempo & Rapp (1997) who tested different contact lens materials in protein-only and protein/lipid ATS. d) Determine the effect of protein deposits on the wettability of PMMA material and the wettability of PMMA disks polished to different standards of finish.

7.3.1.2 Methods

Preparation of samples of prosthetic eye material

The sample disks for the experiments in this study were manufactured from a single mix of Vertex heat cure, clear polymethyl methacrylate (PMMA) prepared using 1 part monomer (liquid) to 2.5 parts polymer (powder). Polymerisation was completed in a water curing tank. The water was brought to the boil over a 30 minute period and held at 100°C for 20 minutes before being allowed to cool to room temperature. The 1mm thick sample disks were cut from a 12mm diameter rod before being trimmed and
polished to the required finishing grades. Diatomaceous earth applied with a wet calico polishing mop was used to achieve the low polish grade. BEGO (2012) polishing compound for plastics final polish was applied with a dry calico polishing mop to achieve the normal polish grade. Aluminium oxide paste was applied with a foam polyurethane rotating cone to achieve the optical quality contact lens polish grade.

Rate of deposition on low, normal and high polished PMMA

Seventy two PMMA sample disks were decontaminated by wiping with a tissue soaked in 70% ethanol. Half of the disks were assigned for testing with a protein-only artificial tear solution (ATS) and half for a protein/lipid ATS.

A set of six sample disks (two low, two normal and two high grade standard of polish) were individually incubated for one second in 400µL of protein only (Sigma) ATS at 37°C containing equal parts of human albumin, lysozyme and lactoferrin. Another set of six were incubated in the ATS with constant agitation using a 100 RPM Innova® 40 Incubator Shaker for thirty minutes. Further sets were incubated for one hour, four hours, twenty four hours and 14 days. After each period of incubation the supernatants were removed and the sample disks rinsed with saline and placed in 200µL 1M Tris HCl buffer (pH 6.8) which was then heated to 70°C for ten minutes to extract any bound proteins from the sample disk surface. A protein assay was carried out to measure protein concentration using the Microplate procedure of Pierce® BCA Protein Assay Kit with a set of BSA standards. This procedure was repeated using the balance of the sample disks only this time, the protein-only ATS was replaced with a protein/lipid combination ATS which was made by adding 20mL of 25µL/mL lipid standard (Sigma) in 50/50 chloroform and methanol to 20mL of the protein-only ATS.

Wettability of PMMA with different surface finishes

Ten PMMA sample disks with low, normal and high surface polishes (30 in total) were decontaminated by wiping with a tissue soaked in 70% ethanol, allowed to dry and set up in a goniometer using distilled water droplets. Wetting angles (the angles made between the edge of the droplets and the surface of the material) were measured and the average of right and left angles for each droplet of water was calculated for each sample disk. Finally, averages were calculated for each of the three sets of ten sample disks.
Wetting angles of PMMA with different surface finishes after incubation in ATS and after protein deposits were cleaned off.

A further 17 sample disks with low, normal and optical quality contact lens standard finishing grades (51 disks in total) were incubated in the protein-rich ATS for 24 hours with constant agitation. They were removed and blotted with tissue paper before being set up in a goniometer using distilled water droplets. The wetting angles were assessed for each coupon before and after they were firmly wiped clean with a wetted paper towel. Average wetting angles were calculated as described in the previous section.

7.3.1.3 Results

Rates of deposition on low, normal and high polished PMMA

Sample disks polished to optical quality contact lens standard attracted significantly less protein than low (p<.0001) or normally polished disks (p<.0001). There was weak evidence to show that low polished surfaces may have attracted more protein than normally polished surfaces but the difference was not statistically significant (p=.06) (Figure 1). Total protein extracted from the sample disks after immersion in protein-rich ATS did not increase over the two weeks of incubation on low and normal polished disks and fluctuated on disks polished to optical quality contact lens standard. (Figure 7.1)
The addition of lipids to protein only ATS made no difference to the amount of protein deposited on the sample disks for any of the standards of surface polish tested.

Wetting angles of PMMA with different surface finishes

The average wetting angles for the different polishing standards were 86.8° (SD 4.9°) for low polish, 92.9° (SD 9.6°) for normal and 71.9° (SD 9.2°) for high polish. The average wetting angle of PMMA polished to optical quality contact lens standard was significantly greater (the surface was less wettable) than for low (p=.0005) or normally polished surfaces (p=.0001). There was no difference between the wetting angles on low or normally polished PMMA (p=.1). (Figure 7.2.)

**Figure 7.1** Protein concentration on PMMA surfaces finished to low, normal and optical quality contact lens standard (high) as a function of incubation time.
The average wetting angles after 24 hours of incubation in ATS were significantly lower than before incubation. After the PMMA coupons were cleaned they returned to their pre-incubation levels (Table 7.1 and Figure 7.3).

Table 7.1 Average wetting angles of low, normal and high polished surfaces after incubation in protein only ATS and after protein deposits were cleaned off.

<table>
<thead>
<tr>
<th>Surface Finish</th>
<th>After deposition and before clean</th>
<th>Std Dev.</th>
<th>After clean to remove deposits</th>
<th>Std Dev.</th>
<th>Difference</th>
<th>P value (Paired t-test)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>27.26°</td>
<td>17.53</td>
<td>77.73°</td>
<td>3.02</td>
<td>50.47°</td>
<td>0.003</td>
</tr>
<tr>
<td>Normal</td>
<td>14.07°</td>
<td>6.85</td>
<td>77.37°</td>
<td>4.83</td>
<td>63.30°</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>High</td>
<td>14.08°</td>
<td>11.19</td>
<td>68.48°</td>
<td>5.97</td>
<td>54.40°</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

Figure 7.2 Wetting angles of different PMMA surface finishes. High wetting angles indicate that surfaces are less wettable than low wetting angles. Standard deviation bars are depicted.

Wetting angles of PMMA with different surface finishes before and after protein deposition

The average wetting angles after 24 hours of incubation in ATS were significantly lower than before incubation. After the PMMA coupons were cleaned they returned to their pre-incubation levels (Table 7.1 and Figure 7.3).
7.3.1.4 Discussion

The polymethyl-methacrylate (PMMA) sample disks used in this study were made from the same material used for the manufacture of prosthetic eyes. The material is also the same used in the manufacture of dentures and is sourced from dental supply companies. The low finish and normal finish polishing agents were chosen because they are commonly used for finishing dentures in dental laboratories and for prosthetic eyes by extension. The low polish removes tooling marks left by abrasive arbour bands used to trim PMMA and the normal polish is the normal standard of finish for dentures and most prosthetic eyes (at least in New Zealand). The optical quality contact lens polishing technique is the common technique for polishing hard contact lenses and has been recommended for prosthetic eye polishing by Joseph LeGrand (1999).

There have been numerous studies of lipid and/or protein deposition on contact lens materials (Fowler et al., 1984; Franklin & Tigue, 1991; Franklin, 1997) but no investigations of deposits on prosthetic eye material appear to have been carried out. Bontempo and Rapp (1997) investigated protein-lipid interactions responsible for surface deposition on four types of hydrophilic contact lenses and two types
of rigid gas permeable (RGP) contact lenses. They found that the presence of lipid in ATS enhanced protein deposition on type IV hydrophilic lens and on both types of rigid gas-permeable contact lenses examined, but made no difference to protein deposition on type I, II or III lenses. This study followed the methods used by Bontempo and Rapp (1997) as closely as possible by using sample disks with similar surface areas to contact lenses and using similar artificial tear solutions in order to be able to compare results with PMMA material directly to results with contact lens materials. The results of PMMA disks with low, normal and optical quality standards of finish are compared with those of Bontempo and Rapp (1997) in Table 7.2. It was not surprising that no relationship appeared to exist between the findings of the two studies because protein deposition is driven by the composition, charge and water content of the different contact lens materials (Lorentz & Jones, 2007) and clearly, PMMA is different from the materials tested by Bontempo and Rapp (1997). Similarly, adding lipids to the protein-only ATS made no apparent difference to the rate of protein deposition in this study.
Table 7.2 A comparison of total protein extracted from protein only ATS and from protein/lipid ATS after 24 hours of incubation. The results for prosthetic eye materials (PMMA) with different surface finishes have been added (in the highlighted rows) to the contact lens results reported by Bontempo and Rapp (1997).

<table>
<thead>
<tr>
<th>Material</th>
<th>Total protein extracted from protein only ATS (µg) mean ± standard error of the mean</th>
<th>n</th>
<th>Total protein extracted from protein/lipid ATS (µg) mean ± standard error of the mean</th>
<th>n</th>
<th>P value (paired sample t-test)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PMMA low polish</td>
<td>87.12 ± 3.79</td>
<td>2</td>
<td>58.33 ± 0.76</td>
<td>2</td>
<td>.067</td>
</tr>
<tr>
<td>PMMA normal polish</td>
<td>58.33 ± 7.58</td>
<td>2</td>
<td>49.24 ± 3.03</td>
<td>2</td>
<td>.55</td>
</tr>
<tr>
<td>PMMA optical quality contact lens polish</td>
<td>10.61 ± 6.06</td>
<td>2</td>
<td>6.82 ± 0.76</td>
<td>2</td>
<td>.68</td>
</tr>
<tr>
<td>Lens group I hydrophilic lens</td>
<td>9.06 ± 1.05</td>
<td>8</td>
<td>6.95 ± 0.67</td>
<td>8</td>
<td>Ns</td>
</tr>
<tr>
<td>Lens group II hydrophilic lens</td>
<td>23.94 ± 15.9</td>
<td>8</td>
<td>10.35 ± 2.52</td>
<td>8</td>
<td>Ns</td>
</tr>
<tr>
<td>Lens group III hydrophilic lens</td>
<td>7.59 ± 1.87</td>
<td>8</td>
<td>15.31 ± 1.79</td>
<td>8</td>
<td>Ns</td>
</tr>
<tr>
<td>Lens group IV hydrophilic lens</td>
<td>157.66 ± 6.69</td>
<td>8</td>
<td>91.64 ± 18.74</td>
<td>8</td>
<td>.0009</td>
</tr>
<tr>
<td>Siloxanyl alkyl acrylate RPG lens</td>
<td>1.54 ± 0.26</td>
<td>12</td>
<td>6.82 ± 0.39</td>
<td>12</td>
<td>.0023</td>
</tr>
<tr>
<td>Fluorosiloxanyl alkyl acrylate RPG lens</td>
<td>3.76 ± 0.57</td>
<td>12</td>
<td>13.42 ± 0.69</td>
<td>12</td>
<td>&lt;.0001</td>
</tr>
</tbody>
</table>

The finding that sample disks polished to optical quality contact lens standard attracted less protein than normally polished surfaces after two weeks in ATS may be compared with the observation that pros-
thetic eyes polished to the same standard accumulated deposits at slower rates than normally polished prosthetic eyes after two weeks of continuous wear. Similarly, the finding that sample disks polished to optical quality contact lens standard had greater wettability compared to normally polished disks may be compared to the findings that prosthetic eyes polished to optical quality contact lens standard also had greater wettability. Also, the reduction in wettability that occurred when protein deposits were removed from the sample disks after 24 hours of incubation in ATS may be compared to the finding that wettability reduced significantly when deposits were removed from prosthetic eyes. Finally, the finding that protein was extracted from the sample PMMA disks one second after immersion in protein-rich ATS appeared to correlate with the in-vivo result that wettability increased after ten minutes of prosthetic eye wear following re-insertion after polishing.

Not all the results of the in-vitro tests were comparable to the in-vivo results. Deposits on sample disks did not accumulate over time as they did on prosthetic eyes worn continuously. This may be an example where in-vitro results are not directly transferrable to the in-vivo state because the conditions of incubation in ATS are not the same as those in the socket.

7.4 Acknowledgement

This study was supported by The University of Auckland Post-graduate Research Student Support fund. Ms Kyu Yeon Ivy Han, Department of Optometry and Vision Science at the University of Auckland was the Summer Research Scholarship recipient. Ms Han carried out the experiment (including protein assays) to determine rates of deposition on low, normal and high polished PMMA. Ms Han’s work was done under the supervision of Dr Simon Swift, Dr Robert Jacobs and the author.

7.5 Contribution and significance

The finding from both in-vivo and in-vitro experiments that the presence of deposits significantly improves the wettability of prosthetic eye surfaces provides a causal link between the presence of substantial deposits and less conjunctival inflammation and discharge in anophthalmic sockets (see Chapter 6). This finding also explains why frequent cleaning resulted in more discharge than infrequent cleaning (see
The effect of different standards of polish on surface wettability and rate of deposit build-up was demonstrated for the first time and provided evidence for the recommendation that an optical quality standard of finish be the minimum standard for polishing prosthetic eyes.

A further outcome of the work reported in this chapter was the observation that two distinct areas of deposition exist on the surface of prosthetic eyes: an inter-palpebral zone where deposits are exposed to the air and the action of the eyelids and the rest of the prosthesis where surfaces are in continuous contact with the conjunctiva. Recognition of these separate regions is useful because it helps to reconcile the generally negative view of deposits on contact lens surfaces with the seemingly positive view of deposits on prosthetic eye surfaces discussed in this study.

### 7.6 Next steps

These findings lead to a need for further research into the nature of deposits in the inter-palpebral zone and into the characteristics of anophthalmic socket fluids and bacterial flora. In addition, following the lead of contact lens researchers, it may be possible to find new prosthetic eye materials or coatings that increase surface wettability, reduce the need for an initial layer of deposits to restore comfort after prosthesis cleaning, and delay the build up of excessive deposits. Such a innovative material might reduce drying of the inter-palpebral surface and facilitate tear flow and the removal of debris in this area. Future research will be discussed in more detail in Chapter 9. The next chapter will draw conclusions from the evidence found in this thesis and the literature to compile recommendations for a protocol for the management of non-specific mucoid discharge associated with prosthetic eye wear.
8.1 Introduction

The thesis is focussed primarily on mucoid discharge associated with prosthetic eye wear because of its importance to patients (Chapter 2), the scale of the problem (Chapter 3) and the lack of standard protocols for its management (Osborn & Hettler, 2010). Evidence presented in Chapter 3 showed that personal prosthetic eye cleaning regimes were more important for managing non-specific discharge than professional re-polishing but determining how often prosthetic eyes should be cleaned remains an open question. The change that takes place in the micro-environment of the socket (including the accumulation of deposits on prosthetic eye surfaces) is central to the cleaning question and to the management of mucoid discharge.

Prosthetic eye wear may be modelled in three phases starting from when the prosthesis is re-inserted after cleaning: the initial phase is when homeostasis is being established within the micro-environment of the socket, the second is a steady state or equilibrium phase where prosthesis wear is comfortable and safe, and the third (breakdown) phase where there is an increasing likelihood of harm from continued prosthesis wear. The initial phase will be discussed first followed by the other phases in turn. The aim of the discussion is to arrive at a model of prosthetic eye wear which will then be used to develop a cleaning regime that can be confidently recommended to most anophthalmic patients. This cleaning regime is a key component of the evidence based protocol for managing mucoid discharge associated with prosthetic eye wear that follows.
8.2 Proposed model of the response of the socket to prosthetic eye wear

8.2.1 The initial phase after prosthesis insertion when homeostasis is being established (or re-established) within the micro-environment of the socket

When a patient or caregiver removes, cleans and re-inserts a prosthetic eye it is inevitable that the micro-environment of the socket is disturbed to some extent. The process also has the potential to irritate the conjunctiva and eye-lids. Physical disturbance or irritation may arise from stretching and deforming the conjunctiva and eye-lids (a particularly vulnerable area is the lateral commissure), disturbance of the conjunctival mucus substrate, frictional forces produced by the prosthesis rubbing unnaturally against the conjunctiva and irritation from foreign materials entering the socket such as dirt and grime, makeup, stray eyelashes and/or residues of cleaning or polishing agents. Sudden temperature changes and associated evaporative drying of the conjunctiva may also disturb or irritate the conjunctiva when the prosthesis is removed and differences between body temperature and the prosthesis may trouble the conjunctiva when the prosthesis is re-inserted. Bacteria may also enter the socket during removal and re-insertion of the prosthesis. It has been shown that patients who frequently handled their prosthesis had a significantly higher proportion of gram negative bacteria in their sockets than in their companion eye (Vasquez & Lindberg, 1989).

The recovery time from the stresses of removal and re-insertion is usually rapid (a few minutes) but the establishment of stable homeostasis may take longer due to the time taken for tears and the conjunctival mucus substrate to be re-distributed evenly around the prosthesis and socket, for foreign materials to be diffused and eliminated and for socket tear production to balance with tear loss. The build-up of the coatings and films that make up the deposits to an optimum depth and coverage on prosthetic eye surfaces must also occur before stable homeostasis is reached. While deposits were shown to be present on polymethyl methacrylate (PMMA) disks as soon as they were immersed in artificial tear solution and within ten minutes of wear on prosthetic eyes (Chapter 7) these initial deposits do not appear to moderate inflammation and discharge at this early stage. It is only after some time that they begin to facilitate the lubricating effect of the socket fluids as suggested in Chapters 6 & 7. Furthermore, cleaned prosthetic eyes have reduced wettability and tears readily break up when prostheses are first introduced to the socket.
as illustrated in figure 8.1. This interrupted coverage reduces the ability of tears to lubricate the pros thesis and exposes the raw, unmediated PMMA surface to the conjunctiva.

![Figure 8.1](image)

**Figure 8.1** Slit lamp view of tear break-up on the surface of a recently inserted prosthetic eye. The patient’s fingerprint smudged across the cornea is an example of foreign material entering the socket during re-insertion of the prosthesis. Photograph provided by Brian Sloan and used with permission.

### 8.2.2 The equilibrium phase

Once the disturbing effects of reinserting and removing the prosthesis have abated and surface deposits have been re-established to a minimum depth and coverage, a stable physiological homeostasis (Biology online, 2012) is established within the socket. An example of physiological homeostasis in the eye is the system of feedback controls that involves natural killer T cells (a subset of T lymphocytes) which produce interleukin 13 (a cytokine) in the conjunctival mucosa which in turn regulates conjunctival goblet cell homeostasis (De Paiva et al., 2011). The finding reported in Chapter 6, that deposits of themselves, did not appear to inflame the conjunctiva or cause discharge suggests that they contribute to stable physiological homeostasis in the socket. The deposits mediate between the raw surface of the prosthesis and the conjunctiva and provide wettable surfaces which improve the ability of socket fluids to lubricate the
prosthesis. If mucins are present in prosthetic eye deposits as they are in contact lens deposits (Fowler & Allansmith, 1980), components of glycoproteins such as the surfactant glycocalyx (Liolet et al., 1985) may also facilitate the lubricating function. Goblet cells and epithelial cells in the conjunctiva produce a mucus substrate which forms a network over the conjunctiva, lubricating the prosthesis and acting as a sponge that enables aqueous tears to remain in contact with the palpebral conjunctival epithelium (Liolet et al., 1985). This substrate, together with the coating of surface deposits that facilitates lubrication of the prosthesis outside the palpebral zone may be a key component of physiological homeostasis in the socket. Bacteria homeostasis may also play a role. Bacteria homeostasis refers to the self-regulation of bacteria adjusting to their changing environmental conditions. The main self-regulating mechanisms for bacteria include membrane lipid homeostasis, iron homeostasis and pH homeostasis (Zinni, 2012).

8.2.3 The breakdown phase where there is an increasing likelihood of harm from continued wear

Gradually, physiological homeostasis in the micro-environment of the socket becomes less benign. Physiological mechanisms keep going and while some minor inflammation and discharge occurs, it may not be enough to warrant attention by the wearer. However, once the balance has shifted, further perturbations rapidly lead to homeostasis breakdown. This may be initiated by an excessive build-up of layers of deposits which possibly harbour increasing amounts of harmful bacteria and/or environmental and metabolic debris. The thicker layers of deposits may physically batter the conjunctiva causing damage and/or triggering an allergic reaction associated with giant papillary conjunctivitis (GPC) as reported by Bozkurt et al. (2007). A further cause of breakdown of physiological homeostasis may be pooling of socket fluids that become trapped in spaces behind the prosthesis. These secretions may become infected and cause recurrent discharge (Jones & Collin, 1983). Also, inefficient socket drainage may result in an accumulation of environmental debris and the waste products of normal metabolism of the conjunctiva which build to levels that upset homeostasis. The three phase model of the response of the socket to prosthetic eye wear is summarised in Figure 8.2.
8.3 Recommended cleaning regime for prosthetic eyes

The three phase model of prosthetic eye wear suggests that there is an initial period when physiological homeostasis is becoming established within the socket following the insertion of a clean prosthetic eye. The length of this initial period is the time taken for the socket to recover from the effects of manipulating the lids, handling the prosthesis and for a stable coating of deposits to form on the prosthetic eye. An estimate of the length of this initial period may be determined for the majority of prosthetic eye wearers from an examination of the data assembled for the investigation described in Chapter 4. Results show that for those who cleaned monthly compared with those who cleaned weekly or more frequently than weekly, discharge frequency was less (Independent samples t-test P=.002), discharge volume was less (Independent samples t-test P=.006) and discharge colour was less yellow (Independent samples t-test P=.053). There was no change for discharge viscosity (Independent samples t-test P=.129) (see Figure 2 in Chapter 4). The improvement in discharge characteristics between weekly or more frequently than weekly and monthly cleaning suggests that physiological homeostasis may be established over a period.
that could extend as long as a month and that prosthetic eyes should be left undisturbed for at least this long. During this initial month, the qualitative evidence from the two participant experiment in Chapter 7 (Figures 3 & 4) limited as it was, suggests that for some wearers at least, the intensity and extent of deposits may reach grade five on the 0 – 10 deposits scale after two weeks of continuous wear and grade six after one month.

Beyond a month when stable homeostasis has been reached (presumably), the length of time before it starts to break down is likely to vary for individuals. For example, the amount of deposit build-up on contact lenses (and presumably on prosthetic eyes) varies between wearers and between the eyes of the same wearer (Keith et al., 2003). The length of time may also vary with medical conditions. For example, contact lens induced papillary conjunctivitis occurs more frequently in allergy sufferers (Donshik, 2003). The patient’s environment (eg, dusty conditions) and behaviour (eg, activities that strain the eyes) may also affect the length of time stable homeostasis lasts. Finally, the standard of surface polish on the prosthetic eye may influence the period of stability as it has been shown to affect the rate of deposit build-up (deposit build-up is faster on less highly polished prostheses) and potentially, the periods of establishment and stability of homeostasis.

Studies of giant papillary conjunctivitis (GPC) in anophthalmic sockets with prosthetic eyes have concluded that prolonged wear of prosthetic eyes is associated with GPC (Srinivasan et al., 1979) and that GPC is an allergic disease of the eye associated with increased numbers of mast cells, eosinophils and lymphocytes in the conjunctiva (Bozkurt et al., 2007). Fowler et al. (1984) reported that GPC may be related to the amount of surface deposits because it occurred less with PMMA contact lenses that attracted less deposits than soft contact lenses. Interestingly, they also found that patients with GPC had deposits that differed morphologically from deposits of asymptomatic patients and that after a day of wear GPC patients had deposits on 90% of the lens surface compared with 5% for asymptomatic patients (Fowler et al., 1984).

No studies of GPC or conjunctival cytologic changes in anophthalmic sockets have investigated the role of deposits but if prolonged wear of prosthetic eyes is associated with GPC (Srinivasan et al., 1979), thicker layers of mature deposits may be more likely to contain antigens that could be a cause. The qualitative evidence from the two participant experiment in Chapter 7 indicates that deposit grades of
about nine out of 10 will be reached after 12 months of continuous wear. The regression line in Figure 3 of Chapter 7 suggests that a deposit grade of eight might be reached after six months of continuous wear. This amount of deposit build-up may be enough to provide the conditions necessary for GPC as suggested by Fowler et al. (1984) or for deposits to begin to encroach on the inter-palpebral zone where they dry out and physically irritate the conjunctiva when blinking. Aside from overly thick deposits, another potential cause for the breakdown of physiological homeostasis is an accumulation of environmental debris and metabolic waste products in the deposits and elsewhere in the socket. Also, pooling of socket fluids and an overgrowth of normally un-harmful bacteria may occur and while different cleaning regimes do not seem to alter the flora of the socket (Christensen & Fahmy, 1974), in cases with lowered resistance, bacteria may produce inflammation and discharge.

If the breakdown of physiological homeostasis is to be avoided it is necessary to intervene at some point and clean the prosthetic eye. When this should happen will vary for individuals and it may be that wearers should judge for themselves how often they clean their prostheses. This was the opinion of 53% of members of the American Society of Ocularists who recommended to patients that they remove and clean their prosthesis whenever the socket felt irritated or whenever it was dirty (Osborn & Hettler, 2010). This is reasonable advice but it suggests that the prosthesis should be cleaned after the breakdown of physiological homeostasis has occurred rather than before. A better recommendation for a prosthetic eye cleaning regime might be one that allows for individual variability but sets a limit on how long the prosthesis should remain in the socket before it is removed for cleaning. Based on the evidence available, it is suggested that a conservative estimate of this limit might be six months.

Taking account of the three phase model of the socket’s response to prosthetic eye wear and the evidence presented above, it is recommended that prosthetic eyes should be cleaned not more frequently than monthly and not less frequently than six monthly. The optimum cleaning regime for most individuals will lie within these parameters but many more wearers may achieve longer periods of physiological homeostasis in their sockets due to good health, a clean environment and a well-fitting and highly polished prosthetic eye.
8.4 Recommended protocol for managing mucoid discharge

The following protocol for managing non-specific mucoid discharge associated with prosthetic eye wear is proposed. The evidence for the individual items that make up the protocol has been obtained from results described in previous chapters and from the above discussion on cleaning regimes. This evidence and the reasons for including each item in the protocol are summarised in Table 8.1.

The protocol has six elements as follows:

Prosthetic eyes should be blemish free with smooth rounded edges.

The minimum standard of surface polish should be optical quality contact lens standard.

Prosthetic eyes should not be removed and cleaned more frequently than monthly.

All patients should clean their prostheses at least six monthly.

A method for cleaning prosthetic eyes is by firmly wiping all surfaces with a paper towel wetted with cold water.

Prosthetic eyes should be professionally re-polished to optical grade contact lens standard annually.
Table 8.1 Proposed protocol for managing non-specific mucoid discharge associated with prosthetic eye wear.

<table>
<thead>
<tr>
<th>Protocol for managing discharge</th>
<th>Reason for the protocol</th>
<th>Evidence for the protocol</th>
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<tbody>
<tr>
<td>Prosthetic eyes should be blemish free with smooth rounded edges.</td>
<td>Avoids mechanical irritation of the conjunctiva and consequent mucus production.</td>
<td>Jones and Collin (1983) classified causes of discharge and examined eight patients with discharge using a method based on their classification. They reported that mechanical irritation from prosthetic eyes with scratches or chips was a cause of chronic discharge with recurrent symptoms not responding to topical antibiotics. (Chapter 4)</td>
</tr>
<tr>
<td>The minimum standard of surface polish should be optical quality contact lens standard.</td>
<td>This standard produces the best available wettable surface on PMMA prosthetic eyes. This standard may be particularly important for the inter-palpebral surface to assist the cleansing action of tears.</td>
<td>Research described in chapter 7 showed how wetting angles on prosthetic eyes from 18 patients were measured with a goniometer before and after different interventions. The results demonstrated that an optical quality contact lens standard of finish produced a more wettable surface than a normal finish. The results were confirmed in-vitro, using PMMA samples with different surface finishes.</td>
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<tr>
<td>Prosthetic eyes should not be removed and cleaned more frequently than monthly.</td>
<td>Cleaning removes surface deposits and their ability to improve the lubricating properties of socket fluids which in turn, results in less frictional irritation of the conjunctiva and less mucoid discharge. Mechanical irritation caused by removing the prosthesis and the introduction of foreign materials and bacteria into the socket occurs with cleaning and should be avoided.</td>
<td>The findings in Chapter 6 demonstrated that the presence of deposits was associated with less inflammation and discharge, and that deposits do not inflame the conjunctiva of patients who do not clean frequently. Reasons for this (presented in Chapter 7) were that the presence of deposits improved the lubricating properties of socket fluids. The improvement in discharge characteristics between ≤ weekly and monthly cleaning described in Chapter 4 suggested that prosthetic eyes can and should be left undisturbed for at least a month. Beyond monthly, the length of time before deposits should be cleaned off may vary for individuals with medical conditions (for example, contact lens induced papillary conjunctivitis occurs more frequently in allergy sufferers (Donshik, 2003), or the amount of deposition which varies between wearers and between the eyes of the same wearer (Keith et al., 2003). The length of time may also depend on the patient’s environment and the surface finish of the prosthetic eye as this affects the rate of deposition (Chapter 7) and potentially, the period between cleanings.</td>
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## Protocol for managing discharge

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<tr>
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<tbody>
<tr>
<td>All patients should clean their prostheses at least six monthly.</td>
<td>The amount of deposit build-up over this time may be enough to provide the conditions necessary for GPC or for deposits to begin to encroach on the inter-palpebral zone where they dry out and physically irritate the conjunctiva when blinking.</td>
<td>Cleaning at least six monthly is an arbitrary time but deposits accumulate continuously and after six months of wear were projected to reach grade 8 (on a 10 point scale) which may be rough enough to batter the conjunctiva (Chapter 7). Srinivasan et al. (1979) concluded that prolonged wear of prosthetic eyes is associated with GPC. The cause of papillary conjunctivitis associated with contact lens wear is thought to be a combination of an immune response to antigenic protein deposits and physical trauma to the conjunctiva adjacent to the surface and edge of the lens (Donshik, 1994). Wide variation between patients has been reported in the contact lens literature (Keith et al., 2003). Therefore, the ideal cleaning regime for most individuals will be influenced by medical conditions such as allergies, the wearing environment and the standard of surface finish of the prosthesis (Chapter 7) but will lie between monthly and six monthly parameters.</td>
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<tr>
<td>A method for cleaning prosthetic eyes is by firmly wiping all surfaces with a paper towel wetted with cold water.</td>
<td>This cleaning method is simple and its use ensures that all surface deposits are removed effectively.</td>
<td>The qualitative evidence for this cleaning method is based on the author’s experience of removing deposits from over 350 prosthetic eyes during the course of the research project. The effectiveness of the recommended method was able to be judged because the deposits were stained and visible. Other methods trialled included using wetted tissue paper (too soft and broke up), industrial strength paper towels (affected the surface polish), wetted cloth (just as effective but not disposable after cleaning) and soap and warm water with fingers (difficult to remove all deposits). Interestingly, rubbing with a dry paper towel or tissue polished the deposits to a high gloss but did not remove them.</td>
</tr>
<tr>
<td>Prosthetic eyes should be professionally re-polished to optical grade contact lens standard annually.</td>
<td>Polishing removes micro scratches and refreshes the surface finish.</td>
<td>Annual review of anophthalmic patients is indicated to assess the prosthesis for damage, to re-assess fit and to assess the socket for signs of post enucleation syndrome including ptosis of the upper lid and lower lid laxity. Despite the reservations about the effect of professional polishing reported in Chapter 4, it is convenient to re-polish at this time. Re-polishing removes micro scratches and restores the benefits of an optical contact lens standard of finish to the prosthesis (Chapter 7).</td>
</tr>
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8.5 Contribution and significance

The model of prosthetic eye wear proposed in this chapter puts the evidence from the literature and from investigations carried out in this thesis into an elegantly simple and novel framework. The model makes a significant contribution towards an understanding of the response of the socket to prosthetic eye wear and anticipates future research directions.

The provision of the protocol for managing non-specific mucoid discharge associated with prosthetic eye wear has major implications for clinical practice and for anophthalmic patients’ quality of life. The protocol has the potential to resolve ocular prosthetists’ varied and contradictory opinions about the management of discharge (reported in Chapter 4) and to clarify discharge advice given to patients. The protocol accords with Le Grand’s (1999) recommendations about the standard of surface finish for prosthetic eyes, although not for his view about the length of time deposits should remain on the prosthesis. Finally, the protocol answers the call by Osborn & Hettler’s (2007) for a standardised set of protocols for managing mucoid discharge.

8.6 Next steps

The broad aims for this thesis were to investigate mucoid discharge associated with prosthetic eye wear and to help address gaps in the literature by reporting findings that impact on current clinical practice. These aims were achieved by designing and carrying out a systematic set of individual investigations into mucoid discharge and preparing six manuscripts for publication. The work produced three concrete outcomes that contribute to clinical practice and open the door to many new research opportunities. These were the three photographic grading scales for measuring conjunctival inflammation and the intensity and extent of surface deposits, the model of the response of the socket to prosthetic eye wear and the protocol for managing mucoid discharge associated with prosthetic eye wear.

Future research directions that derive from the investigations described in this thesis are presented in the next chapter.
Chapter 9
Future research

During the course of the work of this thesis several avenues for future research were identified. The topics listed here all derive from the research initiated in this thesis.

9.1 The psychological impact of eye loss

The study described in Chapter 2 found that the second most commented-on topic was patients’ concerns about their appearance and that patients’ occupations influenced their concerns about appearance and reduced visual range. These results warrant further investigation, perhaps using the questionnaire for assessing the psychosocial profile of anophthalmic patients developed by Nicodemo & Ferreira (2006).

9.2 Biosocial profile of prosthetic eye wearers in different countries

The study described in Chapter 3 established a baseline for future prosthetic eye research in New Zealand and internationally, making it possible for researchers to compare changing demographics of anophthalmic populations and the aetiology of eye loss over time and between countries.

9.3 The effect of different cleaning regimes and methods on the surface finish of prosthetic eyes.

It was recommended in Chapter 7 that the minimum standard of surface polish for prosthetic eyes should be optical quality contact lens standard. However, it is not known what effect different cleaning regimes or methods have on the maintenance of this standard during routine wear. An experiment could be set up to answer these questions using a surface profilometer (Dektak Surface Profilometer, 2012) to measure the surface finish on prosthetic eyes after different periods of wear and for different cleaning methods. The results would have implications for the length of time before re-polishing prosthetic eyes becomes
necessary and help determine the best method for cleaning prosthetic eyes.

9.4 Investigation of prosthetic eye cleaning methods

Observations on the effectiveness of different prosthetic eye cleaning methods were reported in Chapter 5. It was suggested that these observations be followed up with an investigation using the tools developed for measuring surface deposits on prosthetic eyes in that chapter. This investigation could examine cleaning agents as well as cleaning methods. Osborn & Hettler (2010) surveyed members of the American Society of Ocularists in 2007 and found that 47.28% of members recommended the use of mild soap or baby shampoo as cleaning agents and a further 12.73% recommended hard contact lens cleaners. The investigation might compare different cleaning methods and agents by grading deposits after prostheses (worn continuously for set periods) were cleaned. The results of this research would inform clinical practice and might also have implications for the protocol for managing mucoid discharge proposed in Chapter 8.

9.5 The duration of effects associated with removing and re-inserting prosthetic eyes

In Chapter 8 it was suggested that there were irritating or disturbing effects associated with removing and re-inserting prosthetic eyes. Little is known about the severity of these effects or how long they last, but future investigations could determine this by using the conjunctival inflammation scale developed in this thesis to measure inflammation before and after removal and re-insertion. The time taken for the socket to settle down after re-polishing or replacing a prosthetic eye could also be determined in this way. The findings from this research would be valuable for clinicians and would also enable the effects of different prosthetic eye handling methods to be evaluated.

9.6 The physiology of anophthalmic sockets with a prosthetic eyes

The proposed three phase model of prosthetic eye wear developed in Chapter 8 would benefit from more detailed studies of the mechanisms underlying the processes described in the model. For example, Greiner et al. (1980) found that contact lens wearers developed more non-goblet epithelial cells in the con-
junctiva than non-wearers suggesting that these cells contribute to an increase in mucus production. The experiments of Greiner et al. (1980) using light and transmission electron microscopy and muco-protein staining techniques might be repeated with prosthetic eye wearers during different phases of the model.

9.7 The characteristics of deposits in the inter-palpebral zone of prosthetic eyes

An experiment using the same techniques as Greiner et al. (1980) could be set up to investigate the presence of deposits in the inter-palpebral zone after different periods of wear. This would extend the investigations described in Chapter 7 and provide a better understanding of the mechanisms involved in the inter-palpebral zone. An investigation of Marx’s line on the eye-lids of prosthetic eye wearers using Korb et al’s (2002) method for examining “lid-wiper epitheliopathy” in contact lens wearers might also shed more light on this unexplored area. The results of these investigations would have important implications for the wearing comfort of prosthetic eyes and the protocol for managing mucoid discharge. Later investigations could explore new prosthetic eye materials or coatings that increase surface wettability, reduce drying of the inter-palpebral zone and facilitate tear flow and the removal of debris from this area.

9.8 The function of tears in anophthalmic sockets with prosthetic eyes

Tear volume in anophthalmic sockets with prosthetic eyes was discussed in Chapter 6. In this chapter, research questions were raised about how tears function in the anophthalmic socket compared with the companion eye, how they lubricate the prosthesis and how they are influenced by surface deposits on the prosthetic eye. A thin lipid layer covers the tear film over the outer surface of soft hydrogel contact lens but no lipid layer covers a rigid lens (Lorentz & Jones, 2007). This observation suggests that no lipid layer covers prosthetic eyes either but no research results are available to confirm this. Lorentz & Jones (2007) suggest that to remain ‘totally’ biocompatible during wear, the overlying tear film should be structured similarly to the natural eye and that this is the ultimate aim of contact lens materials research. This should be the ultimate aim of prosthetic eye materials research as well and further investigations into the function of tears in anophthalmic sockets with prosthetic eyes would begin to lay the foundations for this.
9.9 Tear characteristics in anophthalmic sockets with prosthetic eyes

Tear ferning techniques (Horwath et al., 2001) or measurement of tear-film particle dynamics (Varikooty et al., 2012) used in the contact lens field and equipment such as a tear-scope could be employed to measure tear characteristics in anophthalmic sockets with prosthetic eyes. In addition, stains such as sodium fluorescein (Norn, 1972), might be used to investigate how the socket fluids flow over and around prosthetic eyes. The results of these investigations would refine the model of prosthetic eye wear proposed in Chapter 8 and would also have implications for the recommended protocol for managing mucoid discharge.
Chapter 10. References


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