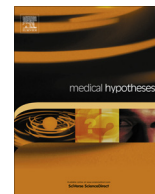


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## A proposed model of the response of the anophthalmic socket to prosthetic eye wear and its application to the management of mucoid discharge

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### ABSTRACT

Mucoid discharge associated with prosthetic eye wear can be a distressing condition that affects the quality of life of people who have lost an eye. Discharge is the second highest concern of experienced prosthetic eye wearers after health of the companion eye and is prevalent in anophthalmic populations. Specific causes of mucoid discharge such as infections and environmental allergens are well understood, but non-specific causes are unknown and an evidence based protocol for managing non-specific discharge is lacking. Current management is based on prosthesis removal and cleaning, and professional re-polishing of the prosthesis. Tear protein deposits accumulate on prosthetic eyes. These deposits mediate the response of the socket to prosthetic eye wear and their influence (good and bad) is determined by differing cleaning regimes and standards of surface finish.

This paper proposes a three-phase model that describes the response of the socket to prosthetic eye wear. The phases are: An initial period of wear of a new (or newly-polished) prosthesis when homeostasis is being established (or re-established) within the socket; a second period (equilibrium phase) where beneficial surface deposits have built up on the prosthesis and wear is safe and comfortable, and a third period (breakdown phase) where there is an increasing likelihood of harm from continued wear. The proposed model provides a rationale for a personal cleaning regime to manage non-specific mucoid discharge. Professional care of prosthetic eyes is also important for the management of discharge and evidence for effective surface finishing is reported in this study. Taken together, the proposed regimes for personal and professional care comprise a protocol for managing discharge associated with prosthetic eye wear. The protocol describes prosthetic eye cleaning methods and frequency, and suggests minimum standards for professional polishing. If confirmed, the protocol has the potential to resolve the current varied and contradictory opinions about the management of discharge, and to clarify advice given to patients about how to personally care for their prosthetic eyes.

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### Introduction

A regular complaint of anophthalmic patients is mucoid discharge associated with wearing their prosthetic eyes. This problem is the second highest concern of experienced prosthetic eye wearers after health of their remaining eye [1]. A study of the anophthalmic population of New Zealand found evidence that 33% experienced discharge at least twice a day [2] and no standardised treatment protocol has been developed to deal with it [3]. Current discharge management protocols are based on: (a) prosthesis removal and cleaning, (b) professional re-polishing of the prosthesis, and (c) steroid and antibiotic medications. Pine et al. [4] suggested that personal prosthetic eye cleaning regimes were more important for managing discharge than professional re-polishing, but

how often prosthetic eyes should be cleaned remained an unanswered question.

When commenting on the frequency of cleaning, the United Kingdom NHS National Artificial Eye Service [5] advises via its web-site that: “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.” On the other hand, Le Grand [6] states 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.” Both claims cannot be completely right.

It is logical to propose that the changes that take place in the micro-environment of the socket during prosthesis wear determine the interventions required to manage mucoid discharge. This micro-environment must include the deposits that accumulate on the surface of the prosthesis. It is also logical to assume that the

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rate at which deposits form depends on the finish of the surface of the prosthesis and the material from which it is made. The prosthesis (including its surface and deposits) will in turn affect the conjunctiva and other tissues and how these respond to the presence of the prosthesis.

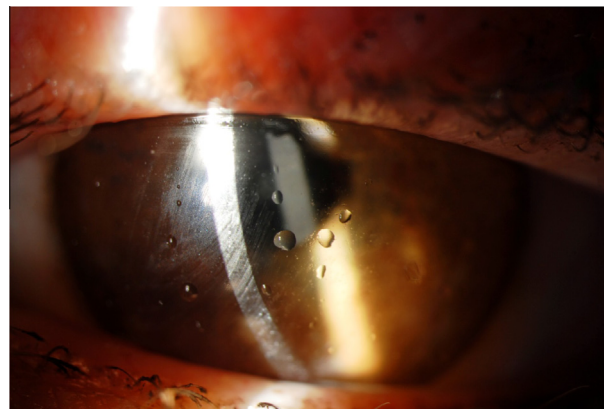
This study aims to review the prosthetic eye and contact lens literature to provide evidence for a proposed three phase model to describe prosthetic eye wear and the surface interactions that occur between the prosthesis and the socket tissues. The model provides a rationale for a proposed personal cleaning regime to manage non-specific mucoid discharge associated with prosthetic eye wear. The cleaning regime is presented as part of an overall treatment protocol for which there is increasing evidence.

### Three phase model of the response of the anophthalmic socket to prosthetic eye wear

**PHASE 1 (Establishment):** *The phase when physiological homeostasis [7] is being established (or re-established) within 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 (Fig. 1). The process may introduce bacteria to the socket as 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 [8]. Removing, cleaning and re-inserting a prosthetic eye may also irritate the conjunctivae and eye-lids. Irritation may arise from stretching and deformation of the conjunctiva and eye-lids (a particularly vulnerable area is the lateral canthus), from disturbance of the conjunctival mucus substrate, from frictional forces produced by the prosthesis rubbing unnaturally against the conjunctiva and from abrasion by foreign materials (such as dirt and grime, makeup, stray eyelashes and/or residues of cleaning or polishing agents) entering the socket. Rapid temperature reduction and evaporative drying of the conjunctiva may also disturb or irritate the conjunctiva when the prosthesis is removed. Temperature differences between the socket and the prosthesis may trouble the conjunctiva when the prosthesis is re-inserted.

The recovery time from the stresses of prosthesis removal and re-insertion appears to be rapid (perhaps only a few minutes). However, the establishment of stable physiological homeostasis may take longer because the conjunctival mucus substrate needs to be re-distributed evenly around the prosthesis, foreign materials need to be encased and eliminated, and the balance between tear production and tear loss needs to be re-established. It is hypothe-



**Fig. 2.** 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 the wearer's permission.

sised that the build-up to a minimum depth of the coatings and films that cover the prosthesis surface must also occur before stable homeostasis is reached. It is likely that the coverage of these coatings and deposits to an optimal level is associated with less conjunctival inflammation and less severe discharge [9]. This proposal is supported by reports in the contact lens literature that the activity of deposited lysozyme rather than the total amount of protein or total lysozyme, correlates with subjective symptoms of comfort [10]. Newly cleaned prosthetic eyes have reduced wettability [11] and tears readily break up when a prosthesis is first introduced to the socket (Fig. 2). This interrupted coverage reduces the ability of tears to lubricate the prosthesis and exposes the raw, unmediated surface of the prosthesis to the conjunctiva.

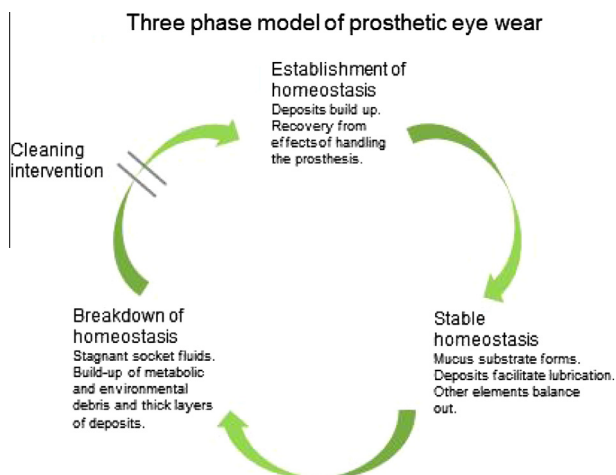
**PHASE 2 (Equilibrium):** *The phase when homeostasis is being maintained in equilibrium within the socket and when it is relatively robust to perturbations.*

Once the disturbing effects of reinserting and removing the prosthesis have abated and surface coatings and deposits have been re-established to a minimum depth and coverage, a stable physiological homeostasis is established within the socket. During this phase it is proposed that tear deposits mediate between the surface of the prosthesis and the conjunctiva and provide a wettable surface which improves the ability of socket fluids to lubricate the prosthesis. If mucins are present in prosthetic eye deposits as they are in contact lens deposits, [12] components of glycoproteins such as the surfactant glycocalyx [14] may also facilitate the lubricating function and contribute to stable physiological homeostasis in the socket. Conjunctival goblet and epithelial cells 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 [13]. This substrate, together with the coatings of surface deposits that facilitate lubrication of the prosthesis in the retro-palpebral zone may be key components of physiological homeostasis in the socket. Bacterial homeostasis may also play a role.

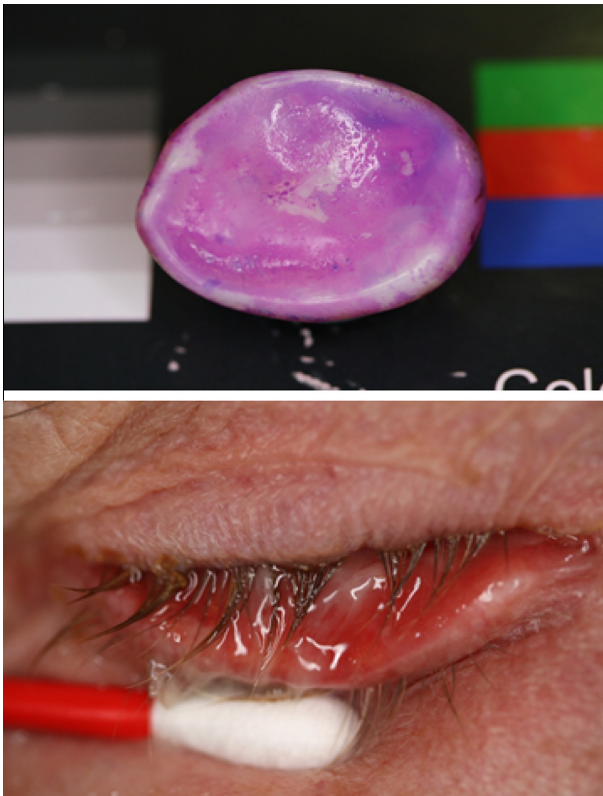
Bacterial homeostasis refers to the self-regulation of bacteria adjusting to their changing environmental conditions. The main self-regulating mechanisms for bacteria include membrane lipid homeostasis, iron homeostasis and pH homeostasis [14].

**PHASE 3 (Breakdown):** *The phase when homeostasis within the socket is no longer maintained without difficulty and where there is an increasing likelihood of harm from continued prosthesis wear.*

It is proposed that the physiological homeostasis in the micro-environment of the socket gradually becomes less benign. Over



**Fig. 1.** Three phase model of the response of the socket to prosthetic eye wear.



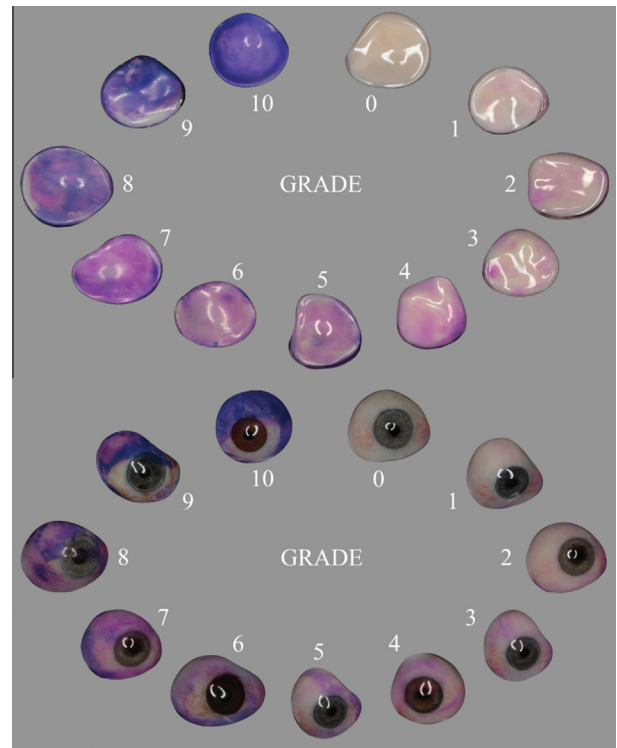
**Fig. 3.** Excessive build-up of deposits on this prosthetic eye (stained using the method described by Pine et al. [17]) possibly harbour harmful bacteria and/or environmental and metabolic debris. The prosthesis was removed from the discharging socket shown.

time some minor inflammation and discharge begins although it may not be enough to warrant attention by the wearer. However, once the balance has shifted, further perturbations lead to homeostasis breakdown. The breakdown 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 (Fig. 3). The thicker layers of deposits may physically batter the conjunctiva causing damage and/or components of the deposits may trigger an allergic reaction such as is seen with giant papillary conjunctivitis (GPC) [15].

A further cause of breakdown of physiological homeostasis may include pooling of socket fluids that become trapped in spaces behind the prosthesis. These secretions may act as a growth medium for bacteria causing recurrent discharge [16]. The accompanying inefficient socket drainage may result in an accumulation of both environmental debris and the waste products of normal metabolism further upsetting homeostasis.

### Cleaning regime for prosthetic eyes

The proposed 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 socket and prosthesis and for a sufficient coating of tear 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 the finding that monthly cleaning resulted in less discharge than cleaning weekly or more frequently than weekly [4]. This improvement in discharge suggests that physiological homeo-



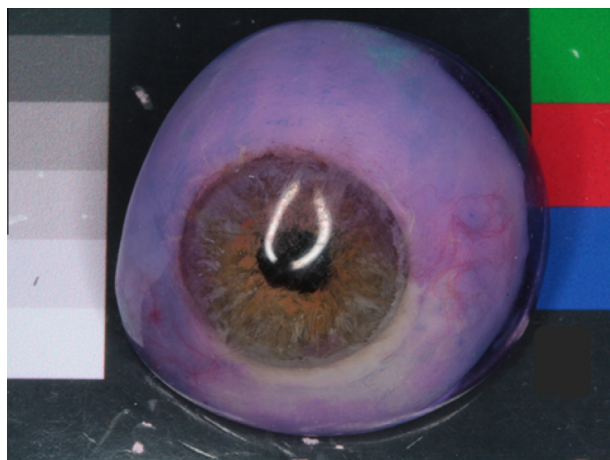
**Fig. 4.** Photographic grading scales measuring the intensity and extent of deposits on prosthetic eyes. Reproduced by the kind permission of Wiley Publications from [17].

stasis may be established over a period that could extend for a month and that prosthetic eyes should be left undisturbed for at least this long. During this initial month for some wearers at least, the intensity and extent of deposits may reach grade five on the 0–10 deposits scale [17] (Fig. 4) after 2 weeks of continuous wear and grade six after 1 month [11].

Beyond a month when stable homeostasis has been reached, 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 varies between wearers and between the eyes of the same wearer [18]. The length of time may also vary with medical conditions. For example, contact lens induced papillary conjunctivitis occurs more frequently in allergy sufferers [19]. The patient's environment (e.g., dusty or windy conditions) and behaviour (e.g., activities where concentrated visual tasks are undertaken and blink rate is reduced [20]) 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 stable homeostasis. Surface polish level has been shown to affect the rate of deposit build-up (deposit build-up is faster on less highly polished prostheses) [11] and potentially, the length of 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 [21]. GPC is an allergic disease of the eye associated with increased numbers of mast cells, eosinophils and lymphocytes in the conjunctiva [22]. 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 [22]. Fowler et al. [23] in the context of contact lens research reported that GPC may be related to the amount of surface deposits because it occurred less with wear of hard contact lenses (which attracted less deposits) than





**Fig. 5.** Tear deposits (stained using the method described by Pine et al. [17]) encroaching on the inter-palpebral zone after 9 months of continuous wear.

soft contact lenses. Interestingly, they also found that patients with GPC had contact lens deposits that differed morphologically from deposits of asymptomatic patients and that after a day of wear GPC patients had deposits on 90% of the contact lens surface compared with 5% for asymptomatic patients [23].

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, [21] then a cause could be thicker layers of mature deposits more likely to be containing antigens. Deposits of grade of eight on the 0–10 deposits scale in Fig. 3 might be reached after 6 months of continuous wear and deposit build up to about grade nine is likely after 12 months [11]. This amount of deposit build-up may be enough to provide the conditions necessary for GPC as suggested by Fowler et al. [23] or for deposits to begin to encroach on the inter-palpebral zone where they dry out and physically irritate the conjunctiva when blinking (Fig. 5) [11].

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. Stagnation of socket fluids and an overgrowth of normally un-harmful bacteria may also occur and while different cleaning regimes do not seem to alter the flora of the socket, [24] 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 [2]. 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 6 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.

### Proposed 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 elements that make up the protocol has been obtained from results described in previous research, from the proposed three phase hypothesis and from the discussion on cleaning intervals above.

The protocol has five elements as follows:

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

Cleaning removes surface deposits, reduces the wettability of the prosthesis and reduces the ability of socket fluids to lubricate. A certain level of surface deposition is needed for the socket fluids to be able to lower frictional irritation on the conjunctiva and lessen the likelihood of the mucoid discharge response. Mechanical irritation caused by removing the prosthesis and the introduction of foreign materials and bacteria into the socket occurs with cleaning and should be minimised. Pine et al. [9] 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. The reason for this was that the presence of deposits improved the lubricating properties of socket fluids [11]. The improvement in discharge characteristics between  $\leq$  weekly and monthly cleaning reported by Pine et al. [4] suggests 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), [19] or the amount of deposition which varies between wearers and between the eyes of the same wearer [18]. 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 [11,25] and potentially, the period between cleanings.

*All patients should clean their prostheses at least six monthly*

Cleaning at least six monthly is an arbitrary time but deposits accumulate continuously and after 6 months of wear may be thick enough to batter the conjunctiva and begin encroaching on the inter-palpebral zone.

Wide variation in the amount of deposits between patients has been reported in the contact lens literature [18]. 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 but will lie between monthly and six monthly parameters.

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

This cleaning method is simple and its use ensures that all surface deposits are removed effectively. The qualitative evidence for this cleaning method is based on the authors' experience of removing stained deposits from over 350 prosthetic eyes. The effectiveness of the recommended method was able to be judged because the deposits are visible when stained. Other methods trialled included using wetted tissue paper (too fragile), industrial strength

paper towels (affected the surface polish), wetted cloth (just as effective as a wetted paper towel 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.

*Prosthetic eyes should be blemish free with smooth rounded edges and polished to optical contact lens standard*

A perfectly smooth surface avoids mechanical irritation of the conjunctiva and consequent mucus production. Jones and Collin [16] 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.

An optical quality standard of surface finish produces the best available wettable surface on poly (methyl methacrylate) prosthetic eyes. Le Grand [6] recommended this standard for polishing prosthetic eyes and Pine et al. used in vivo [11] and in vitro [25] studies to show that an optical quality contact lens standard of surface polish produced a more wettable surface than a normal standard of finish. An optical quality contact lens standard of polish may be particularly important for the inter-palpebral surface to assist the cleansing action of tears.

*Prosthetic eyes should be professionally re-polished to optical grade contact lens standard annually*

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-socket-syndrome including ptosis of the upper lid and lower lid laxity [26]. Despite the reservations about the effect of professional polishing, [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 [11,24].

## Future research

We recommend that the proposed three phase model of the response of the socket to prosthetic eye wear and the personal and professional maintenance regimes that are derived from it be tested with further research.

*The physiology of anophthalmic sockets with prosthetic eyes*

The proposed three phase model of prosthetic eye wear would benefit from more detailed studies of the mechanisms underlying the processes described in the model. For example, Greiner et al. [27] found that contact lens wearers developed more non-goblet epithelial cells in the conjunctiva than non-wearers suggesting that these cells contribute to an increase in mucus production. The experiments of Greiner et al. using light and transmission electron microscopy and muco-protein staining techniques might be repeated with prosthetic eye wearers during different phases of the model.

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

Item 4 of the protocol for managing mucoid discharge recommends 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 [28] 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 determine the best method for cleaning prosthetic eyes.

*Investigation of prosthetic eye cleaning methods*

The evidence for item 4 of the protocol for managing discharge (cleaning method) is qualitative and a more quantitative experiment is recommended. This investigation could examine cleaning agents as well as cleaning methods. Osborn & Hettler [3] surveyed members of the American Society of Ocularists in 2007 and found that 47% of members recommended the use of mild soap or baby shampoo as cleaning agents and a further 13% recommended hard contact lens cleaners. The investigation might compare different cleaning methods and agents by staining and grading deposits that remain 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 here.

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

An experiment using the same techniques as Greiner et al. [26] could be set up to investigate the presence of deposits in the inter-palpebral zone after different periods of wear. This would provide better understanding of the interactions between the lids and the surface of the prosthesis in the interpalpebral zone. An investigation of Marx's line on the eye-lids of prosthetic eye wearers using the method employed by Korb et al. [29] 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.

## Conclusions

A proposed three phase model of prosthetic eye wear is presented as a basis for suggesting a personal cleaning regime to manage non-specific mucoid discharge associated with prosthetic eyes wear. It is proposed that periodic professional care of prosthetic eyes is also important for the management of discharge and evidence for effective surface finishing has been reported in this study. Taken together, the proposed regimes for personal and professional care comprise an evidence based protocol for managing non-specific discharge associated with prosthetic eye wear. The protocol accords with the recommendations of Le Grand [6] about the standard of surface finish for prosthetic eyes (although not for his view about the length of time between cleanings) and has implications for clinical practice and for the quality of life of anophthalmic patients.

Future research to test the hypothesis is recommended. If confirmed, the hypothesis has the potential to resolve the current varied and contradictory opinions about the management of discharge, and to clarify advice given to patients about how to personally care for their prosthetic eyes.

**Conflict of interest statement**

None.

**Sources of Support**

None.

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