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FACTORS AFFECTING MUCOID DISCHARGE ASSOCIATED WITH ARTIFICIAL EYE WEAR

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FACTORS AFFECTING MUCOID DISCHARGE ASSOCIATED WITH ARTIFICIAL EYE WEAR.

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(vi) Short Running Title: Discharge associated with artificial eyes

(vii) Statement of any conflict or commercial interest

Keith Pine The participants in this study were recruited from the NZ Artificial Eye Service which is owned and operated by Keith Pine.

Brian Sloan No conflicts or commercial interest

Joanna Stewart No conflicts or commercial interest

Robert Jacobs No conflicts or commercial interest

ABSTRACT

Background:

This study aimed to a) review what is known about mucoid discharge associated with artificial eyes, b) develop new measurement tools and c) begin the assembly of evidence to understand discharge causes and treatments.

Design:

This observational study was carried out in a number of private clinic locations.

Participants:

Forty three participants were recruited from the New Zealand Artificial Eye Service.

Methods: A survey of Ocularists' websites was carried out. Patients self-measured 4 discharge characteristics. Hand-washing instructions were given, observations made and deposits on artificial eyes were stained and photographed.

Main outcome measures:

Patients' discharge experience was measured with age, hand-washing, shape and weight of the prosthesis, removal and cleaning frequency and amount of surface deposits on the prosthesis as explanatory variables. Ocularists' opinions were summarised.

Results:

Yellower post-meridiem discharge was associated with patients not washing their hands prior to handling their prosthesis (p=.04) and when the artificial eye had a hollow shaped back compared to full-fit (p=.01). Removal frequency was associated with surface deposition

(p=.006) and those with continuous wear for 3 months or longer had greater surface deposition. No other associations could be shown between the explanatory variables and volume, viscosity or frequency of discharge.

Conclusions:

A standardised treatment protocol for managing discharge is lacking. Associations with yellower discharge were found with not hand-washing and with hollow backed prostheses. New methods for staining, photographing and grading artificial eyes were developed. The elements present at the interface between prosthesis and conjunctiva (including surface deposits) warrant further investigation.

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

INTRODUCTION

Mucoid discharge associated with artificial eye wear is a common occurrence that impacts on anophthalmic patients' quality of life. Pine et al 2010[1] report that discharge is the second most important concern for experienced artificial eye wearers after health of their remaining eye and affects 93% of wearers - 60% of these on a daily basis.

The formal literature does not provide a complete understanding of the nature and causes of discharge associated with artificial eye wear. This is reflected in the inconsistent and contradictory advice given to patients by ocularists and the lack of a standardised treatment protocol for this distressing condition. This study begins the assembly of evidence to understand the causes of discharge by reviewing what is known about mucoid discharge and its management and by examining aspects of artificial eye wear that are likely to be associated with discharge. During the study new measurement tools to measure surface deposits on artificial eyes are developed. The result is an investigation of the influence on discharge of hand washing before handling the prosthesis, removal and cleaning regimes, the weight and shape of the prosthesis, patients' age and deposits on artificial eyes.

METHODS

Literature review

A search of the formal literature was carried out together with a survey of 18 ocularist web-sites[2-20] providing advice about anophthalmia and artificial eyes.

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 between 250 and 300 people who were aged 18 years and over and who had at least two years' experience wearing an artificial eye. Letters were sent to 278 individuals inviting them to consider the research and 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 and after the study was explained to them in more detail 43 agreed to participate. The participants were aware that this study was part of a wider investigation into factors affecting artificial eye wear. The method of recruitment, the experiment and the wider study had ethics approval from the University of Auckland Human Participants Ethics committee.

Experimental Protocol

A self assessment form containing visual analogue scales (VAS) for describing discharge was posted to participants. The scales were used to self measure 4 discharge characteristics: colour, viscosity, volume and frequency. These are shown in Fig 1.

Insert Fig 1.

Participants commenced using the form to chart their ante meridiem (AM) & post meridiem (PM) experience with discharge at least 2 weeks prior to the first clinical session. At the first visit participants' demographic details, hygiene habits and artificial eye cleaning regimes were recorded and their artificial eyes weighed and categorised as being either hollow-back or full fitting. See photographs of full fitting and hollow backed artificial eyes (Fig. 2). The prostheses were rinsed and returned to the patients without cleaning or polishing. All patients regardless of their hygiene history were instructed to continue their usual wearing and

cleaning regimes but to ensure that they washed their hands before touching their artificial eyes. They continued to chart their experience with discharge until the second visit which took place no less than 2 weeks later. At the second visit, the charts completed by the patients were collected for analysis and the participants' artificial eyes were removed, stained for grading of deposits, and photographed.

Insert fig 2.

Method for staining deposits on artificial eyes

A dental plaque disclosing compound was chosen (see table 1 for the composition). Specifically, 5gms of GC Corporation's plaque disclosing gel[21] was dissolved in 30ml of OcuPure Saline solution[22] . The prosthesis was immersed in the solution at 20 degrees C for a period of 2 minutes. The time was carefully controlled so that the intensity of stain uptake could be measured without the influence of the staining method.

Insert table 1,

After the immersion period, the artificial eyes were lifted out and gently blotted with tissue paper to remove excess staining solution.

Method for photographing stained deposits on artificial eyes

Insert table 2

The stained artificial eye was photographed (see Table 2 for photography parameters) against a black background card which included a standard greyscale and colour scale that allowed the printed photographs to be examined periodically to ensure the consistency of the process. All the photographs used in the experiment were printed in a single session using a colour laser printer and satin finish photographic paper from a single batch.

Insert Fig 3

Method of grading the extent of deposition on prostheses

Photographic grading scales to measure the extent and the intensity of deposits on artificial eyes were developed. Each of these scales consisted of 11 photographs of the anterior surface of stained artificial eyes and 11 photographs of the posterior surface. (See figures 4 and 5) Each scale ranged from 0 to 10 with the photo for scale 0 having zero deposits and that for scale 10 having the most intense colouration and coverage. The scales were developed so that they were as close to an equal interval scale as possible with photo 5 being subjectively half way between 0 and 10 and the intervening photos providing equal subjective changes. The scales are shown in figure 3.

The photographs of the stained artificial eyes were graded front and back by comparing them with photographs from the previously developed grading scale.

Insert Fig 4 and Fig 5

Finally, the stained deposits were completely removed and the artificial eyes returned to the participant.

Statistical analysis

Only data recorded by patients in the week prior to each examination visit were used in the analysis. For the second visit this allowed a period of at least 7 days for any effects from the first visit to wash out. The outcome data was the log of the average over the 7 days of the discharge outcomes for colour, viscosity, volume and frequency, separately for AM and PM for each visit.

Three separate analyses were carried out:

1. To investigate what baseline behaviours or demographic variables influenced mucoid discharge a general linear model was fitted to the outcome data as measured at the first visit with whether or not they hand washed prior to handling the eye, the shape and weight of the eye, how often they removed the eye (daily, weekly to 6 weekly and greater than 6 weekly intervals), gender and age as explanatory variables.
2. To investigate whether previous hand washing influenced the change in mucoid discharge from pre to post hand-washing instruction, a general linear mixed model was fitted to the data with the log of the average of the discharge outcomes over the past week from the first and second visits as the outcomes and week, whether they hand-washed prior to instruction, and the interaction of these variables as explanatory variables. This analysis was repeated without the interaction term to look at the effect of hand-washing instruction.
3. To investigate variables associated with surface deposits at visit 2 ordinal logistic regression was used with deposits categorised into 0-2, 3-5, 6+. As front and back deposit grades were very highly correlated only front deposit grade was used. The explanatory variables included were removal, age, gender, weight and shape of the artificial eye.

RESULTS

Factors associated with discharge outcomes

Hand washing

Whether a patient washed or did not wash their hands prior to handling their prosthesis could not be shown to affect frequency, volume or viscosity of discharge in either AM or PM (all had p values >.2). Only the colour of PM discharge was affected by hand washing (p=.04) with patients who washed their hands having less yellow discharge. A similar relationship in the morning was not found (p=.83). Whether or not they had usually hand washed before they were given instructions to do so could not be shown to influence the change in discharge after instructions. However there was evidence of an association of having been given hand-washing instruction with morning colour (p=.04). Discharge was less coloured after instruction. This relationship could not be shown with PM discharge (p=.17) although the estimate of the effect of instruction was in the same direction and only a little less than in the morning. Instruction to hand-wash could not be shown to be associated with other discharge outcomes (all had p values >.4).

Shape of prosthesis

Patients wearing hollow backed artificial eyes experienced more coloured PM discharge than those with full fit artificial eyes (p=.01) but the shape could not be shown to be associated with AM colour (p=.37) nor any other discharge outcome (AM and PM volume p=.11 and .13 respectively both with less volume for full fit, viscosity and frequency p values all >.2 but again estimates all less for full fit).

Weight of prosthesis

There was weak evidence of an association of weight with AM colour (p=.07), AM frequency (p=.07) and PM frequency (p=.08) suggesting that heavier artificial eyes may produce yellower morning discharge and more frequent discharge throughout the day. No association could be demonstrated with PM colour (p=.75), AM or PM volume (p=.13 and .22) or viscosity (p=.19 and .23).

No associations of wearer age or frequency of removal with any of the discharge outcomes could be demonstrated.

Factors associated with deposit formation on artificial eyes

There was strong evidence of an association of removal and cleaning regimes with deposit formation (p=.006) with those wearing the prosthesis continuously for 3 months or more having the most deposition. There was possible evidence of an association with weight of the eye (p=.08) with heavier having more deposition. Neither shape (p=.78), wearer age (p=.49) nor gender (p=.25) could be shown to be associated with deposit formation.

DISCUSSION

The survey of ocularists' websites carried out on the 22nd July 2010 (table 3) revealed that the majority considered that mucoid discharge was associated with deposits that built up on the surface of artificial eyes. Yet 68% of the sites appeared to contradict this by recommending that the artificial eye a) never be removed and cleaned or b) only removed and cleaned if causing discomfort or discharge. Osborn and Hettler[23] 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". Twenty-five percent (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 standardised set of treatment protocols developed.

Insert Table 3.

The United Kingdom NHS National Artificial Eye Service web-site[20] advises patients to remove and clean their artificial 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, non scented soap. The web-site suggests that cleaning the artificial eye removes the main cause of discharge which is a build up of dirt and dust from the environment. This advice may be compared with the opinion of Le Grand[24] 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. Le Grand 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 formal literature has paid limited attention to the problem of discharge. Vasquez and Linberg (1989)[25] and Kim, Lee, et al. (2008)[26] found that there were bacteriologic and

cytologic differences between anophthalmic and natural sockets but these were not found to be associated with symptoms of discharge. Jones and Collin[27] in 1983 classified the causes of discharging sockets. They associated acute discharge with viral or bacterial conjunctivitis. Chronic discharge with recurrent symptoms frequently did not respond to topical antibiotics so causes other than infection were implicated. Their simple 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 al in 1980[28], 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 artificial lubricants might be of value. Fett et al[29] in 1984 evaluated the need for additional lubrication in 200 anophthalmic patients and found that 23% required supplementation. However, neither Allen et al nor Fett et al directly linked low basic tear production or the use of artificial lubrication with the discharge problem. Deposit formation on contact lens materials has been investigated extensively but this work has not yet been extended to artificial eyes. Furthermore, deposits on artificial eyes do not readily accumulate in the inter-palpebral zone where they are exposed to air – unlike contact lens.

A summary of the putative causes of discharge noted in the above literature sources together with patients' comments about discharge taken from a survey of 63 anophthalmic patients in 2009[1] are summarised in table 4

Insert table 4

This study has found evidence of an association between patients who habitually washed their hands before touching their artificial eyes and less yellow PM discharge. Less yellow AM discharge was associated with hand washing instruction. Vasquez and Linburg[25] did not investigate hand washing behaviour in their 1989 study but this may have been a factor in their finding that patients who frequently manipulated their prosthesis had a significantly higher proportion of gram-negative bacteria in the conjunctiva of their sockets. Either way the evidence suggests that hand washing may be an important part of artificial eye management and care.

No similar associations between historic hand washing or hand washing instruction were found for volume, viscosity or frequency of discharge.

Patients who wear hollow backed artificial eyes experienced yellower PM discharge than those with full fit artificial eyes. Jones and Collin (1983)[27] claimed that one of the causes of chronic discharge was a poorly fitting prosthesis which allowed a dead space behind where pooling of secretions could occur. They associated this type of prosthesis with large volume deficit sockets but all hollow-backed artificial eyes allow some pooling of secretions. As there was no association between artificial eye shape and discharge volume, viscosity and frequency, it might be that the pooling of secretions behind hollow backed prostheses has no clinical effect. On the other hand if yellower discharge is indicative of greater bacterial activity then pooling of secretions behind hollow backed artificial eyes may ultimately contribute to chronic discharge due to infection. The finding that less yellow secretions are associated with full fit artificial eyes may be because secretions are forced out of the socket before they pool and become yellower.

A limitation to the study was that only 11 of the 43 participants wore full fit artificial eyes. To address this, the authors intend to repeat the experiments with a larger group of participants.

The association between the extent and intensity of deposits on both the anterior and posterior surfaces of artificial eyes with historic removal and cleaning regimes is not surprising. The extent and intensity of the stained deposits ranged from small residues caught in scratches or depressions to full contiguous coverage with deposits of the areas in permanent contact with the conjunctiva. The stain used in the study is a 2 tone gel traditionally used to disclose dental plaque[21]. In dental work the pink stain represents new plaque and the blue stain represents plaque that has been in place longer. The explanation for this was provided by the GC Corporation (Personal communication 2010.) as follows: "*Plaque becomes more and more dense over time. Blue dyes in disclosing gel are easier to diffuse than red dyes. When the blue dyes penetrate into the old dense plaque, they remain in plaque, which means the color of the gel turns blue or purple. However the blue dyes come out from the new rough (nondense) plaque. Therefore a pink or red gel colour on the tooth surface indicates fresh plaque accumulation, where as a blue or purple gel colour indicates mature plaque.*" It is assumed that the stain behaved the same way when it was applied to deposits on artificial eyes.

The finding that discharge experience may not be associated with any particular removal and cleaning regime suggests that discharge may be influenced more by the physical interface between the prosthesis and the conjunctiva. Present at this interface are the physical, chemical and biological elements of the prosthesis, the conjunctiva, the socket fluids and the

deposits which cover the artificial eye. The least studied of these elements appears to be the deposits.

There appears to be no consensus for treatment of mucoid discharge associated with artificial eye wear and there remains a large and under investigated group of patients with non specific discharge, for which there have been many causes postulated. Further research is warranted because artificial eye wearers ranked discharge as the second most important concern after health of their remaining eye. We have taken initial steps to address the discharge issue with this observational study and found associations between yellower discharge and not hand washing and with hollow backed prostheses. We have used a new and innovative method for disclosing and quantifying deposits that form on prosthetic eyes

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Fig 1. Visual analogue scales for self measuring watering, crusting and discharge.

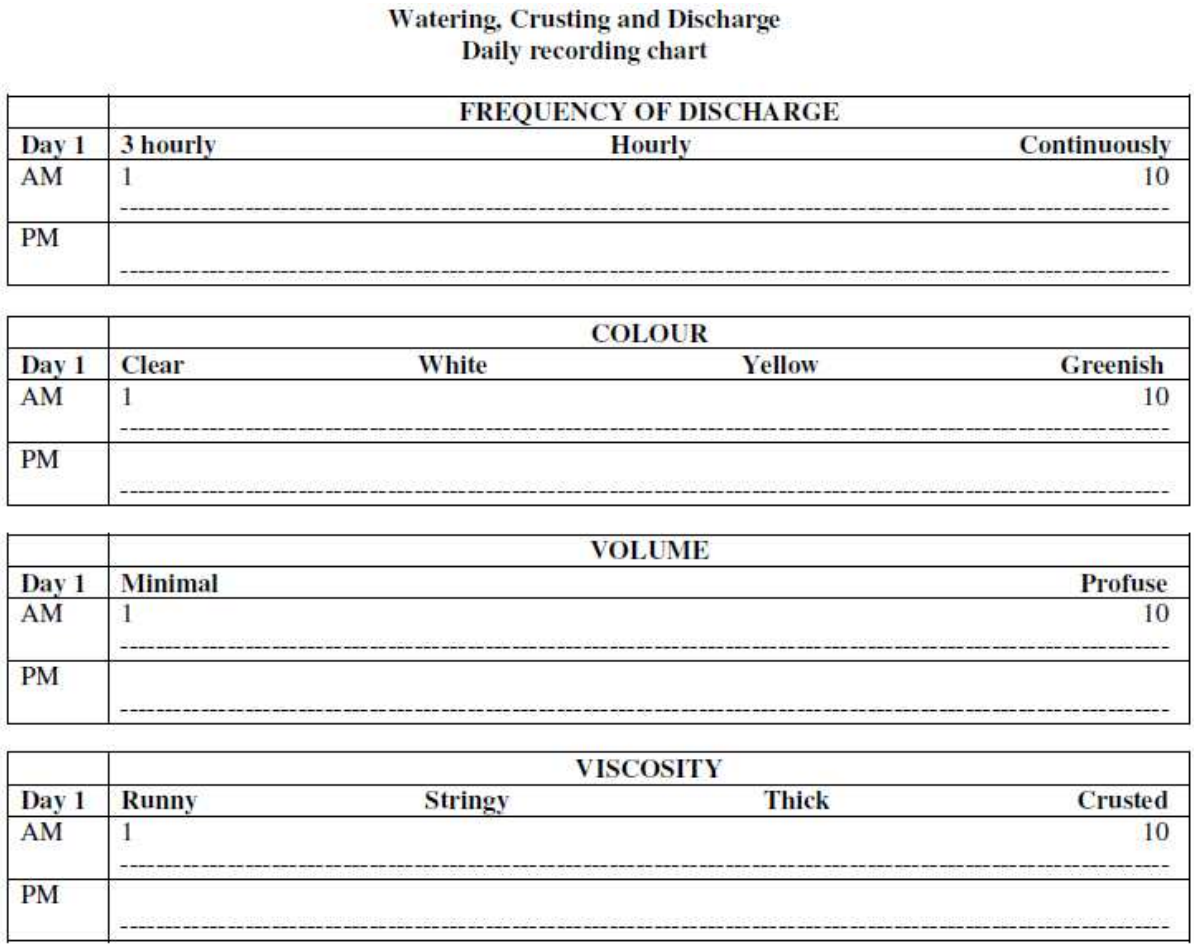
Fig 2. Full fit and hollow backed artificial eyes

Fig 3. Stained deposits on a right artificial eye. Note that no deposition occurs in the inter-palpebral zone.

Fig 4 Grading scales for stained deposits on the anterior surface of artificial eyes.

Fig 5 Grading scales for stained deposits on the posterior surface of artificial eyes.

Fig 1. Visual analogue scales for self measuring watering, crusting and discharge.



Watering, Crusting and Discharge
Daily recording chart

	FREQUENCY OF DISCHARGE		
Day 1	3 hourly	Hourly	Continuously
AM	1 ----------		10
PM	----------		

	COLOUR			
Day 1	Clear	White	Yellow	Greenish
AM	1 ----------			10
PM	----------			

	VOLUME	
Day 1	Minimal	Profuse
AM	1 ----------	10
PM	----------	

	VISCOSITY			
Day 1	Runny	Stringy	Thick	Crusted
AM	1 ----------			10
PM	----------			

Fig 2. Full fit and hollow backed artificial eyes

Fig 3. Stained deposits on a right artificial eye. Note that no deposition occurs in the inter-palpebral zone.

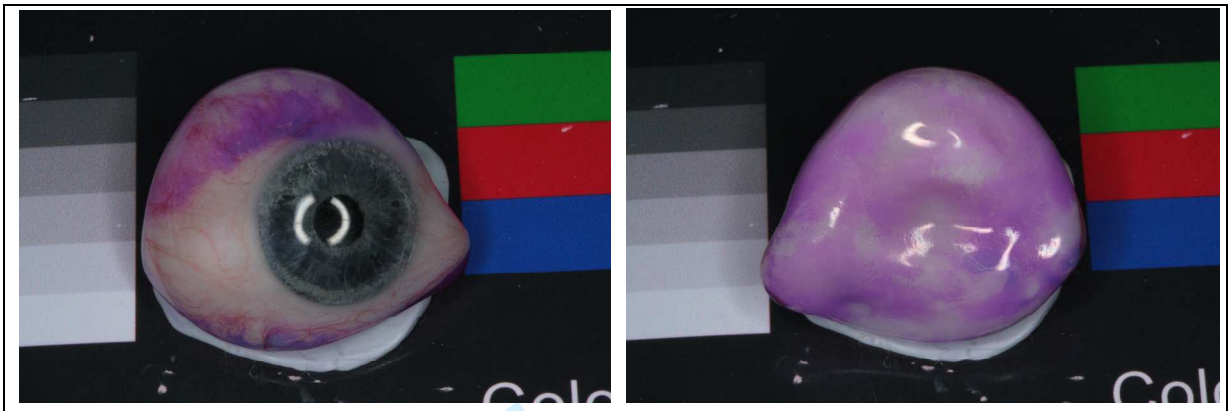


Fig 4. Grading scales for stained deposits on the anterior surface of artificial eyes.

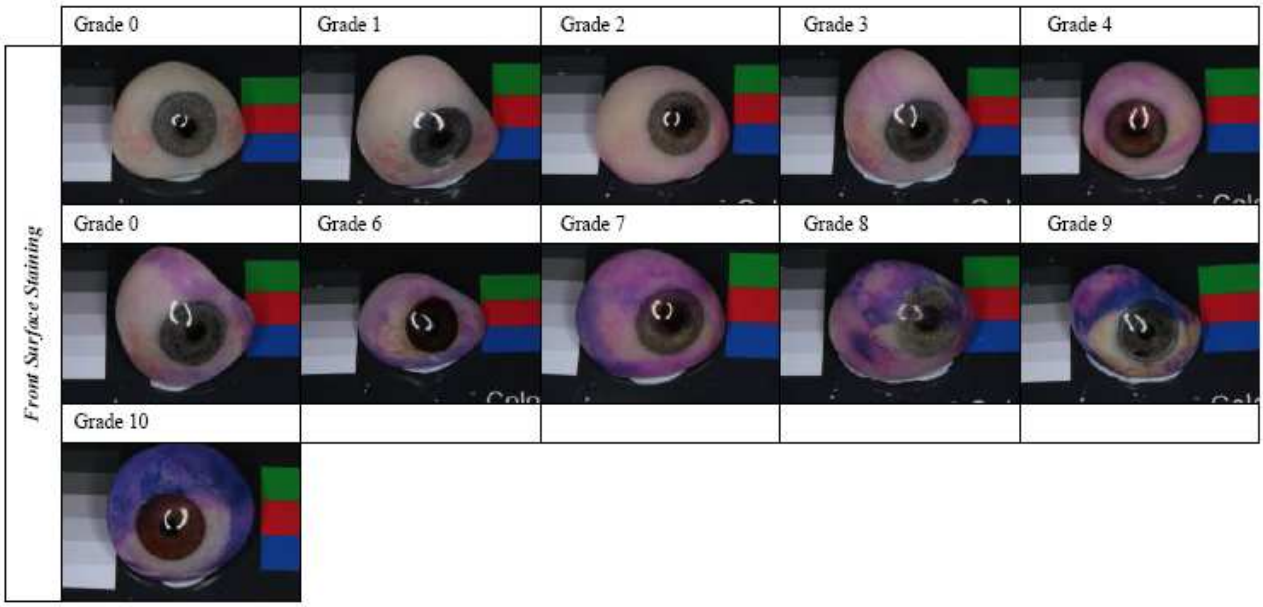


Fig 5. Grading scales for stained deposits on the posterior surface of artificial eyes.

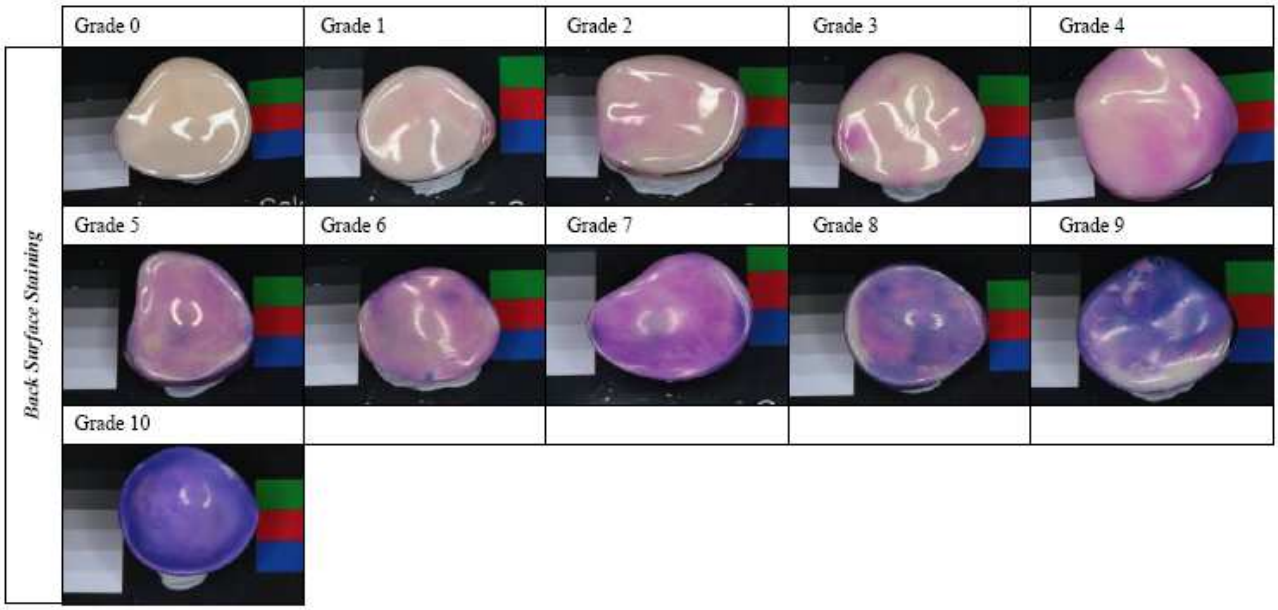


Table 1. GC Corporation plaque disclosing gel ingredients

Water	70 -75%
Ethyl alcohol	18 – 20%
Food red 105 (Rose Bengal)	4%
D sorbitol	3%
Sodium Carboxymethyl Cellulose (CMC-Na)	2%
Butyl p-hydroxybenzoate	<1%
Flavouring	<1%
Sodium salicylate	<0.1%

Table 2. Camera specifications and photography settings

Camera	Canon 1000D
Lens	Macro EF-S 60mm f/2.8 USM
Flash	Cannon Macro Ring Light MR-14X
Camera setting	Manual
Exposure time	1/125 second
Aperture size	F/32
Focus	Automatic
Picture style	Faithful
White balance	Flash
Sensitivity	ISO 400
Flash setting	Manual exposure
Flash output	1/16
Distance from sensor plane to the prosthesis for photography	22cm – 27cm

Table 3 Summary of discharge advice published on ocularists' web-sites

Main cause of discharge (n=15)	**Percent**
Build up of deposits	53%
Handling the prosthesis	27%
Other (eg, poor fitting prosthesis, scratched surface, etc)	20%
Recommended cleaning regime (n=16)	
Do not remove unless uncomfortable or discharging.	44%
Set regime – daily to 2 monthly.	31%
Leave in and do not handle.	25%

Table 4. Putative causes of mucoid discharge summarised from ocularists' websites, formal literature and subjective comments from patients in a previous study.

Specific causes	
Viral or bacterial infections	Common cold, etc.
Environmental allergens	Pollens, dust mites, etc.
Irritants in the socket	Dust, stray eye-lashes, smoke filled rooms etc.
Eye stress	Night driving, reading, computers, etc.
Drying conditions	Wind, air conditioners, etc.
Clinical intervention	Impression taking, etc
Damaging behaviour	Excessive rubbing of prosthesis, etc.
Nonspecific causes	
Physical irritation from prosthesis	Size, surface finish, surface deposits, weight, material and manufacturing process, etc.
Deposits on prosthesis	Protein, dirt, etc
Shape and fit of prosthesis	Full fit or hollow back
Removal regime	Daily, monthly, never
Cleaning agents	Soap, detergents
Socket hygiene	Contamination from fingers and eye-lids
Lacrimal system	Defective tear production and drainage. Infective focus (dacryocystitis)
Anatomical limitations	Poor lid closure, grafted tissue, scarring, etc.
Medical conditions	Unwell, side effects from drugs
Orbital implant	Extrusion, conjunctival inclusion cysts, granuloma. Infective focus (blepharitis, meibomianitis).

Cytological features	Squamous metaplasia
Patient demographics	Age, life style, etc.

end