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Key Words

Artificial eyes, custom ocular prosthesis, Schirmer's test, dryness, dry eye, prosthetic eye, tears secretion, anophthalmic socket, disfigured eye, phthisical eye

Tears Deficiency in the Anopthalmic Socket in the Absence of a Diagnosis of Tear Deficiency Prior to the Patient's Eye Loss

ABSTRACT

A common consequence of the loss of an eye is a reduction of tear secretions in the patient's now analthalmic socket. This artical discusses the author's comparitive study of the analthalmic socket to the patient's healthy companion eye socket with an emphsis on patients/study subjects who, prior to their eye loss, did not have a history of problems associated with a diagonsis of dry eyes.

Introduction

Loss of an eye is a very unfortunate circumstance in one's life. The cases identified in this study include patients with an anophthalmic socket or disfigured globe. A well-fitting ocular prosthesis can help to restore a normal appearance, however these patients often find that they now have symptoms commonly associated with the use of an ocular prosthesis that they had not anticipated. These include frequent discharge, discomfort, dryness, crusting of eyelids and lashes over the prosthetic eye. 1,2 The underlying causes for these symptoms include a rough surface on the prosthesis itself, tenacious surface deposits, meibomianitis or other infectious conditions, an ill-fitted prosthesis which may include the presence of any unfilled spaces/gaps between the socket and the prosthesis and/or any uncured polymer left in the intermolecular spaces of the PMMA network.² The use of a custom-designed prosthetic eye has tremendously improved the aesthetic appearance as well as comfort in these patients, however the patients still have these persisting symptoms.

Reduction in tear secretion is known to cause dry eye and often initiates the rather common clinical practice of investigating the tear levels present in these patients who complains of dryness. Therefore, it is meaningful to study and compare the tear secretion level between the normal eye and the prosthetic eye to know the causative factor for dryness and discomfort.

Understanding Tears And The Wetting Process

The main function of the tears is to keep the eyes moist. Tears are mainly secreted by the lacrimal gland. Basal (basic), emotional and reflex tears are 3 types of tear secretions. They are also a source of many biologically

active substances, immunoglobulins and proteins, all of which play a major role as defense mechanism in protecting the eye. Blinking action spreads the tears uniformly over cornea and forms a tear film, which consists of 3 layers: lipid layer, aqueous layer and mucous layer. Exposure to air causes the tear film to evaporate and break down; then the next blink action again forms the layer.3

Tear break-up time (TBUT) is a test to measure the relative stability of pre-corneal tear film. It is the time it takes for the tear film to break up after the last blink. A normal TBUT is more than 10 seconds. A value less than 5 seconds is considered abnormal and is an indication of dry eye syndrome.4 Schirmer's test is a measure of the amount of tears produced by the eye in a 5 minutes measure. This test is useful in making a comparison of the tear production between both eyes in a healthy patient, between an anopthalmic socket and a normal companion eye and between the eyes of different personnels.5

A review, by the author, of the currently available literature revealed only one relevant study on comparing the tear measurements in the prosthetic eye (in anophthalmic socket cases) vs. a contralateral normal eye.2 This article, written by Lee Allen, concluded that a significantly lower tear production in the prosthetic eye socket as compared to the contralateral normal eye (when there was no anesthetic effect). In contrast, with the effect of topical anesthesia, no significant difference was found between the prosthetic eye and the normal eye.2

Methodology Used In This Study

The main aim of this research was to compare the tear secretion levels between the prosthetic eye socket and a contralateral normal eye socket in monocular patients with an anophthalmic socket or disfigured globe.

This study represented a cross–sectional of patients with an emphasis on producing a precise case control study. Approval from the Investigative Research Bureau and Ethics Committee at LV Prasad Eye Institute, India was obtained prior to its commencement. The study was conducted at the Department of Ocularistry, LV Prasad Eye Institute, India.

Subjects in this study ranged in age between 16 to 40 years. These subjects had undergone an evisceration or enucleation in one eye followed by the fitting of a custom ocular prosthesis 6 weeks after their surgery. Also included in the study were one-eyed patients who were fitted with a custom-made prosthetic shell

over phthisis or atrophic bulbi eyes. Requirements for study subjects included those who were voluntarily willing to participate, cooperative and who had been using a prosthesis for 6 months or more. Informed consent was obtained from every person in the study.

Subjects with a known history of dry eyes, severe orbital trauma cases, prior history of radiation/ chemotherapy, systemic disease such as Steven Johnson syndrome, immunosuppressive drug users, the patients with socket inflammation and those wearing ill-fitted prosthesis were excluded.

A questionnaire including the known symptoms associated with wearing a prosthesis was prepared and presented to each subject by a third party (in order to maintain impartiality). Both eyes of each subject were examined including a socket assessment which was undertaken by an Ophthalmologist as well as an Ocularist. This was done in the same room by the same examiner and by the same ocularist each time. The entire examination and all tests were carried out while keeping the room temperature at 23°C.

A comprehensive ophthalmic examination was undertaken, which included: visual acuity assessment by Snellen chart, objective and subjective refraction, and a slit-lamp examination with Haag-striet slit-lamp. An Ocularist examined the socket and the prosthetic eye.

A series of Schirmer's tests and TBUT tests were undertaken. Schirmer's test was performed by inserting Schirmer's Strip into the lower lateral fornix of right eye and the left eye for 5 minutes duration. Tear levels indicated by the wetness on the Schirmer's strip were recorded.5

The test was grouped into the following:

- Schirmer's Ia (Tear level measurement with the prosthesis insitu without the effect of topical anesthesia)
- Schirmer's Ib (Tear level measurement with the prosthesis insitu with the effect of topical
- Schirmer's IIa (Tear level measurement of empty socket without the effect of topical anesthesia)
- Schirmer's IIb (Tear level measurement of empty socket with the effect of topical anesthesia)

A questionnaire was presented to the subjects, which included questions on the cleaning schedule/ regimen they used for their prosthesis, duration of the prosthesis wear between periods when it was removed for whatever reason, symptoms of gritty feeling, itching, dryness, burning sensation, watering, pain,

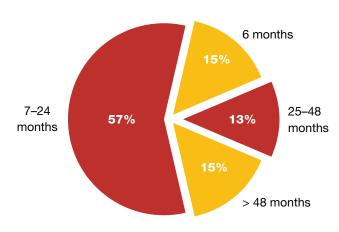


FIGURE 1: Duration of prosthesis wear

discharge; and whether their sensitivity was increased in the presence of strong air currents, changing levels of light, in the presence of smoke and/or in an air conditioned atmosphere. The patients were asked to categorize their symptoms according to their preference on the following scale: 1. Never, 2. Seldom, 3. Often, and 4. Always.

The data was entered in MS Excel windows version 2000, and was analyzed using Spearman's Rank Correlation on the Graph Pad (5.0) software with a significance level of α = 0.05. The aim was to know the correlation of the patient's symptoms to the clinical signs that were found on the examination.

Results

There were A total of 50 patients, 31 males and 19 females with a mean age of 23.67 (16-58) years. Out of 50, 30 were anophthalmic sockets (60%),

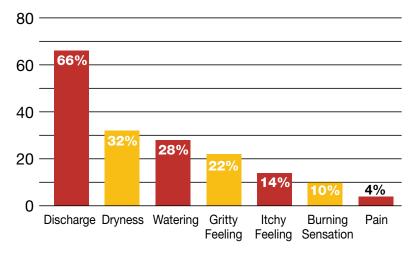


FIGURE 3: Symptoms reported by the patients

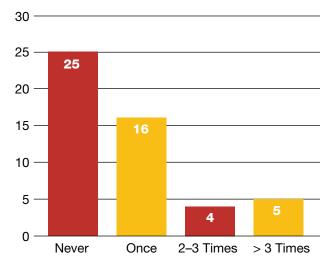


FIGURE 2: Polishing of the prosthesis

19 (38%) were disfigured globe and 1 (2%) with microphthalmos. The amount of time that the subjects had been wearing a prosthesis ranged between 6 and 48 months in 87% of the cases. In 13% of the cases the subjects had been wearing a prosthesis for more than 48 months.

The patients with anophthalmic sockets were advised to wear their prosthesis even during sleeping hours, and to clean the prosthesis once in 15 to 30 days. The patients with disfigured globe were advised to remove the prosthesis at night and clean the prosthesis before wearing in the morning. All the patients were instructed to clean the prosthesis with water and a baby shampoo.

There were 8 (16%) subjects who had the habit of removing their prosthetic eye for cleaning it with water and /or shampoo once in a prescribed duration of more than 15 days to 30 days and the remaining sub-

> jects were, astonishingly, cleaning it daily with water or shampoo (which included 50% of those having disfigured globes and 34 % having anophthalmic sockets).

Figure 1 shows the duration of prosthesis wear, and Figure 2 demonstrates how many times the patients got their prosthesis polished. There were 50% of the patients who never got their prosthesis polished, and 32% who got their prosthesis professionally polished only once since it had first been fitted. The results of the symptoms reported by the patients in the questionnaire were illustrated in Figure 3.

TABLE 1 Correlation of Schirmer's la value with the symptoms and sensitivity factors

Schirmer's la	Total number of subjects	Spearman r	95% confidence interval	P value (two-tailed)
Gritty	50	-0.1681	-0.4334 to 0.1241	0.2433
Itchy	50	-0.2137	-0.4711 to 0.07720	0.1362
Burning	50	-0.03564	-0.3186 to 0.2531	0.8059
Dryness	50	-0.1229	-0.3952 to 0.1693	0.3953
Watering	50	-0.07591	-0.3544 to 0.2150	0.6003
Discharge	50	0.09792	-0.1937 to 0.3736	0.4987
Pain	50	0.0399	-0.2491 to 0.3224	0.7833
Smoke	50	-0.3317	-0.5643 to -0.05026	0.0186
Light	50	-0.1876	-0.4497 to 0.1041	0.1919
Air	50	-0.07769	-0.3560 to 0.2132	0.5918

Discharge (66%) was the major complaint followed by dryness (32%). In 24% of these subjects/patients it was found that they were sensitive to smoke, 62% to light (including sunlight) and 54% were sensitive to air. The questionnaire included questions related to any sensitivity to the use of computers and/or air-conditioning, however, more than 50% of subjects had no regular access to computers nor to air-conditioning. Only six patients were using artificial tear drops on a regular basis.

The correlation of Schirmer's Ia and Schirmer's Ib test results with each of the symptoms and sensitivity factors (smoke, light and air) were summarized in Tables 1 and 2 respectively. There was no statistically significant correlation found with the symptoms (p>0.05). Smoke was the only significant factor that correlated with Schirmer's Ia (p=0.0186) and Schirmer's Ib (p= 0.034) value.

Schirmer's IIa and Schirmer's IIb correlation with the symptoms and other sensitivity factors (smoke,

TABLE 2 Correlation of Schirmer's Ib value with the symptoms and sensitivity factors

Schirmer's Ib	Total number of subjects	Spearman r	95% confidence interval	P value (two-tailed)
Gritty	50	-0.1132	-0.3869 to 0.1787	0.4336
Itchy	50	-0.04461	-0.3266 to 0.2447	0.7584
Burning	50	0.115	-0.1770 to 0.3884	0.4264
Dryness	50	-0.01584	-0.3007 to 0.2716	0.9131
Watering	50	-0.08839	-0.3653 to 0.2029	0.5416
Discharge	50	0.1748	-0.1173 to 0.4390	0.2248
Pain	50	0.02125	-0.2666 to 0.3056	0.8835
Smoke	50	-0.2952	-0.5361 to -0.009805	0.0374
Light	50	-0.1141	-0.3876 to 0.1779	0.4302
Air	50	0.05513	-0.2348 to 0.3360	0.7037

TABLE 3

Correlation of Schirmer's IIa value with the symptoms and sensitivity factors

Schirmer's Ila	Total number of subjects	Spearman r	95% confidence interval	P value (two-tailed)
Gritty	50	-0.2447	-0.4986 to 0.04777	0.0901
Itchy	50	-0.3154	-0.5540 to -0.02898	0.0273
Burning	50	-0.1285	-0.4027 to 0.1668	0.3789
Dryness	50	-0.2652	-0.5148 to 0.02590	0.0655
Watering	50	-0.01085	-0.2990 to 0.2791	0.941
Discharge	50	-0.1219	-0.3970 to 0.1733	0.4039
Pain	50	-0.009251	-0.2976 to 0.2806	0.9497
Smoke	50	-0.3463	-0.5776 to -0.06358	0.0148
Light	50	-0.4179	-0.6308 to -0.1464	0.0028
Air	50	-0.1698	-0.4374 to 0.1255	0.2434

light and air) were summarized in Tables 3 and 4 respectively. There was no statistically significant correlation was found between Schirmer's IIa and Schirmer's IIb value and symptoms (p>0.05). Only significant factors that correlated was between Schirmer's IIa value and sensitivity to smoke (p = 0.0148) and light (p=0.0028) as shown in Table 3.

Mean values of Schirmer's Ia, Ib and TBUT in the prosthetic eyes and the contralateral normal eyes has been described in Table 5, which showed a statistically significant difference between both the eyes.

Discussion

An ideal healthy anopthalmic socket has complete eyelid closure, a smooth prosthetic surface is on the prosthesis and a healthy tear film is found on the prosthetic eye surface. 6 The author's opinion is that patients with an anophthalmic socket or a disfigured globe would achieve the most comfortable and optimum prosthesis by being fitted with a custom-made ocular prosthesis. However, these patients would still have some concerns that would have to be addressed.

TABLE 4

Correlation of Schirmer's IIb value with the symptoms and sensitivity factors

Schirmer's IIb	Total number of subjects	Spearman r	95% confidence interval	P value (two-tailed)
Gritty	49	-0.1633	-0.4320 to 0.1320	0.2622
Itchy	49	-0.1801	-0.4460 to 0.1150	0.2155
Burning	49	-0.1372	-0.4101 to 0.1582	0.3471
Dryness	49	-0.1314	-0.4051 to 0.1640	0.3682
Watering	49	0.0411	-0.2510 to 0.3263	0.7792
Discharge	49	0.04619	-0.2462 to 0.3309	0.7527
Pain	49	-0.04098	-0.3262 to 0.2511	0.7798
Smoke	49	-0.168	-0.4360 to 0.1273	0.2485
Light	49	-0.1675	-0.4355 to 0.1278	0.2499
Air	49	-0.07937	-0.3602 to 0.2147	0.5877

The most common symptoms associated with wearing an ocular prosthesis, according to this study, include mucous discharge (in 66% cases) followed by dryness (in 32% cases).

The following reasons could be anticipated as a cause for the symptom of mucous discharge:

- Mild mucous discharge is common in the patients with a prosthetic eye even in healthy sockets. This is due to alteration in tear production (decreased tears) stimulating the goblet cells to produce more mucous. This happens in response to the presence of a prosthetic eye due to a "foreign body reaction".7,8
- Delaying the polishing of their prosthesis by a professional ocularist or not getting the prosthesis polished on time could lead to socket infection and symptoms. The study subjects were advised to get the prosthesis polished once in every 6 months. However, in this study, it was noted that 50% of the patients had never had their prosthesis polished. Some were wearing their prosthesis for more than 3 years without getting their prosthesis polished. The patients with anophthalmic socket were advised to clean the prosthesis once in 15 to 30 days. Taking out the prosthesis very frequently and maintaining an excessive cleaning regiment might also be one of the reasons for their symptoms.
- Once the socket adapts to the prosthesis, fit can alter slightly or significantly. Any significant change in the prosthesis fit could cause the symptoms of discharge.

Lee Allen² et al. found that 63% of the patients in his study had no symptoms, others complained of dryness, stringy mucous discharge, "smarting", draggy eyelids and bloody tears. When the Schirmer's values were compared between the subjects who had no symptoms vs. the subjects who had symptoms, it was noted that the symptomatic subjects had an average

tear production of 5 mm. In contrast, non-symptomatic group had an average tear production of 17mm in 5 minutes Schirmer's test.

In this study, mean Schirmer's values (tear secretion when there was no effect of topical anesthesia) and TBUT values were low in the prosthetic eye as compared to the contralateral normal eye (Table 5). Lee Allen² et al. had found similar results in the subjects with anophthalmic sockets. Median Schirmer's values were < 11 mm in the prosthetic eye and <20 mm in the contralateral normal eye.

One reason is the surface of the prosthesis is hydrophobic. The other reason is the overall aqueous tear volume in the prosthetic eye is less because the reflex tears were not produced by the prosthetic eye. The reflex tears are produced against external stimulations due to corneal and eyeball sensations. When the eyeball is removed, the sensations present in the eye were lost, and the reflex tear production action is affected. Also, the presence of a prosthetic eye might further act as a barrier to feeling the stimuli that causes this type of tear production.² Excess tear production due to the presence of a foreign body is occasionally found in some cases among those who have a disfigured globes and who have a high degree of sensations in that globe.

Reduced levels of aqueous volume could result in improper flushing of mucin and oily components; and in a thick mucoid residue build up on the prosthetic eye surface. The combined effect of tear deficiency, deposit build-up and micro trauma associated with the mechanical rubbing of the prosthesis into the tarsus and posterior lid margins could also lead to excretory duct obstructions. The author recommends warm compresses followed by meibomian gland orifices expression should relieve the symptoms to some extent. 6 Thus; lack of enough tears in the prosthetic eye could be one of the causes for most symptoms including dryness, mucoid discharge, deposit buildup, crusting, etc.

TABLE 5 Mean values of Schirmer's Ia, Ib and TBUT values in prosthetic and normal eyes

	Prosthetic eyes (SD)	Control eyes (SD)	P value (t-test)
Schirmer's la (in mm)	10.26 (6.10)	17.74 (7.39)	0.0001
Schirmer's lb (in mm)	7.68 (5.60)	11.44 (6.05)	0.0001
TBUT (in Seconds)	3.66 (2.56)	14.82 (4.52)	0.0001

Kelly et al.9 has invented the Self Lubricating prosthesis (SLP[™]) to provide comfort in the patients with dry eyes. It is a uniquely designed prosthesis that consists of a chamber within the prosthesis filled with lubricant, which is released and spread on the front surface through a fenestration on the front surface of the prosthesis. Not all patients require SLP™ prosthesis. Many of the symptoms described in this study are due to problems related the prosthetic eye surface. These symptoms can be mitigated by either polishing the prosthesis, prescribing artificial tears / lubricating eye drops, or both.2,6

All the subjects presented to us were asked to get their prosthesis polished and 35 (70%) of them were prescribed artificial tears drops and 6 (12%) were prescribed antibiotic eye drops to treat socket infection and severe discharge.

In the author's opinion it would be useful to compare the Schirmer's and TBUT values between the patients with anophthalmic sockets vs. disfigured globes; as well as between the symptomatic vs. non-symptomatic subjects. These topics need to be researched in the future.

In conclusion, the most common symptom in prosthetic eye users was discharge followed by dryness. The underlying causes for these symptoms include lack of enough tear production, deposits/buildup on the prosthesis and delayed polishing/cleaning by a professional ocularist.

Absence of corneal nerves and the bulbar conjunctiva shielded by the prosthetic eye eliminate the stimulus for production of reflex tears, thus reducing the volume of overall tears produced in the prosthetic eye.

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