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## Tear Measurement in Prosthetic Eye Users

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**A**n eye is like a window to the outer world. Loss of an eye is probably regarded as the greatest misfortune, which can happen to anyone. The loss of an eye or a disfigured eye has a far-reaching impact on a person's psyche; in addition it has distressing consequences on their social and professional life. The person is always in the fear of losing the other eye and has to live with the social stigma of having one eye. Management of these cases includes the fitting of an artificial eye or ocular prosthesis for cosmetic rehabilitation<sup>1, 3, 4</sup>. There is minimal public awareness about the cosmesis and benefits of an artificial eye.

Now in the modern era, the prosthesis eye can be so much life like; can mimic like a real eye in appearance, movements and emotions that a normal eye does.

Very simple but a delicate procedure can bring the patient back to the normal life style. Many artificial eye wearers, maintaining good care, hardly have any complaints regarding it. But there can be significant number of reports mentioning in the patient complaints like dryness, discomfort, crusting of lids and lashes with their artificial eyes causes for these problems could be roughened surface, tenacious surface deposits, meibomitis or any infectious allergy in the eye, unfilled space between eye and toxic materials collected in the intermolecular spaces with in PMMA (plastic) artificial eyes.<sup>1,4,6</sup>

Even advanced techniques to reduce dryness in the prosthetic wearers as described by Kevin et al<sup>2</sup> in the form of a unique adventure in the world of ocularist called the Self Lubricating

the ocular Prosthesis (SLP™).

SLP™ provides the needed lubrication to the artificial eye surface for the relief of dryness and related problems.

More often as he describes in his study that most of the patients does not need a Self Lubricating Prosthesis (SLP), their problem is related to the surface of the prosthesis. Some patients who report having discomfort due to dryness<sup>5,6,7,8,9</sup> in the ocular cavity with the prosthesis have benefited from either polishing of their prosthesis, prescribing lubricating in the form of eye drops, or both. But it is noted that few patients have a reappearance of the similar discomfort immediately after discontinuing the medications.

### Justification

Very little recent documentation is found on the tear levels in the artificial eye wearers. This information is very important because it is noted that dryness and discomfort is a frequent complaint found in them.

Lee Allen<sup>1</sup> et. al conducted a study in 1980 to demonstrate deficient tear production in anophthalmic socket as compared to normal eyes<sup>1</sup>. They inferred that artificial lubricants might be beneficial in people wearing artificial eyes.

As it is a known fact that Indian eyes have slightly different responses due the different climatic conditions here. Thus recent recording in this aspect is important.

### Literature Review

In a prospective study on 94 consecutive

unilateral cases of enucleated and eviscerated eyes Lee Allen et al concluded that,

- The control eyes produced more tears without topical anesthetic than with it in a normal manner. The sockets of artificial eyes produced as many tears with anesthetic as without it.
- The median total tear measure in 50% of the 94 control eyes was 20 mm or less in 5 mins while the median measure on 50% of the artificial eyes was 11 mm or less.
- 63% of 94 subjects reported “no problems”, 31 patients reported one or more problems including “dryness”, “stringy mucous”, “smarting”, “draggy eyelids” and “bloody tears”.
- Those with no problems measured 17 mm in 5 minutes while those with problems measured an average of 5mm in 5 minutes.

### Results

- To find out whether all patients complaining of dry eye require lubricating drops to rectify the problem of acute or chronic dryness.
- To provide the data available so that we can know that how much tears formation happen in an anophthalmic cavity and disfigured globe.
- To compare the tear secretion level between the fellow eye of unocular prosthetic user so as to classify them into true tear deficient patients and tear deficiency due to other physiological (systemic) problems among unocular prosthetic user in South India.

### Materials and Methods

**Study Design:** Cross –Sectional, Case Control Study.

**Study Area:** Department of Ocular Prosthesis, L V Prasad Eye Institute, Hyderabad, India

#### Inclusion Criteria

1. All subjects who underwent evisceration or enucleation in only eye (unocular) at Ocular Prosthesis Service at L.V. Prasad Eye Institute and fitted with the custom ocular prosthesis.

2. All subjects using prosthetic eyes for more than 6 months.
3. All subjects who have phthisical globe and atrophic globe and using the prosthesis eye.
4. All subjects who provide good cooperation.
5. All subjects between 16 to 40 years of age are considered.

#### Exclusion Criteria

1. Subjects with a prior history of radiation
2. Subjects who are undergoing chemotherapy
3. Subjects with ill-fitted prosthesis
4. Subjects with socket inflammation
5. Subjects with a known history of dry eyes
6. Subjects who are having the systemic disease such as Steven Johnson Syndrome
7. Subjects with severe orbital trauma
8. Subjects on immunosuppressive drugs

The study was carried out on 62 subjects but the data of 50 subjects could be considered 25 in each group and 50 controls (fellow) eyes using the Schirmer’s test<sup>2</sup>. It was carried out in the following procedure.

All the patients who visited, the department of Ocular Prosthesis after fitting of the custom ocular prosthesis, for a follow up visit were selected according to the criterias mentioned above and informed consent was taken from each subject. It was after their approval that a questionnaire related to their symptoms was presented by a third person (a person from non-optometric background and one who was not aware of the study protocol).

All subjects had undergone a comprehensive ophthalmic examination. The ophthalmic examination includes: visual acuity assessment by Snellen chart, objective and subjective refraction, and and Slit- lamp examination with Haag-striet Slit-lamp for any ocular problems followed by consulting the ocularist’s examination of eye was done including the socket and the prosthetic eye all done in the same room (with an average temperature of 15 degree Celsius) by the same examiner and same ocularist each time.

**Table-1**

<b>Schirmer's I A</b>	<b>Gritty</b>	<b>Itchy</b>	<b>Burning</b>	<b>Dryness</b>	<b>Watering</b>
Total number of subjects	50	50	50	50	50
Spearman r	-0.1681	-0.2137	-0.03564	-0.1229	-0.07591
95% confidence interval	-0.4334 to 0.1241	-0.4711 to 0.07720	-0.3186 to 0.2531	-0.3952 to 0.1693	-0.3544 to 0.2150
P value (two-tailed)	0.2433	0.1362	0.8059	0.3953	0.6003

**Table-2**

<b>Schirmer's I B</b>	<b>Discharge</b>	<b>Pain</b>	<b>Smoke</b>	<b>Light</b>	<b>Air</b>
Total number of subjects	50	50	50	50	50
Spearman r	0.09792	0.0399	-0.3317	-0.1876	-0.07769
95% confidence interval	-0.1937 to 0.3736	-0.2491 to 0.3224	-0.5643 to -0.05026	-0.4497 to 0.1041	-0.3560 to 0.2132
P value (two-tailed)	0.4987	0.7833	0.0186	0.1919	0.5918

**Table-3**

<b>Schirmer's I B</b>	<b>Gritty</b>	<b>Itchy</b>	<b>Burning</b>	<b>Dryness</b>	<b>Watering</b>
Total number of subjects	50	50	50	50	50
Spearman r	-0.1132	-0.04461	0.115	-0.01584	-0.08839
95% confidence interval	-0.3869 to 0.1787	-0.3266 to 0.2447	-0.1770 to 0.3884	-0.3007 to 0.2716	-0.3653 to 0.2029
P value (two-tailed)	0.4336	0.7584	0.4264	0.9131	0.5416

**Table-4**

<b>Schirmer's I B</b>	<b>Discharge</b>	<b>Pain</b>	<b>Smoke</b>	<b>Light</b>	<b>Air</b>
Total number of subjects	50	50	50	50	50
Spearman r	0.1748	0.02125	-0.2952	-0.1141	0.05513
95% confidence interval	-0.1173 to 0.4390	-0.2666 to 0.3056	-0.5361 to -0.009805	-0.3876 to 0.1779	-0.2348 to 0.3360
P value (two-tailed)	0.2248	0.8835	0.0374	0.4302	0.7037

**Table-5**

<b>Schirmer's 2 A</b>	<b>Gritty</b>	<b>Itchy</b>	<b>Burning</b>	<b>Dryness</b>	<b>Watering</b>
Total number of subjects	50	50	50	50	50
Spearman r	-0.2447	-0.3154	-0.1285	-0.2652	-0.01085
95% confidence interval	-0.4986 to 0.04777	-0.5540 to -0.02898	-0.4027 to 0.1668	-0.5148 to 0.02590	-0.2990 to 0.2791
P value (two-tailed)	0.0901	0.0273	0.3789	0.0655	0.941

**Table-6**

<b>Schirmer's 2 A</b>	<b>Discharge</b>	<b>Pain</b>	<b>Smoke</b>	<b>Light</b>	<b>Air</b>
Total number of subjects	50	50	50	50	50
Spearman r	-0.1219	-0.009251	-0.3463	-0.4179	-0.1698
95% confidence interval	-0.3970 to 0.1733	-0.2976 to 0.2806	-0.5776 to -0.06358	-0.6308 to -0.1464	-0.4374 to 0.1255
P value (two-tailed)	0.4039	0.9497	<b>0.0148</b>	<b>0.0028</b>	0.2434

Table-7

Schirmer's 2 B	Gritty	Itchy	Burning	Dryness	Watering
Total number of subjects	49	49	49	49	49
Spearman r	-0.1633	-0.1801	-0.1372	-0.1314	0.0411
95% confidence interval	-0.4320 to 0.1320	-0.4460 to 0.1150	-0.4101 to 0.1582	-0.4051 to 0.1640	-0.2510 to 0.3263
P value (two-tailed)	0.2622	0.2155	0.3471	0.3682	0.7792

Table-8

Schirmer's 2 B	Discharge	Pain	Smoke	Light	Air
Total number of subjects	49	49	49	49	49
Spearman r	0.04619	-0.04098	-0.168	-0.1675	-0.07937
95% confidence interval	-0.2462 to 0.3309	-0.3262 to 0.2511	-0.4360 to 0.1273	-0.4355 to 0.1278	-0.3602 to 0.2147
P value (two-tailed)	0.7527	0.7798	0.2485	0.2499	0.5877

Table-9

Occupation	Gritty	Itchy	Burning	Dryness	Watering
Total number of subjects	50	50	50	50	50
Spearman r	0.1964	0.2818	0.3405	0.1778	0.2033
95% confidence interval	-0.09513 to 0.4569	-0.004768 to 0.5256	0.06013 to 0.5710	-0.1142 to 0.4416	-0.08801 to 0.4626
P value (two-tailed)	0.1716	0.0474	0.0155	0.2166	0.1568

Table-10

Occupation	Discharge	Pain	Smoke	Light	Air
Total number of subjects	50	50	50	50	50
Spearman r	0.1051	0.3659	0.2142	0.2109	0.2227
95% confidence interval	-0.1868 to 0.3798	0.08908 to 0.5903	-0.07671 to 0.4715	-0.08018 to 0.4688	-0.06780 to 0.4784
P value (two-tailed)	0.4678	0.009	0.1353	0.1416	0.12

Table-11

Polishing	Schirmer's 1	Schirmer's 2	Schirmer's 3	Schirmer's 4
Total number of subjects	50	50	49	49
Spearman r	0.1133	0.07085	0.1143	0.06496
95% confidence interval	-0.1787 to 0.3870	-0.2198 to 0.3499	-0.1808 to 0.3905	-0.2284 to 0.3475
P value (two-tailed)	0.4333	0.6249	0.4341	0.6575

Table-12

	Prosthetic eyes	Control eyes
Schirmer's I a	10.7	17.7
Schirmer's II b	7.21	10.5
TBUT	3.62	14.4



Fig-1

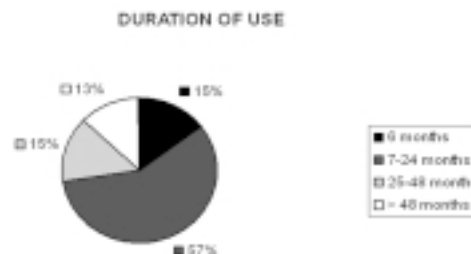


Fig.-2

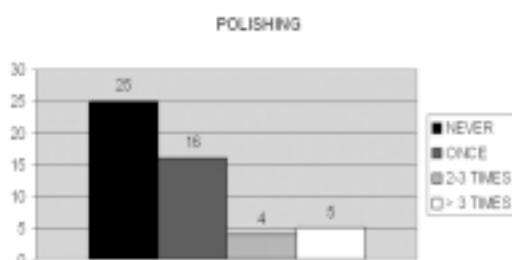


Fig-3

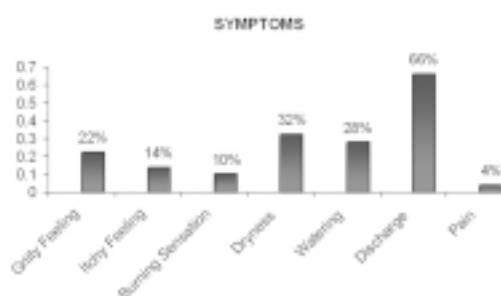


Fig.-4

For the convenience we had divided the SCHIRMER'S TEST<sup>2,3</sup> into two groups,

Schirmer's I a	Tear level measurement with the prosthesis insitu
Schirmer's I b	Tear level measurement with anesthesia with the prosthesis insitu
Schirmer's II a	Tear level measurement in the socket without the prosthesis

Schirmer's II b Tear level measurement in the socket with anesthesia without the socket.

The questionnaire presented to the subjects had questions on the details of their cleaning schedule , duration since the start of use of prosthesis , the symptoms like gritty feeling , dryness , burning sensation , pain , discharge , their sensitivity being more in air , light , smoke or air conditioned atmosphere .The symptoms were categorized according to the subjects preference being giving them option on a scale saying

- NEVER - 1
- SELDOM - 2
- OFTEN - 3
- ALWAYS - 4

### Analysis

All the data collected, was entered into Microsoft EXCEL windows version 2000. The entered data was analyzed using Spearman's Rank Correlation in the software named Graph Pad Prisms 5.0 for deriving at the correlation of the symptoms faced by the subjects to the clinical signs we found on examination.

### Results

The study was completed with fifty patients (31 Male and 19 Female) with their mean age being 23.67 (16 -58) years.

There were 30 out 50 (60%) having anophthalmic socket , 19 (38 %) with atrophic globe and 1 (2%) with microphthalmos (Fig- 1).

There were 27 (57%) using the prosthetic eye for a duration of 7 months to 24 months and only 6(13%) using it for more than 48 months (Fig.-2).

There were 8 (16%) subjects 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 remaining subjects were astonishingly cleaning it daily

with water or shampoo (which included 50% having disfigured globe and 34 % having anophthalmic socket).

There were 25 (50%) patients who never got their prosthesis polished, with just 18% polishing it more than 2 times (Fig.-3).

According to the symptoms as reported by the patients in the questionnaire we found that , there were patients complaining of the following symptoms, Thus it was seen that discharge (66%) is the symptom which is maximally faced including dryness 32%. Whereas pain(4%) and burning sensation (10%) showed low propensity .

We had 24% patients sensitive to smoke, 62 % to light (including sunlight) and 54 % to air. We had tried to collect information on the sensitivity towards computers and air-conditioners. But more than 50% of subjects had no exposure to either of these things ever.

On further questioning it was even found that, there were 18 patients who ever using certain kinds of medication like anti histamines, blood pressure medication and only 12 out of 50 (24%) using various topical medications including 6 using artificial tear substitutes (4 among them were having anophthalmic sockets and 2 with phthisical eye)

Table 1 and 2 show that the Schirmer's 1 a value correlated with the symptoms presented.

The Schirmer's I a value was correlated with each of the symptoms and found that none of the symptoms correlated statistically significantly except smoke ( $p=0.0186$ ).

Table 3 and 4 show that the Schirmer's 1 b value correlated with the symptoms presented The Schirmer's I b value was correlated and similar findings could be obtained with smoke having a higher significance ( $p= 0.034$ ). Table 5 and 6, 7 and 8 show the Schirmer's 2a , 2b value correlated with the symptoms presented.

The Schirmer's 2a and 2b showed statistically significant correlation with sensitivity to smoke and light.

The data was correlated by dividing subjects into two groups of each in either of the anophthalmic sockets and the other with disfigured globe, and in a similar way the

symptoms were correlated accordingly as describe above, and similarly the data remained consistent with smoke having higher significance for both the groups in both Schirmer's 1 and 2.

Table 9 and 10 -showing the correlation between occupation and symptoms.

Occupation of all the subjects differed from (25%) being students,(29%) farmers, (39%) employees and 7% being housewife. It was correlated with the symptoms like itchiness, burning sensation, pain were correlating with the occupation of the subjects presented to the clinic and was found that itchy sensation , burning sensation ,pain was significantly correlated with ( $p=0.0474$ ) ,(p=0.0155) and ( $p=0.009$ ) respectively.

Table 11 showing the effect of number of times of polishing the eye on the value of Schirmer's. Effects of polishing on the value of any of the Schirmer's were tried but no deducible significance could be drawn in any of the cases.

Table 12 shows the values of Schirmer's I a and b (i.e. with and without anesthesia with the prosthesis insitu respectively) as well as the tear break up time (TBUT) in both the prosthetic eyes and the control eyes. There was a considerable difference in both the times in both the eyes.

## Discussion

Indian population aged between 16 to 58 using unioocular prosthesis were found to produce less tears as normal eyes .The mean value of Schirmer's 1a was found to be 10.7 for the subjects with prosthesis and 17.7 on the contra lateral normal side of the same patient. The mean value of Schirmer's 1b was found to be 7.21 for the eyes with prosthesis and 10.5 on the contra lateral side of the control eyes . This result was consistent with the study done by Lee Allen et al<sup>1</sup> where they had found out that the tear levels was less than /equal to 20 mm in the control eyes whereas less than /equal to 11 mm in the artificial eyes.

Remarkable increment was found in the symptom towards discharge (66%) .The reason for this increase can be attributed to the finding that most of the subjects who used it for a

duration of 6 months. And this can be considered as an initial adjustment factor for the patient. But the reasons for higher values in subjects using since a long time could be due to excessive cleaning regimen followed or due to climatic conditions or due to any other unspecified reasons.

There was an increased sensitivity found to light (62%), which included lights of all kinds sunlight, tube lights, car lights. No specified reasons could be qualified for this finding.

The increase in symptoms could be due to the cleaning regimen followed by 84 % of the population who clean the prosthesis daily or once in two days, which is contradicted and may aggravate the symptoms in these groups, which was well explained even during the time of dispensing of the prosthesis.

There were subjects using the prosthesis for more than 3 years who haven't got their artificial eye polished even once. Very little percentage of subjects had undergone polishing of the eye recently.

In addition to the Schirmer's level evaluation, the tear break up time (TBUT) and tear film height was evaluated and was found to be 3.62 in the prosthetic eye and 14.4 in the control eyes of the similar patients and less than 2 mm in 34 (68%) patients respectively .

It was even found that the subjects with anophthalmic sockets cleaned their prosthesis not very often than those with disfigured globes who cleaned it much more often .As a result they were much more comfortable than those disfigured globe.

A 52-year-old businessman was on anti depressants, beta-blockers, anti glaucoma (2% medication) and using even artificial tears substitute. The patient had no symptoms of any discomfort, but the value of the Schirmer's entire test was reduced considerably in both eyes when compared with that of the other subjects. The effect of systemic drugs on dryness has been found out in earlier studies but its effect on anophthalmic sockets in unknown.

A 25 year old student using Rigid contact lenses in the keratoconic eye already on tear substitutes with superficial punctate

keratopathy in the severe most stage in that eye. This was the eye, which had tear level values even lower than 3 mm in both the cases when compared to that of the anophthalmic socket, it was 7 -8 mm.

All the subjects presented to us were asked to get their prosthesis polished and 35 (70%) of them were prescribed tear substitute and 6 (12%) were prescribed antibiotic for all those who complained of severe discharge problems.

There can be many reasons for the decrease in the tear levels and in an increase in the symptoms of the prosthetic users. But we suggest that the most common reason is that the corneal nerves are missing and that the bulbar conjunctiva is covered by the prosthetic eye, thus eliminating stimuli for production of reflex tears. This could be especially true if the normal eye responds in a modulated manner to mild sensations such as moving air and evaporation of tears to produce just an adequate replacement.

Since the reflex tears supply most of the aqueous component, most of the wearers are left with the lipid and the mucin layers causing them to experience dryness, and the thick mucoid residue can be bothersome.

The feasible option for providing comfort to these patients can be by providing them with timely polishing of the surface and artificial tears which can substitute the presence of aqueous layer in the tears and favorable situations to avoid any infections. This might not be the ultimate option but still could help the patients symptomatically and well as psychologically.

Finally it can be even concluded that the subjects with anophthalmic sockets were much more comfortable symptomatically than those with disfigured globes. This piece of information can help us in delivering the care required to the patients according to the group which they belong.

#### **Limitations of The Study**

This study was performed during a particular season i.e. from duration of January to March, which in an Indian scenario is not considered to be the seasons for maximum heat.

Thus the study duration can be a limitation. There were not many subjects using systemic medication, thus the effect of that on decreases tear levels in an artificial eye user could not be established.

#### Recommendations

A multicentred study for a longer duration and with a larger population could help one to determine the exact factors responsible for the reduced tears level in an artificial eye user.

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