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Comparative Evaluation Of The Effect Of Various Ocular Lubricants On The Wettability Of A Prosthetic Eye Material (Poly(Methyl Methacrylate) [Pmma]) Having Different Polishing Standards: An In-Vitro Study

Dr Apurva Deshmukh

Dr Faraz Ahmed

PG Student, Dept of Prosthodontics

Dr. S R Godbole

HOD, Dept of Prosthodontics

Abstract:

Introduction: Research work for materials used for ocular prosthesis especially scleral resin is very limited. There are very few studies related to properties of sclera resin. As there is an air of obliviousness around ocular lubricants that are used for ocular prosthesis these days, this study will help to better understand the choice of ocular lubricant to be used as far as the property of wettability is concerned. The study is conducted in-vitro so its results can be applied to patient in-vivo.

Material and Method: For the research, 120 samples were prepared from scleral resin. Finishing and polishing of samples was done with Pumice (Group A) and Sodium hydrogencarbonate (Group B) and grouping was done. Samples from both groups were stored in biological incubator for 60 days in three different lubricants (Contact lense solution (Subgroups A1,B1), Artificial tear solution (Subgroups A2,B2), Antibiotic ointment (Subgroups A3,B3)). Evaluation of wettability of each sample from each group was done using Goniometer and statistical analysis of the data was done using differential and inferential analysis.

Result: The subgroup B1 (Sodium hydrogencarbonate polished surface, immersed in contact lenses solution) exhibited the least contact angle of 28.52±10.11.

Conclusion: All the subgroups had contact angle values less than 90°, the samples can be termed as hydrophilic surfaces. However, the contact angle of subgroup B1 had the lowest value of all subgroups, indicative of highest wettability amongst all sample types.

Keywords: Maxillofacial prosthetics, Ocular prosthesis, ocular lubricants, wettability, Contact angle, Goniometer.

I. INTRODUCTION

"We restore, repair and make whole those parts of the face which nature has given but fortune has taken away, not so much that they may delight the eye, but that they buoy up the spirit and help the mind of afflicted." - Gaspare Tagliacozzi

Body abnormalities or defects that compromise appearance and function, sufficient to render an individual incapable of leading a relatively normal life, have usually prompted actions that seek to bring the person to a state of acceptable normalcy.

Maxillofacial prosthetics is defined as the branch of prosthodontics concerned with the restoration and/or replacement of stomatognathic and craniofacial structures with prostheses that may or may not be removed on a regular or elective basis.

Maxillofacial prostheses were introduced as a consequence of individual's need to disguise and hide their maxillofacial defects. The rehabilitation treatment of patients with facial defects

helps them to improve their appearance and personal well being. Among the various maxillofacial prostheses, use of ocular prostheses is the commonest since it satisfactorily restores the patient's facial esthetics. The aim of ocular prostheses is to provide alloplastic repair for the loss of or deformities to the ocular bulb.

Currently, research has focused its concerns in the search for ideal materials and techniques for prosthetic eye rehabilitation, with the aim of recovering aspects of patients' physical esthetics and social function. The goal of an ocular prosthesis is primarily to reconstitute esthetics, maintain muscle tonicity of the upper eyelid by preventing it from shrinking due to lack of function, conduct tears to their physiological ducts and thus preventing lashes from sticking and drying of the conjunctival area, and also protect the orbital mucosa from debris and dust.

Acrylic resin is the material of choice for ocular prostheses because of its unique properties such as biocompatibility, dimensional accuracy, ease of manipulation, satisfactory esthetic results and low cost. But like all materials, acrylic resin too presents some disadvantages for ocular prostheses, such as discomfort because of their surface roughness and dryness in the cavity, which can cause irritation and ulceration of the mucosa.

To avoid these possible issues, proper polishing of the prosthesis surface is obsolete. The ocular prostheses should be used with the periodic use of ocular lubricants when inserted in the patient's ophthalmic cavity.

Ocular lubricant is a solution specially formulated to moisten the eyes. Simultaneously it also coats the surface of the prosthesis thereby relieves burning, irritation, and discomfort of the patient. Prosthesis whose surface is not polished appropriately renders a rough surface. Such surfaces exhibit improper lubricant covering over its surface. Many studies have been conducted which conclude that the wettability of surfaces can be strongly affected by surface roughness.

Therefore, this study was carried out to evaluate the effect of various ocular lubricants on the wettability of a prosthetic eye material, FACTOR II scleral resin, having different polishing standards.

II. MATERIAL AND METHOD.

A. PREPARATION OF TWO PIECE SILICON MOULD FOR THE FABRICATION OF SAMPLES

- ✓ Two-piece mould was designed for fabrication of samples. Metal disc of 15mm diameter and 2mm thickness was fabricated from stainless steel sheet.
- ✓ Base and catalyst paste of silicon is mixed and pour into dental flask, eight metal disc coated with petroleum jelly were then invested in silicon and counter flasking was done. The whole assembly was placed at room temperature for vulcanization. After complete vulcanization metal disc is removed. (Fig no. 1).

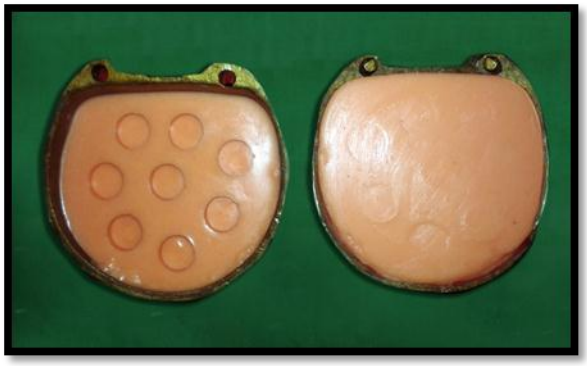

Figure 1: Silicon Mould For Sample Preparation

B. PREPARATION OF SCLERAL RESIN SAMPLES USING STANDARD PROCEDURE

- ✓ The factor II heat cure scleral resin dough was prepared following polymer: monomer ratio (3:1 by volume). The packing was done carefully using prepared acrylic dough.
- ✓ Hydraulic press was used to have perfect closure of the flask and also to closure of the flask and also to ensure the flow of material in the mould space. The excess material came out as a flash.
- ✓ After bench curing for 45 min the dental flask was then subjected to polymerization. Long curing cycle (for 9 hrs. at 72 c) was used for curing all samples.
- ✓ Acrylization was carried out in a digital acrylizer. After curing, the flask were allowed to bench cool. The flasks were then opened and the samples were retrieved carefully. (Fig no.2)

Figure 2: FACTOR II Sclera Resin samples

- ✓ Factor II heat cure sclera resin samples were then inspected for completeness and porosity, if any. Incomplete samples and sample having porosity were rejected.

C. FINISHING AND POLISHING OF SAMPLES & GROUPING OF SAMPLES

All 120 samples were finished and polished with pumice and sodium hydrogencarbonate (60 samples each) and further divided in Groups A and B respectively (Fig No.3).

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- ✓ The following procedures was followed in a sequential order:
  - Step 1: A large lathe-mounted laboratory bur is used to trim the excess material. All specimen surfaces were finished with tungsten carbide burs of three grits – black (extra coarse), followed by green and then red at 15,000 rpm for 60 seconds each.
  - Step 2: The specimens were then finished with silicon carbide waterproof papers (Carborandum universal) of grit size 320 (medium), and 400 (fine).
  - Step 3: The finished specimens were further smoothened with silicone polishing points each for 60 seconds at 5000 - 7000 rpm.
  - Step 4: For polishing, separate cotton buffs for each type of polishing paste in a straight handpiece compatible with the chairside micromotor was used.
- ✓ After completing the polishing, samples were washed thoroughly in water, dried and examined for scratches. If any scratches were visible on the polished surface, the procedure was repeated for polishing.
- ✓ To achieve the final shine on the samples, soft chamois wheel rouge with cotton buff was used.

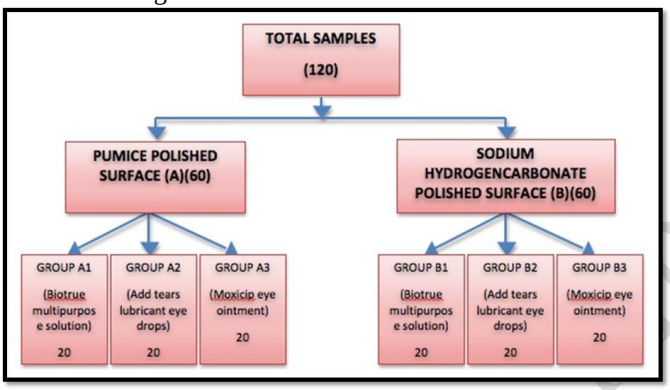

Figure 3: Grouping Of All 120 Samples based on polishing material

D. STORAGE OF SAMPLES IN BIOLOGICAL INCUBATOR

The samples of each group were stored in biological incubator at 37 ± 2 ˚C for 60 days in three different lubricants:

- ✓ Subgroup A1 & B1: CONTACT LENSE SOLUTION: Bausch + Lomb – Biotrue multipurpose solution.
- ✓ Subgroup A2 & B2: ARTIFICIAL TEAR SOLUTION: Cipla – Add tears lubricant eye drops.
- ✓ Subgroup A3 & B3: ANTIBIOTIC OINTMENT: Cipla – Moxicip eye ointment.

Samples were stored in biological incubator to simulate the clinical conditions for prosthesis in the anophthalmic cavity.

E. EVALUATION OF WETTABILITY OF SAMPLES FROM EACH GROUP

- ✓ After storage in the biological incubator, evaluation of wettability was done with Goniometer "Digidrop (GBX, Ireland) – contact angle meter" of each sample from all the sub groups. (fig no. 4)

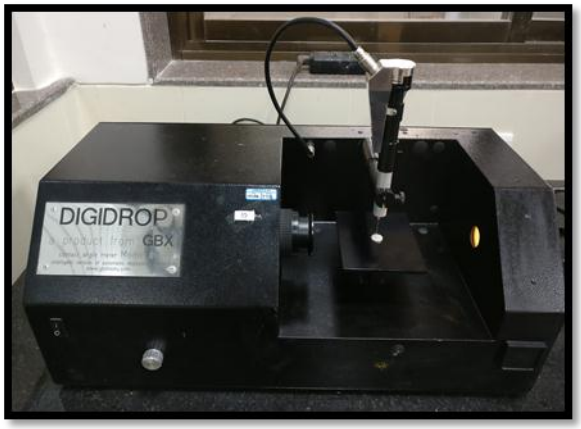

Figure 4: Goniometer

- ✓ Goniometer used in the study is of optical type. In this type, geometry of the drop is captured and analyzed. Drop shape analysis is the convenient way to measure contact angle. (Fig.5)

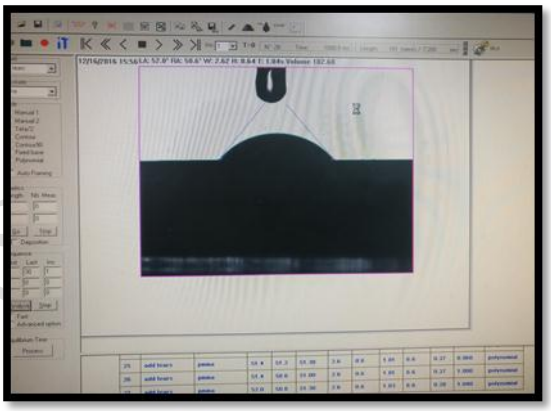

Figure 5: Drop shape Analysis

- ✓ In this, fluid to be analyzed is loaded using a syringe and image is grabbed either as a single snap shot or as a series of shots leading to a movie (Fig. 6). The movie is stored and treated as a database.

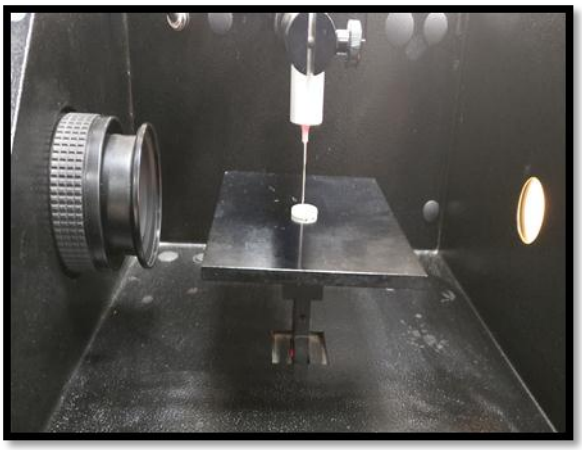

Figure 6: Sample Testing

- ✓ Its contact angle range is 0 – 180° and surface energy range is 0-1000mN/m. Its contact angle accuracy is +/- 0.1°.
- ✓ Samples of each subgroup were disinfected daily using manual friction for 1 min with gauze, followed by 30 second of rinsing.

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STATISTICAL ANALYSIS

Statistical analysis of data was done by using descriptive and inferential statistics using Two way ANOVA, One way ANOVA, Multiple Comparison: Tukey Test and Student's unpaired t test.

III. RESULTS

A. DESCRIPTIVE STATISTICS

Significant differences were found in contact angles of the six groups involved in the study (Table 1). Mean contact angle value in the Subgroup A1 was 30.41±6.30, in the Subgroup A2 was 51.55±7.63, in the Subgroup A3 was 79.08±32.87. In the Subgroup B1 it was 28.52±10.11, in the Subgroup B2 it was 37.19±9.88 and in the Subgroup B3 it was 82.80±29.18. Comparatively contact angle value was highest for Subgroup B3 (polished with sodium hydrogencarbonate and stored in antibiotic ointment), while the lowest for Subgroup B1 (polished with sodium hydrogencarbonate and stored in contact lense solution).

B. INFERENTIAL STATISTICS

a. TWO WAY ANOVA

Two way ANOVA of contact angle in subgroups of group A and B reveals that interaction effect (p=0.99), column factor (p=0.49) and row factor (p=0.99) are found to be statistically insignificant. (Table No. 2).

b. ONE WAY ANOVA

By using one way ANOVA, statistically significant variation was found in mean contact angle in six subgroups (F=31.39,p-value=0.0001) (Table No. 3).

c. MULTIPLE COMPARISON: TUKEY TEST:

On comparing contact angle in six subgroups statistically significant difference was found between Subgroup A1 and A2(p=0.009), A1 and A3(p=0.0001), A1 and B3(p=0.0001), A2 and A3(p=0.0001), A2 and B1(p=0.003), A2 and B3(p=0.0001), A3 and B1(p=0.0001), A3 and B2(p=0.0001), B1 and B3(p=0.0001) and B2 and B3(p=0.0001) and no significant difference was found between other groups. (Table No.4).

d. STUDENT'S UNPAIRED T TEST

- ✓ *Comparison of contact angle between group A1 and B1*: Mean contact angle in Subgroup A1 was 30.41±6.30 and in Subgroup B1 it was 28.52±10.11. By using Student's unpaired t test statistically no significant difference was found in mean contact angle in Subgroup A1 and B1 (t=0.70,p-value=0.48). (Table No.5)
- ✓ *Comparison of contact angle between group A2 and B2:* Mean contact angle in Subgroup A2 was 51.55±7.63 and in Subgroup B2 it was 37.19±9.88. By using Student's unpaired t test statistically significant difference was found in mean contact angle in Subgroup A2 and B2 (t=5.14,p-value=0.0001). (Table No.6)
- ✓ *Comparison of contact angle between group A3 and B3:* Mean contact angle in Subgroup A3 was 79.08±32.87 and in Subgroup B3 it was 82.80±29.18. By using Student's unpaired t test statistically no significant difference was found in mean contact angle in Subgroup A3 and B3 (t=0.37, p-value=0.70). (Table No.7)

	N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum
					Lower Bound	Upper Bound		
A1	20	30.41	6.30	1.41	27.45	33.36	16.58	43.19
A2	20	51.55	7.63	1.70	47.97	55.12	36.27	65.21
A3	20	79.08	32.87	7.35	63.69	94.47	33.63	199.06
B1	20	28.52	10.11	2.26	23.79	33.25	17.04	60.45
B2	20	37.19	9.88	2.21	32.56	41.81	21.96	57.85
B3	20	82.80	29.18	6.52	69.14	96.46	41.39	171.29
Total	120	51.59	29.09	2.65	46.33	56.85	16.58	199.06

Table 1: Comparison of contact angle between six subgroups – Descriptive Statistics

Source of variation	df	Sum of squares	Mean Square	F-value	p-value	% variation
Interaction	19	5538	291.5	0.26	0.99,NS	5.50
Column Factor	1	523.2	523.2	0.47	0.49,NS	0.52
Row Factor	80	88920	304	0.27	0.99,NS	5.73
Residual	80	88920	1111			

Table 2: Comparison of contact angles between six subgroups using Two way ANOVA

Source of variation	Sum of Squares	df	Mean Square	F	p-value
Between Groups	58366.86	5	11673.37	31.394	0.0001,S
Within Groups	42388.86	114	371.83		
Total	100755.73	119			

Table 3: Comparison of contact angles between six subgroups using One way ANOVA

Group		Mean Difference (I-J)	Std. Error	p-value	95% Confidence Interval	
					Lower Bound	Upper Bound
A1	A2	-21.14	6.09	0.009,S	-38.8182	-3.4658
	A3	-48.67	6.09	0.0001,S	-66.3532	-31.0008
	B1	1.88	6.09	1.000,NS	-15.7907	19.5617
	B2	-6.78	6.09	0.875,NS	-24.4582	10.8942
	B3	-52.39	6.09	0.0001,S	-70.0707	-34.7183
A2	A3	-27.53	6.09	0.0001,S	-45.2112	-9.8588
	B1	23.02	6.09	0.003,S	5.3513	40.7037
	B2	14.36	6.09	0.181,NS	-3.3162	32.0362
	B3	-31.25	6.09	0.0001,S	-48.9287	-13.5763
A3	B1	50.56	6.09	0.0001,S	32.8863	68.2387
	B2	41.89	6.09	0.0001,S	24.2188	59.5712

	B3	-3.71	6.09	0.990,NS	-21.3937	13.9587
B1	B2	-8.66	6.09	0.714,NS	-26.3437	9.0087
	B3	-54.28	6.09	0.0001,S	-71.9562	-36.6038
B2	B3	-45.61	6.09	0.0001,S	-63.2887	-27.9363

*. The mean difference is significant at the 0.05 level.

Table 4: Comparison of contact angles between six subgroups using Multiple Comparison: Tukey Test

Group	N	Mean	Std. Deviation	Std. Error Mean	t-value	p-value
Group A1	20	30.41	6.30	1.41	0.70	0.48,NS
Group B1	20	28.52	10.11	2.26		

Table 5: Comparison of contact angle between subgroups A1 and B1 using Student's Unpaired t test

Group	N	Mean	Std. Deviation	Std. Error Mean	t-value	p-value
Group A2	20	51.55	7.63	1.70	5.14	0.0001,S
Group B2	20	37.19	9.88	2.21		

Table 6: Comparison of contact angle between subgroups A2 and B2 using Student's Unpaired t test

Group	N	Mean	Std. Deviation	Std. Error Mean	t-value	p-value
Group A3	20	79.08	32.87	7.35	0.37	0.70,NS
Group B3	20	82.80	29.18	6.52		

Table 7: Comparison of contact angle between subgroups A3 and B3 using Student's Unpaired t test

IV. DISCUSSION

It is important to provide the patient a prosthesis that will render the individual capable of leading a relatively normal life and bring the person to a state of acceptable normalcy.

Surface wettability is one of the factors that influence depositions on contact lenses or ocular prosthesis, with increasing wettability having been shown to decrease deposition. It is recommended that high standards of polishing should be achieved, as it assists the smooth action of the lids over the prosthesis and the cleansing action of tears. Studies have shown that anophthalmic sockets show a change in the composition of tears, precisely an increase in the mucin component and a decrease in the aqueous and lipid components, causing increased tear viscosity. Subjects with frequent prosthesis removal have a significantly greater lagophthalmos (inability to close the eyelids completely) and blinking rate. Artificial eye wearers occasionally experience dryness, irritation, and difficulty in blinking. Adverse weather, dust, wind and air-conditioning tend to evaporate moisture from the front of the prosthesis. Allergies and body changes can also contribute to dryness.

Several ocular prosthesis wearers, carefully fitted by the modified impression method, have no difficulties. Good routines of cleaning and yearly polishing keep others entirely comfortable. Some patients report varying degrees of uneasiness, mucoid discharge, and crusting of lids and lashes with their ocular prosthesis. Causes for these problems can be: roughened surface, persistent surface deposits, infections, allergies, unfilled space behind the eye and noxious materials collected in the intermolecular spaces within the methylmethacrylate resin.

Dryness with eye prosthesis is a prevalent phenomenon. As a result, ophthalmologists and other health care professionals, such as optometrists and general practitioners, often help these patients manage this symptom in the most common form of treatment for its management with the help of tear lubricants. The lubricants work to increase the tear film that coats the surface of the prosthetic eye or scleral shell providing more comfort, easier blinking, and a more natural appearance. These lubricants are developed specifically for artificial eyes. Higher the viscosity, thicker and longer lasts the lubricant. While this would indicate the highest viscosity lubricant as the best choice, but there are a few more factors to consider. The purpose of a lubricant with an ocular prosthesis is to decrease the friction between the eyelids and the prosthetic surface. The best way to decrease friction is to have a smooth prosthetic surface and a good tear film.

Although the present research was carefully done, there are some limitations:

- ✓ The duration for which a patient wears the ocular prosthesis is certainly more than 60 days. Typically, an artificial eye lasts about 5 years before it needs to be replaced. Tissue changes in the socket, anatomical growth, and breakdown of the acrylic are the primary reasons for replacement. But, here in the study, we have observed the changes in the surface properties of the material for a limited period of sixty days.
- ✓ This is an in-vitro study and ocular prosthesis to be placed in an ophthalmic cavity; the environment of the ophthalmic cavity is different with various secretions, which might affect the surface property of prosthesis.
- ✓ To stimulate the ophthalmic cavity environment samples for the study were stored in the biological incubator and immersed in different ocular lubricants. As there are innumerable commercial brands for contact lenses solution, artificial tear solution and antibiotic ointments available in the market today and all these brands differ in their composition, it can lead to different effects on the material surface, which would affect the wettability differently. In this study, only three different types of ocular lubricants could be considered.
- ✓ Individually, the required amount of ocular lubricants utilized by the patient will differ according to their need. In the study, the amount of lubricant used was fixed for all samples.

V. CONCLUSION

Within the limitations of this study, the contact angle of subgroup B1 i.e. samples that were polished with Sodium hydrogencarbonate and immersed in the contact lenses solution had the lowest value of all subgroups, indicative of highest wettability amongst all sample types.

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