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International Journal of Current Research
Vol. 9, Issue, 10, pp.58767-58771, October, 2017

INTERNATIONAL JOURNAL OF CURRENT RESEARCH

ISSN: 0975-833X

RESEARCH ARTICLE

COMPARATIVE EVALUATION OF COLOR STABILITY BETWEEN PREFABRICATED AND CUSTOM MADE EYE PROSTHESIS – AN IN –VITRO STUDY (2017)

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ARTICLE INFO

Article History:
Received 22nd July, 2017
Received in revised form
15th August, 2017
Accepted 16th September, 2017
Published online 17th October, 2017

Key words:

Color Stability,
Custom Made Ocular Prosthesis,
Prefabricated Ocular Prosthesis.

ABSTRACT

Purpose: To evaluate and compare, color stability of prefabricated and custom made ocular prosthesis.
Method: 20 samples of prefabricated ocular prosthesis and 20 samples of custom made ocular prosthesis were taken in 2 groups. Both were checked before the immersion and after immersion in neutral soap solution after 6 weeks. To assess the color change, spectrophotometry test was performed; and the results were statistically analysed by Mann-Whitney U test and Wilcoxon Signed Rank Test.
Result: Among prefabricated and custom made ocular prosthesis as painted with oil paint; prefabricated ocular prosthesis showed more color stability, after immersion in neutral soap solution for 6 weeks.
Conclusion: Prefabricated ocular prosthesis, is more color stable.

Citation: Dr. Deepika Rathi, Dr. Seema Sathe and Dr. S. R. Godbole, Dr. Tejas Bhandari and Dr. Rasika Jibhakate, 2017. "Comparative evaluation of color stability between prefabricated and custom made eye prosthesis – An in –vitro study (2017)", *International Journal of Current Research*, 9, (10), 58767-58771.

INTRODUCTION

Loss of an eye has a great influence on person's psyche; It affects its social as well as personal life. In such cases, cosmetic rehabilitation is of much importance; for which ocular prosthesis came into existence. It does not provide vision but is a visual prosthesis (Guruprasad Handal *et al*., 2016). Material of choice for fabrication of ocular prosthesis includes silicone, autopolymersing acylic resin, heat cured acylic resin. Acrylic resin is the material of choice since it posses the qualities like, completely polymersised acrylic resin is compatible and esthetically acceptable; have adequate compressive and tensile strength; good dimensional stability; virtually insoluble in water; stable to heat; and is also color stable. Acrylic resin for artificial sclera contains white pigments to approximate the color of natural sclera which makes it more natural (Filie, 2011; Bannwart, 2013; Guruprasad Handal *et al*., 2016). Ocular prosthesis, remains an effective option but for shorter period of time, because of changes in the artificial iris color. The artificial iris color is a cosmetic characteristic which is important for the patient, as well as the clinician from esthetic point of view.

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The aim of this study was to evaluate and compare, the color stability of the ocular prosthesis; over a period of time.

Mould preparation

MATERIALS

- J-7 heat cure sclera polymer
- Heat cure liquid
- Oil paint
- Prefabricated ocular prosthesis

- Metal mold (1.5x2) mm
- Neutral soap solution

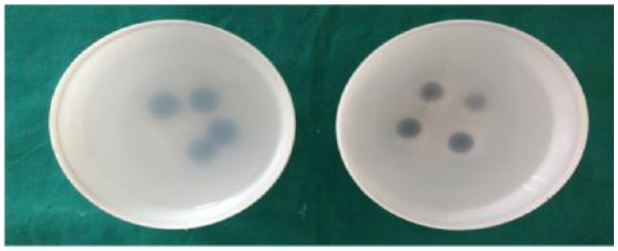
METHODS

Ethical clearance was obtained from the institutional ethical committee from Datta Meghe Institute of Medical Sciences Sawangi (Meghe), Wardha. For evaluation of color stability the samples were divided into two groups:

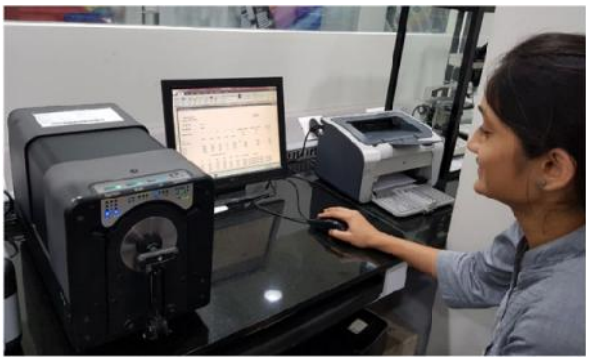
Group A: 20 samples of oil painted colorless scleral acrylic resin disk.

Group B: 20 samples ofprefabricated ocular prosthesis, with preformed iris.

The mould was of internal diameter of 1.5mm and thickness of 2mm. the custom made disks were undergone polymeristion cycle, and then were properly finished and polished. These custom made disks were then surface treated by sandblasting.



Obtained disks, were painted with oil paint (green-brown) layer by layer, allowing the first layer to dry completely. Over this the varnish was applied which not only added glossy finish, to the painted disks but also forms a protective layer or film over the iris paint that reduces the reaction between residual monomer and oil paints polymer components; leading to improvement in the color stability. Group A and Group B were tested initially; before immersion using i7 reflective spectrophotometry. And then the samples were immersed over a period of 6 weeks in neutral soap solution. After the 6 weeks period of immersion, again the samples were tested using i7 reflective spectrophotometry. Initial and final color assessment was done with the help of spectrophotometry. The readings and scannings thus obtained, were statistically analysed.



Statistical Analysis

The data obtained through spectrophotometric analysis were processed using the SPSS (Statistical Package for Social Sciences) Version 20.1 (IBM Corporation, Chicago, USA). The color change (ΔE^*) values for two specimens that is; custom made scleral acrylic resin disks painted with oil paint and prefabricated ocular prosthesis were averaged and the resulting values were considered for statistical analysis. To analyse, the color stability in between the two groups; descriptive and statistical analysis were done. The normality of the data was analysed by Shapiro Wilk test. But the data did not followed the normal distribution, thus the non parametric tests were used. The Mann- Whitney U test and Wilcoxon Signed Rank test were used to check the differences in mean scores in between the groups.

RESULTS

Table 1. Test results for normality of data

Variable	N	Statistic	P-Value*
Baseline L	40	0.867	<0.001†
6 Weeks L	40	0.919	0.007†
Baseline a	40	0.741	<0.001†
6 Weeks a	40	0.763	<0.001†
Baseline b	40	0.928	0.013†
6 Weeks b	40	0.939	0.032†
DL	40	0.691	<0.001†
Da	40	0.898	0.002†
Db	40	0.944	0.048†

*Normality checked by Shapiro-Wilktest;
†significant at p < 0.05

Table no 1: P value is significant, that is it doesnot follow the normal distribution (P<0.05). Table no 2: The mean L^*, a^*, and B^* values at baseline and at 6 weeks of custom artificial iris made for ocular prosthesis was compared. It was found the there were significant differences in L^*, a^* and B^*values between baseline and at six week (p<0.001). The mean L^* value 28.38 at baseline was increased to 29.36 at 6 week and the difference was statistically significant (p<0.001). Similarly the mean a^* 5.58 and B^* value 1.45 was significantly increased to 5.95 (p<0.001) and 1.82 respectively (p<0.001). Table no 3: The mean L^*, a^*, and B^* values at baseline and at 6 weeks of prefabricated ocular prosthesis was compared. It was found the there were significant differences in L^*, a^* and B^*values between baseline and at six week (p<0.001). The mean L^* value 25.74 at baseline was increased to 26.15 at 6 week and the difference was statistically significant (p<0.001). Similarly, the mean a^* 1.41 and B^* value 0.87 was significantly increased to 1.76 (p<0.001) and 1.07 respectively (p<0.001).

Table no 4: The mean ΔL^*, Δa^*, and ΔB^* values of custom made and prefabricated ocular prosthesis was compared. It was found the there were significant differences in $\Delta B^*$and ΔE^*values between custom made and prefabricated artificial iris (p<0.05). The mean ΔB^* value of prefabricated artificial iris 0.37 was found be higher that 0.3 of custom made artificial iris. The difference was statistically significant (p=0.012). There was no significant difference in mean ΔL^*(p=0.343) and Δa^*(p=0.755) between custom made and prefabricated ocular prosthesis. The mean ΔE^* value was also compared between custom made and prefabricated ocular prosthesis. The mean ΔE^* value 0.54 of custom made ocular prosthesis was significantly higher than the prefabricated ocular prosthesis 0.04 (p<0.001)

Table 2. Comparison of mean L, a, and B values at baseline and at 6 weeks of custom artificial iris made disks for ocular prosthesis

	L*		a*		B*	
	Baseline	6 Weeks	Baseline	6 Weeks	Baseline	6 Weeks
N	20	20	20	20	20	20
Mean	28.38	29.36	5.58	5.95	1.45	1.82
S.D.	0.57	1.13	0.32	0.31	0.20	0.25
Median	28.02	29.09	5.56	5.93	1.41	1.84
Min.	28.01	28.01	5.02	5.51	1.12	1.35
Max.	29.54	32.21	6.19	6.79	1.88	2.23
Z-Value	-3.823		-3.921		-3.923	
P-Value[#]	<0.001[†]		<0.001[†]		<0.001[†]	

[#]P-value derived from Wilcoxon Signed Rank test; [†]significant at $p < 0.05$

Colour changes being calculated according to the International Commission on Illumination (CIE) standards using the L*a*b* system with the standard illuminant D65

Table 3. Comparison of mean L, a, and B values at baseline and at 6 weeks of prefabricated artificial iris made for ocular prosthesis

Groups	L*		a*		B*	
	Baseline	6 Weeks	Baseline	6 Weeks	Baseline	6 Weeks
N	20	20	20	20	20	20
Mean	25.74	26.15	1.41	1.76	0.87	1.07
S.D.	0.37	0.54	0.22	0.29	0.10	0.17
Median	25.85	26.20	1.36	1.79	0.87	1.07
Min.	25.25	25.32	1.17	1.19	0.71	0.79
Max.	26.35	27.45	1.97	2.32	1.11	1.31
Z-Value	-3.829		-3.925		-3.827	
P-Value[#]	<0.001[†]		<0.001[†]		<0.001[†]	

[#]P-value derived from Wilcoxon Signed Rank; [†]significant at $p < 0.05$

Colour changes being calculated according to the International Commission on Illumination (CIE) standards using the L*a*b* system with the standard illuminantD65

Table 4. Comparison of meanΔL,Δa, ΔB and ΔE values of custom andprefabricated artificial iris made for ocular prosthesis

Groups	ΔL*		Δa*		ΔB *		ΔE*	
	Custom	Prefab	Custom	Prefab	Custom	Prefab	Custom	Prefab
N	20	20	20	20	20	20	20	20
Mean	0.97	0.41	0.37	0.34	0.20	0.37	0.04	0.54
S.D.	1.20	0.43	0.32	0.19	0.12	0.22	0.04	0.07
Median	0.46	0.37	0.30	0.30	0.20	0.40	0.03	0.55
Min.	0.00	0.00	0.02	0.02	0.00	0.01	0.02	0.20
Max.	4.20	2.00	1.30	0.60	0.47	0.70	0.43	0.67
Z-Value	-0.948		-0.312		-2.480		-5.449	
P-Value[#]	0.343		0.755		0.012[†]		<0.001[†]	

Custom, custom made artificial iris; Prefab, prefabricated artificial iris
[#]P-value derived from Mann-Whitney U test; [†]significant at $p < 0.05$

Colour changes being calculated according to the International Commission on Illumination (CIE) standards using the L*a*b* system with the standard illuminant D65

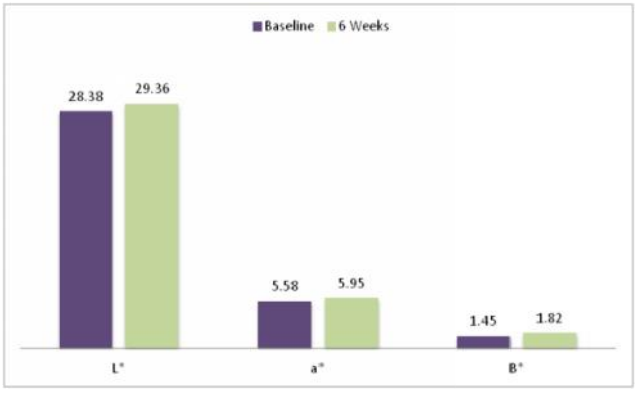


Figure 1. Comparison of mean L, a, and B values at baseline and at 6 weeks of prefabricated artificial iris made for ocular prosthesis

Colour changes being calculated according to the International Commission on Illumination (CIE) standards using the L*a*b* system with the standard illuminantD65

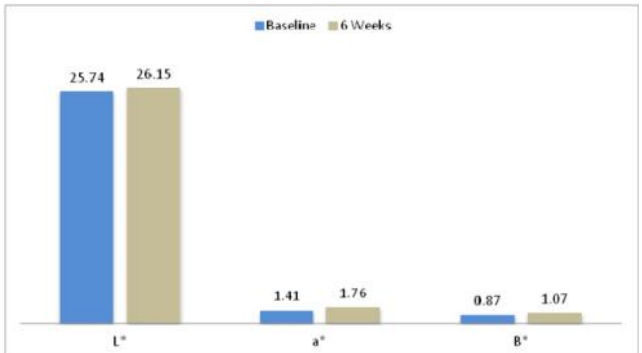


Figure 2. Comparison of mean L, a, and B values at baseline and at 6 weeks of custom artificial iris made for ocular prosthesis

Color changes being calculated according to the International Commission on Illumination (CIE) standards using the L*a*b* system with the standard illuminantD65

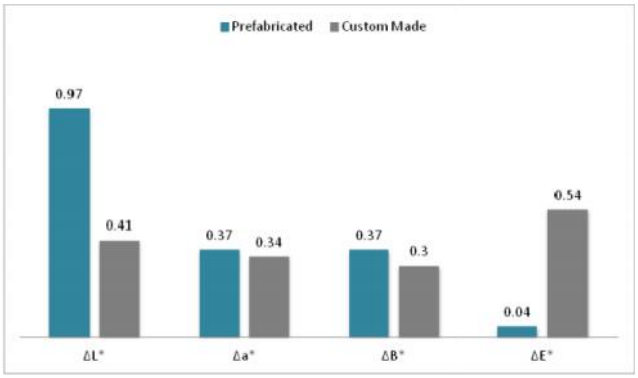


Figure 3. Comparison of mean ΔL, Δa, ΔB and ΔE values of prefabricated and custom artificial iris made for ocular prosthesis

Color changes being calculated according to the International Commission on Illumination (CIE) standards using the L*a*b* system with the standard illuminant D65

DISCUSSION

The functional, esthetic and psychological security achieved by the placement of an ocular prosthesis have encouraged many new and constant investigations for good and acceptable prosthetic rehabilitation (Reis, 2008). The prosthetic iris reproduction and iris painting is a crucial and delicate step during the construction of ocular prosthesis. Different modifications in prosthetic iris painting have been devised using oil paints, stickings, cardboards, papers, artificial pigments and through various other advanced technology. Iris painting requires method, efficient technique and strict discipline in order to be satisfactory (Fernandes *et al*., 2009). Fernandes *et al*, did a study to evaluate the color alteration of paint; he concluded that chromatic alteration of paints assessed may have aggravated effect, due to interaction of paint components with acrylic resin, because of the residual monomer content. As also polymers are present in paints and have resins in their composition (Fernandes *et al*., 2009).

Haddad *et al*, studied the factors like disinfection, pigments and period on maxillofacial silicone. He used efferdent, chlorhexidene for disinfection; and also neutral soap solution as in control group. In the experimental group, the samples disinfected with neutral soap solution exhibited highest color change. But he further concluded that, disinfection alone did not significantly influences the color variation. There are various other factors like artificial aging, material variation which affects the color of the prosthesis. He stated that extrinsic factors such as absorption and adsorption of substances also causes color fading (Filie, 2011). Previous studies have demonstrated that staining of artificial eyes occurs mainly after the colorless acrylic resin has been polymerized (Fernandes, 2009). In the present study, the custom made ocular disks painted with oil paint and prefabricated ocular prosthesis both underwent color variation; which was assessed using i7 reflective spectrophotometer. Spectrophotometry is the quantitative measurement of the reflection or transmission properties as a function of wavelength (color). Spectrophotometry uses photometers that is known as spectrophotometers.

Important features include spectral bandwidths (the range of colors it can transmit through the test sample), the percentage of sample transmission, logarithmic range of sample absorption and sometimes a percentage of reflectance measurement. Spectrophotometer, for the measurement of a color difference, uses the uniformed color space color system; which is closer to the human sensation. Chromatic and whiteness or brighteness changes gets evaluated. The test is done using whole diameter of the sample. The monochromatic color focus on the surface of the sample and part of the light beam is absorbed and the other is reflected. The amount of reflected light is captured by a photocell, which translates its wavelength into electric signals, and is further captured by computer system. This color measurement software provides the CIE L^* a^* b^* color systems. The 'L' value is known as whiteness or brightness of the sample. The 'a' value represents the quantity of red color (positive value) and green color (negative value). While 'b' value represents yellow color (positive value) and blue (negative value) (Bannwart, 2013).

Color variation (ΔE) between two points is calculated using formula, $\Delta E= [(\Delta L)^2+(\Delta a)^2+(\Delta b)^2]^{1/2}$. The color change is considered low when ΔE<1. Clinically acceptable when 1< ΔE<3; and it is considered clinically perceptible if ΔE>3.in present study, color change (ΔE) of custom made ocular prosthesis is 0.54 which is higher than the prefabricated ocular prosthesis which is 0.04. But both the values are less than 1; thus in both the samples the color change was very low or minimal (ΔE<1). Thus, in this study the prefabricated ocular prosthesis proved to be more color stable. Limitations of this study were, as the sample size of custom made scleral acrylic resin disk were smaller, smaller aperture was used in the spectrophotometer, which may cause variation. If larger surface area is covered it gives more accurate results in spectrophotometric analysis. And also, this is an in- vitro study further in-vivo study may be required.

Conclusion

Within the limitations of the study and the results obtained:

- Color changes were seen in both the groups that is in custom made ocular disks and prefabricated ocular prosthesis.
- ΔE(color variation) obtained in the study were clinically acceptable.
- Prefabricated ocular prosthesis proved to be more color stable.

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