Effect of Neutral Soap cleansing on Color Stability of Scleral Acrylic Prosthesis fabricated by Conventional Heat Cure Method and CAD CAM Method: An In-Vitro Study.

Original Article

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ABSTRACT:

AIM: The aim of the present in vitro study was to evaluate and compare the color stability of scleral ocular prosthesis fabricated by conventional heat cure method and CAD CAM method after cleansing with neutral soap.

MATERIALS AND METHOD: 20 Samples were made to simulate the scleral ocular prosthesis, out of which 10 were fabricated by conventional heat cure method and the other 10 by CAD CAM method. The samples were subjected to neutral soap cleansing. The color measurements were recorded after 180 and 360 days using Digital reflectance spectrophotometer.

RESULTS: Clinical and Statistically significant difference was found in the color stability of scleral ocular prosthesis fabricated by conventional heat cure method and CAD CAM method. CAD CAM method of fabrication showed greater color stability when compared to the conventional heat cure method.

CONCLUSION: CAD CAM method of fabrication scleral ocular prosthesis is more color stable than heat cure method.

KEYWORDS: Ocular prosthesis, Color stability, CAD CAM method.

INTRODUCTION

The replacement of missing part in any part of the body is a very challenging task and it could be accomplished by combining the principles of science and art[1]. With the improvement in the medical facilities and technology the average human life span is increased. The eyes are the first feature of the face to get noticed and are considered as the strength of the soul[2]. The loss of an eye is called as the anophthalmia. The loss of eye causes loss of vision and facial disfigurement. Anophthalmia can be of congenital or acquired reasons. The acquired defects can be because of carcinoma, trauma, painful blind eye or sympathetic ophthalmia[3]. The loss or absence of eye can cause a severe disturbance in social and mental well-being of the patient[4,5]. Replacement of the lost eye as early as possible with the ocular prosthesis will promote the physical as well as social acceptance of the patient. Goiato et al in his study found that the use of ocular prosthesis causes a positive influence in patient's personal relations and psychological improvement[6].

The ocular prosthesis is a cost-effective option for the rehabilitation of lost eye. It is a device or a prosthesis which occupies the anterior part of the anophthalmic socket[7]. Ocular prosthesis rehabilitates the facial disfigurement and restores the facial aesthetics, it prevents the tear accumulation in the cavity thereby preventing possible complications like ulcers and infections[8,9]. It restores the lachrymal dynamics and help tear glands to partially recover to their natural position. An ocular prosthesis may be available readymade (Stock ocular prosthesis) or it can be fabricated as per patient (Custom made). Stock ocular prosthesis are available in standard sizes, shape, and shades. Custom made ocular prosthesis have several advantages over stock prosthesis such as improved fit, better adaptation, better motility, more even pressure distribution, enhanced facial contours and aesthetics[10]. A series

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of case reports and studies by Pinar Cevik et al concluded that custom made ocular prosthesis showed better aesthetic and functional results when compared to the stock prosthesis[11].

The method of scleral prosthesis fabrication, weight of the ocular prosthesis, correct choice of the scleral color and its characterization are the important aspects which are of utmost concern while fabricating the custom-made ocular prosthesis[12]. Custom made ocular prosthesis can be fabricated by using various materials and these materials must have better mechanical properties which will prolong the life of prosthesis. Over the past few decades heat cured acrylic resin is considered as one of the best materials for the fabrication of ocular prosthesis. Although the ocular prosthesis has better fit and adaptation, change in color of the sclera is the most common reason to change the ocular prosthesis[13].

With the introduction of CAD CAM in to the dentistry the fabrication of prosthesis was made easier with better precision and accuracy. The previous study by Md Shahid Alam et al comparing the conventional and cad cam ocular prosthesis concluded that the cad cam ocular prosthesis was more comfortable to the patients with less time needed for fabrication and lesser weight of the prosthesis[14].

The present study was planned to compare the color stability of scleral acrylic prosthesis fabricated by conventional heat cure method and cad cam method after cleansing it with neutral soap solution.

The Null hypothesis of the study was that there exists no significant difference in the color stability of scleral acrylic prosthesis fabricated by conventional heat cure method and CAD CAM method after cleansing with neutral soap.

MATERIALS AND METHODOLOGY

A Cross sectional study was performed for 1 year at K M Shah dental college and hospital after the ethical clearance approval from the institutional ethics committee. (SVIEC/ON/DENT/SRP /2/121)

MATERIALS

Heat cure acrylic resin polymer (DPI), Heat cure monomer (DPI), Neutral soap solution (Johnson & Johnson, Mumbai, India), Type IV Dental stone, Metallic flask and clamp, Modelling wax, Mixing bowl and spatula.

METHODOLOGY

A sample size of Minimum 8 per group is required using the following formula for a power 95% and alpha error rate of 1%

$$N = \frac{(Z_{1-\alpha/2} + Z_{1-\beta})^2}{(E / S\Delta)^2}$$

$Z_{1-\alpha/2} = 1.96$ (95 CI)

$Z_{\beta} = 0.8416$ (80% power)

$S\Delta$ = standard deviation = 1

E = effective size = 1

$$N = \frac{(1.96+0.8416)^2}{(1/1)^2}$$

$N = 7.8489/1 = 8$

$N = 8$

For the present invitro study 20 Samples are made to simulate the scleral acrylic prosthesis. 10 samples are fabricated by conventional heat cure

method and remaining 10 samples by cad cam method. Conventional heat cured samples are fabricated according to the technique given by Marilia Canadas[15]. Circular wax pattern of internal diameter 1.5 mm and thickness 5 mm are made, and the base of these wax patterns are inserted into the metallic flask using type IV dental stone. After the crystallisation of the stone in the final inclusion, the flasks are opened and wax is removed. Then the acrylic resin for the sclera is manipulated according to the manufacturer's instructions and inserted into the flasks. The resin is then polymerised using compression moulding technique and long curing cycle. After polymerization the specimens are finished and polished according to the standard protocol. After finishing and polishing the samples are stored in saline solution for 50 hours at room temperature to hydrate them while residual monomer is eliminated. The cad cam samples are fabricated with an internal diameter of 1.5mm and thickness 5mm.

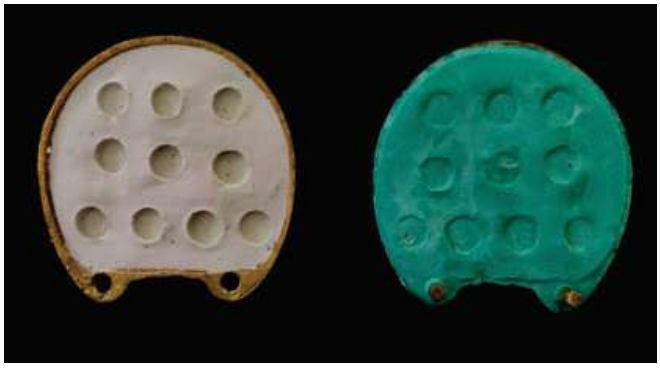

Figure : 2

Figure : 1,2 Fabrication of conventional heat cure samples

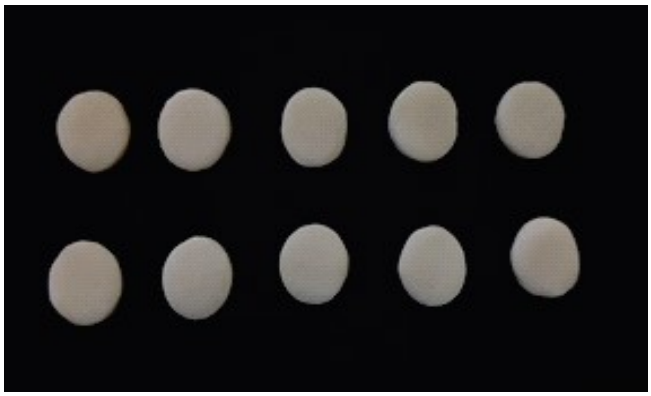

Figure : 3 Heat cure samples

Figure : 1

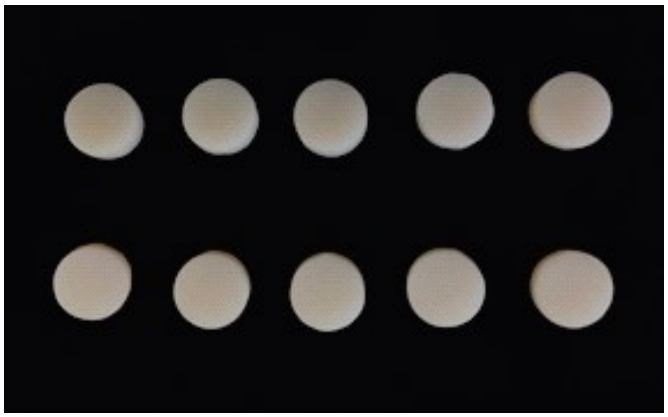

Figure : 4 Cad Cam Samples

Figure : 5 Digital spectrophotometric analysis

The baseline color readings were recorded by using Digital Reflectance spectrophotometer. Then the samples were subjected to cleansing with neutral soap solution. Cleansing involved manual friction with soft gauze for 1 minute followed by rinsing in running water for 30 seconds. All the samples were cleansed once daily and are stored in air tight container at room temperature when not being cleansed. The color readings were measured at 180 and 360 days using spectrophotometer. After the readings the values obtained (L, a, b, ΔL, Δa, Δb, Δ*E*) were analysed using statistical methods. The change in the color (Δ*E*) was measured using the formula ΔE = (ΔL2 + Δb2 + Δa2) ½.

STATISTICALANALYSIS

In this research study, Parametric test were used to analyze the data. Confidence intervals are set at 95% and values of $p < 0.05$ were interpreted as statistically significant. Pre and post results were analyzed by Paired sample t test. The one-way analysis of variance test was used to check the mean difference between the groups. Statistical analyses were performed using SPSS (Version 21) software (IBM, Chicago, IL, USA)

RESULTS

The Mean and standard deviation values of ΔE for conventional heat cure method at 180 and 360 days were 3.41 ± 1.47 and 3.50 ± 1.83 respectively.

The Mean and standard deviation values of ΔE for CAD CAM method at 180 and 360 days were 0.78 ± 0.37 and 1.01 ± 0.50 respectively.

A statistically insignificant difference was observed between conventional heat cure method at 180 and 360 days.

A statistically insignificant difference was observed between CAD CAM method at 180 and 360 days.

Table no 1 ΔE values for conventional heat cure method and CAD CAM method

Name of Variables (n=10)		Mean ± SD	P-Value
CONVENTIONAL HEAT CURE METHOD ΔE	180 Days	3.41 ± 1.47	0.447
	360 Days	3.50 ± 1.83	
CAD CAM METHOD ΔE	180 Days	0.78 ± 0.37	0.127
	360 Days	1.01 ± 0.50	

Table no 2 Comparison of Conventional and CAD CAM Method

ΔE 180 DAYS	3.41 ± 1.47	0.78 ± 0.36	**<0.001**
ΔE 360 DAYS	3.50 ± 1.83	1.01 ± 0.50	**<0.001**

A Statistically significant difference was observed ($p < 0.001$) comparing the ΔE values of conventional heat cure method and CAD CAM method at both 180 and 360 days. (Table 2)

DISCUSSION

The proposed null hypothesis is rejected as there exists a significant difference in the color stability of scleral acrylic prosthesis fabricated by conventional heat cure method and CAD CAM method after cleansing with the neutral soap solution.

The ocular prosthesis is the replacement of the missing or lost eye and majority of the patients who wear ocular prosthesis are the older age group individuals in which the manual dexterity is less, so an ocular prosthesis should be cleaned or rinsed with an appropriate media which is very effective in removing the adhered bacteria as well as causing less detrimental changes in the properties of the ocular prosthesis.

The color stability is one among the many properties of the ocular prosthesis which effects the longevity of the prosthesis. Although, the ocular prosthesis has very good fit with no discomfort to the patient, the change in the color of both sclera and iris part of the ocular prosthesis is the most common reason to change the ocular prosthesis.

The heat cured acrylic resin from the past few decades which is used in various fields of dentistry has better mechanical and physical properties. Previous studies on the color stability of ocular prosthesis which are fabricated by heat cure method also revealed the same. Hence, the present study was planned to fabricate the scleral part of the ocular prosthesis with conventional heat cured method using long curing cycle of processing at 74°C for 8 hours and increasing the temperature to 100°C for 1 hour.

A previous study conducted on evaluating the color stability of ocular prosthesis after immersing in three different immersion media for 8 weeks

concluded that the neutral soap is the best immersion media with the least color changes[16]. Hence, our study was planned to evaluate the color stability of scleral ocular prosthesis fabricated by conventional heat cure method and CAD CAM method after cleansing with the neutral soap.

After cleansing of samples, they were subjected to observation for color change. This was performed using digital reflectance spectrophotometer. All the measurements were recorded in CIELAB coordinates (CIE L*a*b* (CIELAB) is a color space specified by the International Commission on Illumination and transferred to the computer. The CIELAB measurements make it possible to measure the color. "CIELAB" coordinates are considered the gold standard for measurement analysis of the color change (ΔE) value. The "CIELAB" system quantifies color variations through three-dimensional coordinates and hence it is used for the color change (ΔE) analysis. The L^* parameter assesses the luminosity (where 100 represents white and 0 represents black), the a^* coordinate measures the amount of redness (positive values) and greenness (negative values), and the b^* coordinate measures the amount of yellowness (positive values) and blueness (negative values). This system was selected because it recognizes small color changes among specimens and has been extensively used.

The values of ΔE are also expressed as National Bureau of Standards (NBS) units by the following formula to quantify the color changes according to this system $NBS = \Delta E \times 0.92$.

According to NBS, the color change from 0.0 to 0.5 is marked as trace, 0.5 to 1.5 is slight, 1.5 to 3 is noticeable, 3 to 6 is appreciable, 6 to 12 is much, and >12 is very much.

By the formula, NBS values for Conventional heat cure scleral ocular prosthesis are 3.13 and 3.22 after 180 and 360 days of neutral soap cleansing respectively indicating noticeable color change. For CAD CAM scleral ocular prosthesis, the NBS values are 0.71 and 0.92 after 180 and 360 days of neutral soap cleansing respectively indicating slight color change.

Gas chromatography studies on comparing the residual monomer content of conventional heat cured acrylic resin and CAD CAM method showed that less monomer content in CAD CAM method could be attributed to the method of polymerization under pressure[17]. Hence in the present study, the least color change in the CAD CAM method could be because of the less residual monomer content.

The greater color change in the conventional heat cure method could be because of the greater residual monomer content, and the interaction of this residual monomer with the neutral soap solution leading to the leaching away of the polymer and change in the color of the scleral prosthesis. The reason for the greater color change in the conventional heat cure method samples could also be because acrylic resin is hydrophilic and is subjected to water sorption which acts as a plasticizer. Due to this there will be formation of cracking zones resulting from absorption and adsorption cycles, leading to gradual deterioration of acrylic resin and change in the color of the sclera[18].

The color change for both conventional and CAD CAM method samples could also be because of the composition of the neutral soap as it contains EDTA which acts as a plasticizer[16].

The limitation of the present study includes as it is

an invitro study there may be variation in the in vivo because of various factors such as secretions of the anopthalmic socket and environment which affects the surface and color of the ocular prosthesis and only one commonly used disinfecting medium is used for cleansing method.

CONCLUSION

With in the limitations of the present invitro study it can be concluded that the CAD CAM method of scleral prosthesis fabrication showed greater color stability when compared to the Conventional heat cure acrylic method.

The longevity of the ocular prosthesis can be increased by using the CAD CAM method of fabrication.

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