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A spectrophotometric analysis of color stability of maxillofacial silicone elastomer following investment in molds of different materials-An in vitro study

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Abstract

Maxillofacial prostheses are used in rehabilitation of patients with facial defects. Typically, these prostheses are fabricated with medical grade silicone and are tinted corresponding to the patients' natural skin color. However, the type of investment material and curing temperatures can result in color changes. This study aimed to analyse the color stability of maxillofacial silicone elastomer following investment in moulds of different materials at different processing methods.M511 platinum silicone, in a A:B ratio of 10:1 was used and cured in two different investing material mould .Two flasks each containing 25 samples from Group A1(Dental stone) and B1(Die stone) and one stainless steel mould (Group C1) containing 25 samples were cured at 100° C in boiling water for 1 hour according to manufacturer's instruction. Other two flasks each containing 25 samples from group A2 and B2 and one stainless steel mould (group C2) containing 25 samples were cured at room temperature for 24 hours. The color of the samples was tested using a spectrophotometer. Concluded that Die stone when used as investment material showed significant effect on color stability of elastomeric material when cured at room temperature as well as at 100℃.

Dental stone may be preferred over die stone as an investment material for processing the elastomer material under both room temperature and at 100°C.

Keywords: Maxillofacial material, Color stability, Spectrophotometer.

Introduction

Facial irregularities and defects can compromise the appearance, function and well-being of a person. According to the American Academy of Maxillofacial Prosthetics (AAMP 2019), maxillofacial prosthetics is a sub-specialty of Prosthodontics that involves the rehabilitation of patients with defects or deformities that were present congenitally or developing due to disease or trauma. Maxillofacial prostheses are used to make natural appearing replicas of the missing parts and restore aesthetic appearance and functions1.These defects of the head and neck region can be congenital, developmental or acquired. These defects could be present at the sites of the cranial plate, ear, nose or palatal and create psychological problems and social disabilities in such patients. A maxillofacial prosthesis must therefore be biocompatible and functional.

The ideal properties of these material should have high tear resistance, tensile strength and elongation percentage with low hardness. Silicone elastomers have been used for many years in the process of manufacturing maxillofacial prostheses due to their suitable mechanical, chemical and physical properties[2].

According to the type of polymerization process, silicone elastomers may be: (1) the room temperature vulcanizing (RTV) silicones, which are the most common due to their ease of use in the laboratory and (2) high temperature vulcanizing (HTV) silicones, which have excellent mechanical and physical properties compared to RTV silicones, in addition to having high translucency[3]. However, the main drawback of HTV silicones is their complex colouring process[4.]

The coloration of the maxillofacial prosthesis is the most difficult step in obtaining acceptable aesthetic results. With this in mind, intrinsic colouring kits have been used to obtain the basic color of the prosthesis. Further, extrinsic coloration can be used to obtain the final color of the silicone.[5]

As of today, there is still no ideal facial prosthetic material available, although there have been developments in the last few decades, and silicone rubbers have established themselves as current state-of-the-art material.

Past studies have reported that during the setting of the silicone, there was a slight to significant change in the color of the mix, from the time it is packed into the mould until it is removed The type of investing material (gypsum product) can also have a significant effect on the color change of the elastomers during its curing. This can be due to some of the colorants added to the dental stones or the microstructure of the stone following its manufacture or a combination of both 6. Hence, a need was felt for further investigation as to whether investing materials and the processing temperature would have an effect on the color of maxillofacial silicone after polymerization. Aim of our study was to analyse the color stability of maxillofacial silicone elastomer following investment in moulds of different materials at different processing methods [7,8.]

Materials and methods

This In-vitro study was carried out in the Department of Prosthodontics and Crown & Bridge, Mahatma Gandhi Dental College and Hospital, Jaipur after obtaining approval from the Institutional Ethical Committee.

Sample size was calculated as per the formula: n = 2 (Zα+ Zβ)2 [s]2/d2

where Zα is the Z variate of alpha error i.e., a constant with value 1.96, Zβ is the Z variate of beta error i.e., a constant with value 0.84+

n =2 (2.8)2 [4.22]

n = 22.79 (Rounded to 23 samples per group)

Fabrication of stainless-steel mould for control group samples

Two custom made two-piece stainless-steel moulds were made with the dimension of 15x 7x 0.6 cm. Twenty-five circular slots each of 10mm diameter and 3 mm depth were made in the base (of 10 mm diameter and 3 mm thickness) Lids were also cast in stainless steel to cover the base mould for fabrication of samples. Two screws were attached to the lid to tighten the two pieces of the mould end to end. (Figure 1)

Fabrication of investment material mould for experimental group samples

Two different dental stones (dental stone -green, die stone -orange) were used. Using stainless steel mold 100 discs of heavy body putty material were made of 10 mm diameter and 3 mm thickness. (Figure 2) For each investment material two varasity flasks were taken. Each varasity base flask was poured using the respective stone. Twenty-five putty discs were embedded in each flask. After the complete set of investing material, thin layer of separating media (Transparent Die hardener) was applied in the gaps between the discs. Counter flasking was done with the same investing material used in the base flask. After the complete set of investment material, the two parts of flasks were separated and the putty discs were removed using probe from the base flask. Empty slots were achieved for incorporating the maxillofacial silicone material. (Figure 3)

Manipulation and packing of maxillofacial silicone material

M511 platinum silicone (Figure 4), in a A:B ratio of 10:1 was used according to the manufacturer's instructions On a digital scale, 200 g of base and 20 g of catalyst were weighed. Intrinsic pigment (P402) was added to the catalyst to achieve medium brown skin color.

After proper manipulation of base and catalyst paste were clamped under pressure up to 30 psi. (Figure 5) The same mix was packed in both the stainless steel moulds. (Figure 6)

Polymerization of samples

Two flasks each containing 25 samples from Group A1 and B1 and one stainless steel mould containing 25 samples were cured at 100° C in boiling water for 1 hour according to manufacturer's instruction. Another two flasks each containing 25 samples from

group A2 and B2 and one stainless steel mould containing 25 samples were cured at room temperature for 24 hours. (Figure 7)

Sample used for the study is categorized as

Samples cured at room temperature

Dental stone mold	-	Group A_1
Die stone mold	-	Group B_1
Stainless steel mold	-	Group C_1
Samples cured at 100 °C:		
Dental stone mold	-	Group A_2
Die stone mold	-	Group B_2
Stainless steel mold	-	Group C_2

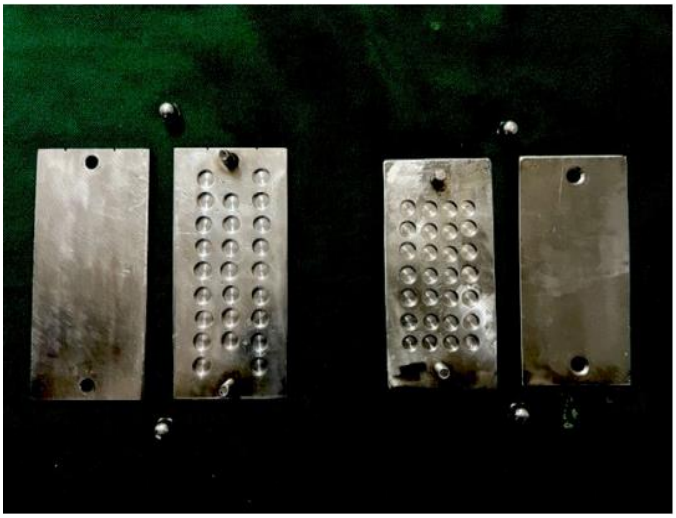

Figure 1: Metal Mould for control group samples.

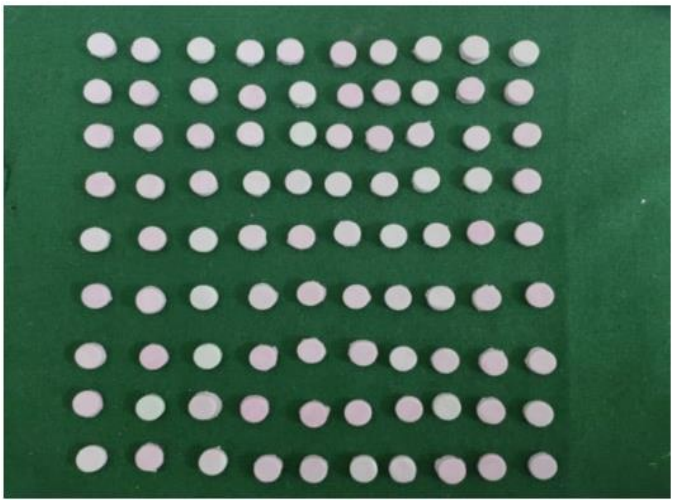

Figure 2: Fabrication of Putty discs for creating spaces for silicone samples.

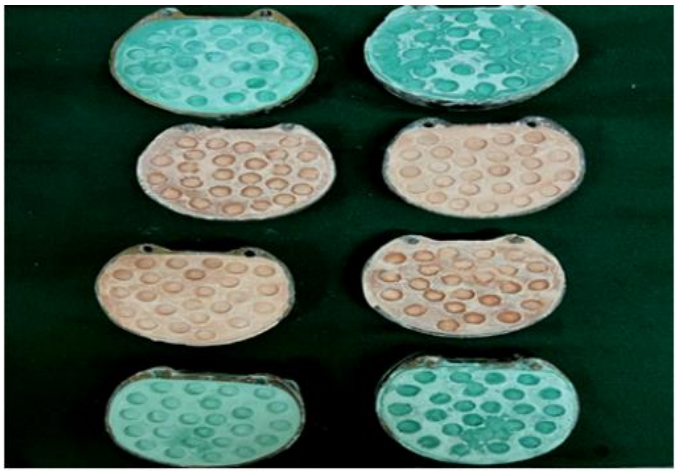

Figure 3: Empty slots for silicone mix incorporation after removal of putty discs from the varasity flasks.

Figure 4: M511 platinum silicone elastomer (Techno vent Ltd., South Wales, UK.

Figure 5: Intrinsic pigment (p402)

Figure 6: Packing of silicone material in stainless steel mould

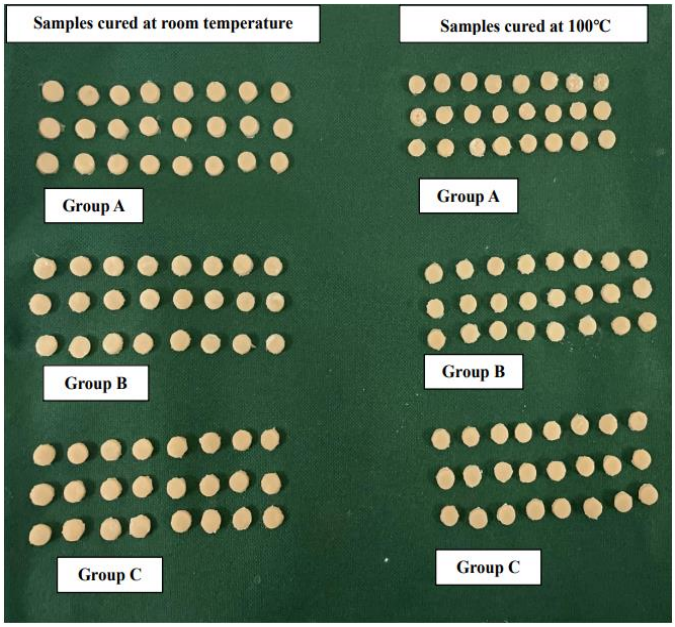

Figure 7: Retrieved silicone samples.

Testing of samples using Spectrophotometer

The color of the samples was tested using a spectrophotometer. (Figure 8,9) The Commission Internationale d' Eclair age L, a, b system was used to assess the color difference between the test and control samples.

The L* coordinates correspond to red or green chroma (a""= red, a = green) and yellow or blue chroma (b = yellow, b = blue), respectively,

whereas the a* and b* coordinates correspond to red or green chroma (a""= red, a = green) and yellow or blue chroma (b = yellow, b = blue). The L*, a*, b* values were obtained and was compiled on a MS Office Excel Sheet.

Figure 8: Spectrophotometer.

Figure 9: Spectrophotometer

Statistical Analysis

The normality of continuous data was analysed by Shapiro-Wilk test. As the data did not follow normal distribution, non-parametric tests were used to analyse the data.

Kruskal Wallis test determined whether the medians of two or more groups were different. The MannWhitney U test (nonparametric test) was used to compare two groups without making the assumption that values are normally distributed.

The p values <0.05 is considered to be statistically significant.

Software: SPSS (Statistical Package for Social Sciences) Version 24.0 (IBM Corporation, Chicago, USA)

Results and Discussion

Table 1: Post hoc pair wise comparison of mean L* values at room temperature among the groups.

Groups	M.D.	95% C.I.	P-value*
A_1 v/s B_1	-4.06	-7.66--0.46	0.037†
A_1 v/s C_1	2.10	-1.48-5.70	<0.001†
B_1 v/s C_1	6.17	2.57-9.76	<0.001†

#P-value derived from Dunn's post hoc test; †significant at $p < 0.05$

Table 2: Post hoc pair wise comparison of mean a* values at room temperature among the groups.

Groups	M.D.	95% C.I.	P-value*
A_1 v/s B_1	0.99	0.72-1.25	<0.001†
$A_1$1v/s C_1	0.35	0.09-0.62	0.066
B_1 v/s C_1	-0.63	-0.90--0.36	<0.001†

#P-value derived from Dunn's post hoc test; †significant at $p < 0.056$

Table 3: Post hoc pair wise comparison of mean b* values at room temperature among the groups.

Groups	M.D.	95% C.I.	P-value*
A_1 v/s B_1	-1.95	-2.58--1.32	0.003†
A_1 v/s C_1	2.21	1.58-2.84	<0.001†
B_1 v/s C_1	4.17	3.54-4.80	<0.001†

#P-value derived from Dunn's post hoc test; †significant at $p < 0.05$

Table 4: Post hoc pair wise comparison of mean L* values at 100 0C among the groups.

Groups	M.D.	95% C.I.	P-value*
A_2 v/s B_2	-2.14	-2.54--1.74	<0.001†
A_2 v/s C_2	2.89	2.49-3.28	<0.001†
B_2 v/s C_2	5.03	4.64-5.43	<0.001†

#P-value derived from Dunn's post hoc test; †significant at $p < 0.05$

Table 5: Post hoc pair wise comparison of mean a* values at 100 0C among the groups.

Groups	M.D.	95% C.I.	P-value*
A_2 v/s B_2	0.80	0.64-0.95	<0.001†
A_2 v/s C_2	0.13	-0.01-0.28	0.045
B_2 v/s C_2	-0.66	-0.81--0.51	<0.001†

#P-value derived from Dunn's post hoc test; †significant at $p < 0.05$

Table 6: Post hoc pair wise comparison of mean b* values at 100 0C among the groups.

Groups	M.D.	95% C.I.	P-value*
A_2 v/s B_2	-2.47	-2.72--2.22	<0.001†
A_2 v/s C_2	1.57	1.32-1.82	<0.001†
B_2 v/s C_2	4.04	3.79-4.29	<0.001†

#P-value derived from Dunn's post hoc test; †significant at $p < 0.05$

Table 7: Comparison of mean delta E among the groups at temperature differences.

Groups	N	Median	Mean	S.D.	S.E.	Min.	Max	F-value	P-value#
Group A	23	1.13	1.11	0.46	0.09	0.51	2.23	22.051	<0.001†
Group B	23	2.25	2.25	1.10	0.23	0.67	4.14		
Group C	23	2.30	2.36	0.89	0.18	0.41	4.10		

#P-value derived from Kruskal Wallis test; †significant at $p < 0.05$

Table 8: Post hoc pair wise comparison of mean delta E values among the groups.

Groups	M.D.	95% C.I.	P-value*
Class A v/s Class B	-1.13	-1.74--0.52	0.001†
Class A v/s Class C	-1.24	-1.85--0.63	<0.001†
Class B v/s Class C	-0.11	-0.72-0.49	1.000

Color change limits the service life of the maxillofacial prosthesis and minimizing the color change of maxillofacial silicone is challenging. Ease of application and retention, color stability, durability, lack of toxicity, strong peripheries, translucency, ease of cleaning, light weight, ease of fabrication, and physical and chemical inertness are the important desirable properties for maxillofacial prosthetic materials9. It has been reported

by many authors that, the color of the final cured prosthesis is often different from the color that was matched in the presence of the patient at the time of shade selection. This could be due to the colorants added into the investment materials which get leached out during the curing process. Hence, this study was designed to evaluate and compare the color stability following investing in mould of different investing materials at different processing methods.

The material used in our study was M511 platinum silicone elastomer. It was selected on the basis of being the most commonly used silicone material in India for both clinical and research purposes. Intrinsic pigment P402 (medium brown) was added to obtain a color to match Asian skin tone. Two different dental stones (Dental stone -green, Die stone -orange) were used as investing materials. These are the most commonly used investing materials for processing maxillofacial silicone in the clinical scenario. Samples prepared from the custom-made stainless-steel mould served as control group with no investing material and no separating media.

A cyanoacrylate-based mold release agent (die hardener) was used in this study. It has been reported that using die hardener as a separating medium produced the less color change, ease of separation of samples from the mould with least porosity10. M511 platinum silicone is a versatile silicone which can be cured at room temperature as well as at high temperature as suggested by manufacturer. Hence the samples from the test and control group of each mold was vulcanized at room temperature for 24 hours and at 100 °C.

The Munsell colour system and the CIE L*a*b* colour system are two of the colour systems used to measure chromatic variations. Methods for evaluating prosthetic facial materials were described by Cantor et al. They used reflectance spectrophotometry to assess the materials' aesthetics and colour matching of skin and facial materials. Since then, colour stability has been assessed using reflectance spectrophotometry, colour and optical density. In the present study a spectrophotometer (VITA Easy shade Advanced V, Germany, H57127) was used to assess the parameters of color for all the groups.

The ADA recommends the use of CIE L*a*b* system, which quantifies the color alterations using a mathematical equation expressed by ΔE * and obtained with the variation of three coefficients (L*a* and b*) were,

L* = Color luminosity (ranging from 0-black to 100-white) a* = Ranges from 90 to 70 and represent the greenness on the positive axis and redness on the negative axis. +

b* = Ranges from 80 to 100 and represents yellowness (positive b*) and blueness (negative b*).

The mathematical equation to evaluate the Delta E is

$\Delta E = ([\Delta L]2 + [\Delta a]2 + [\Delta b]2)1/2$

On comparison of mean L, a, b values of the silicone post curing, statistically significant differences ($p<0.001$) were found at both room temperature & 100 °C. At room temperature mean L* value of samples from Group A1 when compared with Control group, showed statistically significant difference ($p<0.001$) Likewise, when group B1 (Die stone mould group) was compared with control group, a mean difference of 6.17 was seen which was statistically significant ($p<0.001$) .(Table 1). Mean a* of samples of Group B1 was higher than that of samples from Group A1 samples when compared to the control group. (Table 2). Mean b* parameter showed significant difference when group A1 (2.21) & B2 (4.17) was compared with control group (C1) ($p<0.001$) (Table 3)

When cured at 100 ℃ mean L* value of samples from Group A2 when compared with Group C2 (Control group at 100 ℃), showed statistically significant difference of mean (2.89). Likewise when group B2 samples compared with group C2 , a mean difference of 5.03 was seen which was statistically significant ($p<0.001$) (Table 4). When mean a* of group A2 & B2 was compared with control group a mean difference of 0.13 & -0.66 was observed respectively. (Table 5). Mean b* showed significant difference when group A2 (1.57) & B2 (4.04) was compared with C2 group samples ($p<0.001$) (Table 6). Hence, it can be concluded that the l*a* b* parameters significantly changed with the change of investing material mould. The change in l* a* b* values of samples from die stone mould was higher than that of dental stone mould when compared to Control group mould at room temperature as well as at 100℃.

In the present study, when mean delta E values were compared between the samples vulcanized at room temperature and at 100 ℃ there was statistically significant differences ($p<0.001$) among the groups. Dental stone mould group had the mean delta E value of 1.11 ± 0.46. Die stone mould group had the mean delta E value of 2.25 ± 1.10. The control group (Stainless steel mould group) had the mean delta E value of 2.36 ± 0.89. (Table 7)

When pair wise comparative analysis of mean delta E values at temperature difference was done, dental stone mould group was compared Die stone mould group a mean difference of -1.13 was seen which was statistically significant ($p=0.001$). Dental stone mould group when compared with (Stainless steel mould group) at both processing condition, a mean difference of -1.24 was seen which was not statistically significant ($p=0.066$). When group B – Die stone mould group was compared with group C – Stainless steel mould group, a mean difference of -0.11 was seen which was statistically significant ($p<0.001$) (Table 8). Hence,it can be concluded that dental stone mould samples showed less color change when cured both at room temperature and at high temperature. The change in the color parameters of the samples following polymerization at two different temperatures can be due to the increase in wettability of the moulding stone while curing.

Several studies concluded the color transition from molding stone to silicone elastomer in the literature. Among the investing materials studied by Sethi et al 10, die stone produced the maximum color change (Delta E 3.1) in the silicone, which was statistically significant. The dental stone (green) changed the least, while the dental stone (white) changed the most. However there are several studies which were partially inconsistent with the result of the present study. Study done by Cifter et al11. indicate that after 6000 h of darkroom storage, the yellowing of samples was much more evident in the control-group samples that were molded in stainless steel and vulcanized at100 °C ($P = 0.020$). When the green and white molding stones were used together with vulcanization at 100 °C, the yellowing (increase in the b* values) of the elastomer increased significantly after 6000 h ($p = 0.039$, and $p<0.001$ respectively). Hence it can be concluded that colorants that were added to the gypsum color product leach into the silicone. The intrinsic pigments have also been reported to affect the color stability over time. Depending on the pigment color, the ΔE values changed at different levels (Han Y et al)12. Pigments may differ in density, particle size, or morphology, all of which affect their adhesion to the surfaces to which they are applied.

This study was carried out using the common investing materials available in India. The results may differ with

materials of different manufacturers. Further studies can be done using other investing materials and maxillofacial silicone materials available in the market. The study evaluated immediate color change after processing, and the effect of aging under different conditions need to be investigated.

Conclusion

Since both the type of investment material and the temperature at which the elastomer material caused the color change, the Null Hypothesis was rejected. Within the limitations of this study, the following conclusions were drawn.

The color change observed in our study was higher than the threshold value that the human eye can perceive. This indicated that type of investment material and the processing temperature have a perceptible effect on the color of the elastomeric material used in this study.

Die stone when used as investment material showed significant effect on color stability of elastomeric material when cured at room temperature as well as at 100 ℃. Dental stone may be preferred over die stone as an investment material for processing the elastomer material under both room temperature and at 100℃.

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