Comparison of the effect of opacifiers on color stability of a maxillofacial silicone elastomer after accelerated artificial aging: an in-vitro study

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Abstract: Background and objective: Silicone elastomer is commonly used for extraoral maxillofacial prostheses. Resistance to long-term colour change is an important characteristic of facial prosthetic elastomers. Evidence regarding the colour stability of maxillofacial silicones is a primary concern under ageing and various environmental conditions, mainly solar radiation, temperature, and moisture. Thus, the objective was to compare and evaluate the effect of opacifiers on the color stability of maxillofacial silicone elastomer under accelerated artificial aging.

Methodology: A total of 24 specimen disks were obtained from room-temperature vulcanized, maxillofacial silicone elastomer (Teksil25) and further divided into three groups (n=8): Group A (control), Group B (titanium dioxide), and Group C (barium sulphate) based on the addition of opacifier. All the specimens were analyzed with a Spectrophotometer for baseline readings. Next, all the specimens were exposed to accelerated artificial aging for 360 hrs in a weatherometer. Further, spectrophotometric values were recorded. Data was analysed statistically using one way ANOVA and the tukey post hoc test.

Result: In group A (control), the mean ΔE was 5.77±0.25; group B (titanium dioxide) was 5.47±0.27; group C (barium sulphate) was 4.78±0.22 ($p<0.001$). The maximum color change was seen in group A, whereas the least was seen in group C. A statistically significant difference was observed among the three groups ($p \leq 0.05$).

Conclusion: Changes in color for all three groups were clinically unacceptable and visually perceptible. The specimens with the highest color stability were those that contained barium sulphate opacifier.

Key words: silicone elastomer, color stability, opacifiers, maxillofacial prosthesis, artificial aging

Introduction: Maxillofacial prosthetics is a subspecialty of prosthodontics dedicated to the prosthetic correction and management of maxillofacial defects.[1] Maxillofacial deformities are embarrassing for the patient. These defects, which can be congenital or caused by trauma or surgery, generate physical and psychological trauma to the patient.[2]

Despite advances in plastic surgery, there will always be a need for maxillofacial prostheses for cancer and trauma patients.[3] Silicone elastomer is widely used to fabricate extraoral maxillofacial prostheses due to its favourable mechanical and physical characteristics and its ease of manipulation.

Facial prosthesis is composed of a silicone elastomer system and a pigment system. The color instability of a prosthesis may be caused by environmental factors such as ultraviolet (UV) light, humidity, air pollution, careless usage by patients, and incorrect cleaning.[4,5] Surveys have reported color fading as the most frequent reason patients give for disliking their prostheses.[3]

The literature has indicated that adding some pigments and opacifiers increases the lifetime of the material, preserving prosthesis esthetics and color stability during a longer wearing period.[6] Opacifiers like titanium dioxide and barium sulphate have been incorporated to obstruct UV radiation and enhance the colour stability of maxillofacial silicones. However, opacifiers have different levels of opacity that may affect the color stability of maxillofacial elastomers in different ways.[2]

This research has been undertaken to evaluate the effect of different opacifiers on the color stability of maxillofacial prosthetic materials, with the aim of analyzing how these opacifiers influence the color stability of maxillofacial silicone elastomer. The null hypothesis stated that there would be no significant difference in the color stability of the tested maxillofacial elastomer, with or without the addition of opacifiers.

Materials and Methods: A total of 24 samples were obtained from room-temperature vulcanized, maxillofacial silicone elastomer (Teksil 25, Technovent ltd). For the preparation of samples, a customized jig, made up of silicone putty, was fabricated with dimensions of 25mm diameter and 4mm depth, engraved disc-shaped hollow cavity. Flat lid made up of silicone putty fabricated to maintain the even thickness of the samples. Further, wax models (Maarc dental) were fabricated for which molten wax was filled in a customized jig, excess wax was removed, and a lid was placed over to make an even surface.

The wax models (Fig 1) were obtained from the customized jig. These disks were then invested in a flask (Fig 2) with Type III dental stone (Kalabhai Karson Pvt. Ltd.). After the stone had set, the wax disks were removed from the mold, leaving 25×4-mm disk-shaped depressions (Fig 3).

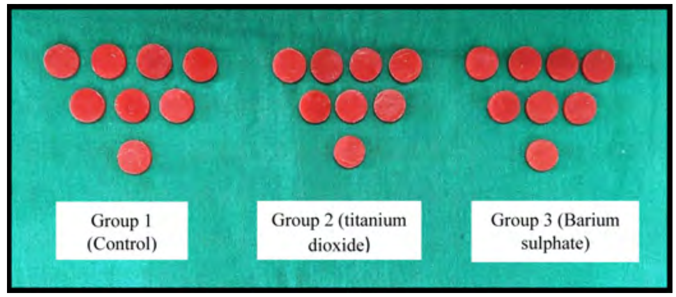


Fig 1: Wax models

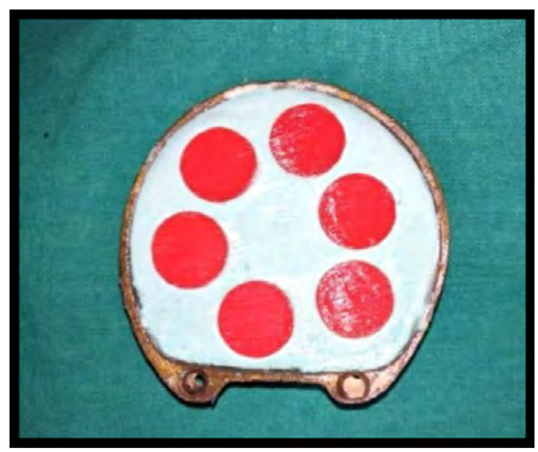


Fig 2: Flasking of wax models

Fig 3: Mould cavity obtained after dewaxing

Silicone samples were fabricated in this mould cavity. The sample size of 24 was divided into three groups, with each group having 8 specimens: Group A (control group), Group B with the addition of titanium dioxide, and Group C with barium sulphate (Fig 4).

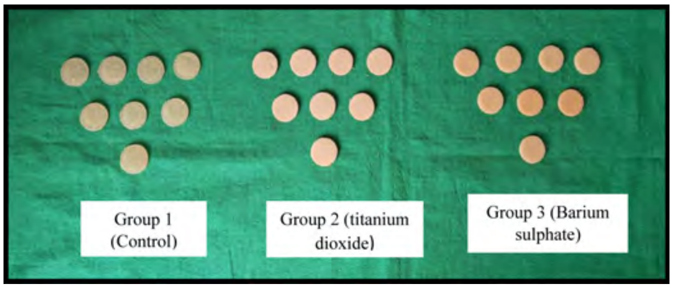


Fig 4: Silicone Samples

For fabrication of the samples, RTV silicone material was used with a base: catalyst ratio of 9:1, to which was added 0.2 wt% of pigment (Technovent ltd). For group A, no opacifier was added; for group B, 2 wt% of titanium dioxide (BRM chemicals) was added; for group C, 2 wt% of barium sulphate opacifier (HiMedia Laboratories) was added. Mix well until a homogeneous mixture is achieved. This mixture was added to the mould cavity in the flasks, followed by packing and clamping of the flasks. For the next 24 hours, the silicone was allowed to set at room temperature.

After 24 hours, the samples were carefully deflasked. Samples without any porosity, uniformly colored, and with the same dimensions were accepted, and the rest were rejected. All the specimens were submitted for Spectrophotometric analysis (Fig 5) (VITA Easyshade® V) for initial readings (Fig 6). After 360 hours of artificial aging (Fig 6,7) (QUV accelerated weathering tester), alteration in color change was analyzed using a spectrophotometer. The conditioning duration was selected to replicate one year of usage of the maxillofacial silicone prosthesis. Each day, patients wear their prosthesis for 8 to 12 hours, assuming that the prosthesis is exposed to daylight, normal environmental conditions for at least 1 hour, while in the defective site. Thus, one year of use is equivalent to 360 hours of accelerated aging.

Fig 5: Spectrophotometer

Fig 6_Weathering Chamber

Fig 7: Samples placed in the weathering chamber

The spectrophotometer was calibrated according to the manufacturer instructions, for each sample one measurement was taken to determine the colorimetric measurements L, a, b. The values were executed in accordance with the CIELAB color system (fig 8). It utilizes the three-dimensional colorimetric parameters L, a, and b, with 'L' indicating brightness, 'a' reflecting the red-green component, and 'b' representing the yellow-blue component.

Fig 8: Spectrophotometric readings

Data analysis: The analysis of data was conducted utilizing SPSS software version 23. The level of significance was kept at 5%. Comparison of the color change between the study groups was done using either One way ANOVA test followed by a Post hoc test for pairwise comparisons. Statistical significance was set at $p < 0.05$.

Result: Mean ΔE was 5.77 ± 0.31, 5.47 ± 0.27, and 4.78 ± 0.22 in Group 1 (control), Group 2 (titanium dioxide), and Group 3 (barium sulphate), respectively. Thus, a significant difference in color change (ΔE) at $p \leq 0.05$. (Table 1)

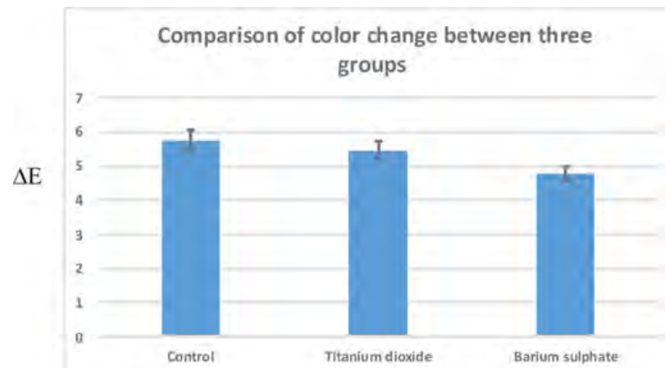
The results showed a significant difference in color change (ΔE) between the control and barium sulfate group ($p \leq 0.05$). Additionally, there was no significant difference found between the control group and the Titanium dioxide group. ($p \leq 0.05$).

Bar graph 1 shows Spectrophotometric color change (ΔE) readings of all the specimens (Graph 1)

Opacifiers	Mean ΔE ± SD
Control	5.77 ± 0.31a
Titanium dioxide	5.47 ± 0.27a
Barium sulphate	4.78 ± 0.22b

Table 1: Mean (SD) for spectrophotometric color change (ΔE) of all the groups

Different lowercase letters indicate statistical difference in the columns at $p \leq 0.05$



Graph 1: Bar graph showing Mean color change (ΔE) readings of all the specimens

Discussion: The null hypothesis that the opacifier would protect maxillofacial silicone from color alteration was partially rejected, as the results of the present study revealed significant differences in color stability between the control and barium sulfate group. However, no significant difference was found between the control group and the Titanium dioxide group.

The design of maxillofacial prosthesis has made extensive use of silicone elastomers, which are typically composed of polydimethylsiloxane (PDMS) elastomers. The material used for the prosthesis and the patient's attitude toward it determine how long maxillofacial prostheses last, and these factors can be directly linked to the prosthesis' efficacy.[7]

Most maxillofacial prostheses must be refabricated about every 6 months because of the degradation of the color and physical properties of the prosthesis.[8] Polyzois affirmed that the exposure of facial silicone to the environment for 1 year resulted in visually detectable color changes.[9]

Temperature, water (moisture), and sun radiation are the three main causes of weathering. The amount of each factor, as well as different types of solar radiation, different types of phases of moisture, and temperature cycling, all affect materials. Air pollution, regular cleaning, and patient mistreatment are additional factors that might induce color changes in the prostheses.[10]

The CIE LAB color standard was used to analyze color change (ΔE).The CIE Lab color system defines color coordinates (L*a*b*), where L* stands for lightness/darkness (where +L is the direction of lightness and L is the direction of darkness), a* for red/green (where a* is in the green direction and a* is in the red direction), and b* for yellow/blue (where b* is in the blue direction and b* is in the yellow direction).[11]

The following formula can be used to determine the color change:

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

Where ΔL, Δa, and Δb are changes in L, a, and b, respectively, between the interval of interest and baseline, and ΔE is the color difference.[9] There is a difference between observable and clinically acceptable values of ΔE concerning facial prosthetics. The relationship between perceptibility and acceptability was detected because color differences that are only just visually perceptible under experimental conditions are not necessarily clinically unacceptable.[10,12]

When $\Delta E < 1$, the color change was considered very low. The situation was clinically acceptable if $1< 3$, and it was considered clinically perceptible if $\Delta E >3$.[13]

The total color change for three distinct groups of specimens in the current investigation is indicated by ΔE values. Group 1 (control) with $\Delta E=5.77 \pm 0.31$ represents the color difference, which is clinically unacceptable and visually perceptible. Group 2 (titanium dioxide) with $\Delta E=5.47 \pm 0.27$ represents the color difference, which is clinically unacceptable and visually perceptible. Also, Group 3 (barium sulphate) with $\Delta E=4.78 \pm 0.22$ represents the color difference, which is clinically unacceptable and visually perceptible.

The result of this color analysis suggests that both the opacifiers used did not show clinically acceptable results but the use of **Barium sulphate** showed improved results for color change as compared to titanium dioxide.

Mahale H2 and Haddad MF14 found similar results, where barium sulphate was found to be most color stable among all the groups, which were consistent with the findings of the present study.

Physical sunshields, such as barium sulphate ($BaSO_4$), Titanium dioxide (TiO_2), and zinc oxide (ZnO) present the advantages of safety, effectiveness, and blockage of ultraviolet rays. Due to their capacity to reflect and scatter sunlight, which is affected by the size of their particles and the thickness of the film they form on the skin. In sunscreen formulations, opacifiers are made up of inorganic particles that stay suspended. The size of these particles is extremely important for the solar blockage effectiveness of the suntan lotion and for the aesthetic appearance of the cosmetic product.[14] As barium sulphate is composed of nanoparticles, it can form strong union to the polymeric chain of the silicone.[14,15]

Specimens that exhibited color alterations regardless of opacifier may be probably due to: intrinsic factors such as discoloration, resulting from the alteration of the elastomeric matrix to oxidation of the double reactions of carbon that generate peroxide, which might lead to color change. Extrinsic factors like solar radiation, thermal variations, humidity, absorption, and adsorption of substances.[10]

Limitations of the present study included that A single brand of RTV maxillofacial silicone material was used. Additional studies with different silicone materials are required. The present study was an in vitro simulation of the clinical usage of prostheses and the photochemical insult that they are subjected to Actual clinical use of the prostheses in daily life can be different and variable. The impact of the opacifiers on mechanical properties must also be assessed.

Conclusions: Considering the limitations of this in vitro study, the following conclusions have been drawn:

1. RTV silicone specimens containing barium sulfate were the most color-stable among all the groups.
2. RTV silicone specimens containing barium sulfate and titanium dioxide showed improved results for color change but are clinically unacceptable and visually perceptible.

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