

**Effect of Opacifier on Color Stability and Surface Roughness of A Maxillofacial Silicone Elastomer Subjected To Accelerated Artificial Aging: An in Vitro Study**

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**Abstract**

Background and objective: Evidence regarding the colour stability and surface roughness of maxillofacial silicones is a primary concern under ageing and various environmental conditions, mainly solar radiation, temperature, and moisture. Thus, the objective was to evaluate the effect of opacifiers on the color stability and

surface roughness of a maxillofacial silicone elastomer under accelerated artificial aging.

**Methodology:** A total of 30 specimen disks were obtained from room-temperature vulcanized, maxillofacial silicone elastomer (Teksil25) were divided into two groups (n=15): Group A (control), Group B (titanium dioxide) based on the addition of opacifier. All the specimens were analyzed with a Spectrophotometer

for color stability and Profilometer for surface roughness for baseline readings. Next, all the specimens were exposed to accelerated artificial aging for 360 hrs in a weatherometer. Further, spectrophotometric and profilometer values were recorded. Data was analysed statistically using Independent samples t-test and two-way ANOVA test.

**Result:** In group A (control), the mean  $\Delta E$  was  $5.36 \pm 1.10$ ; group B (titanium dioxide) was  $5.47 \pm 1.34$ . A statistically Non significant difference was observed among the two groups. In group A (control), Mean Surface Roughness before and after artificial aging was  $0.78 \pm 0.07$  and  $0.96 \pm 0.07$  respectively; group B (titanium dioxide) Mean Surface Roughness before and after artificial aging was  $0.97 \pm 0.10$  and  $1.50 \pm 0.14$  respectively. Two-Way ANOVA test, revealed statistical significant difference in Surface Roughness due to titanium dioxide and accelerated artificial aging at  $p \leq 0.01$ .

**Conclusion:** RTV silicone specimens containing titanium dioxide opacifier exhibited similar results for color change after artificial aging; however, the colour change was clinically unacceptable and visually perceptible for both the groups. RTV maxillofacial silicone (without titanium dioxide) before artificial aging exhibited Ra value lower than clinical threshold for plaque retention; however, after artificial aging its Ra value significantly increased above the threshold. RTV maxillofacial silicone (with titanium dioxide) before artificial aging exhibited Ra value higher than clinical threshold for plaque retention, and the Ra value significantly increased after artificial aging.

**Keywords:** silicone elastomer, color stability, surface roughness, opacifiers, maxillofacial prosthesis, artificial aging

## Introduction

Maxillofacial prosthetics is a subspecialty of prosthodontics dedicated to the prosthetic correction and management of maxillofacial defects.<sup>1</sup> 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.<sup>2,3,4</sup>

Despite advances in plastic surgery, there will always be a need for maxillofacial prostheses for cancer and trauma patients.<sup>5</sup> Silicone elastomer is widely used to fabricate extra oral maxillofacial prostheses due to its favourable mechanical and physical characteristics and its ease of manipulation.<sup>6</sup>

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.<sup>7,8,9</sup> Surveys have reported color fading as the most frequent reason patients give for disliking their prostheses.<sup>5,10</sup>

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.<sup>11,12</sup> Opacifiers like titanium dioxide 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.<sup>2,13,14</sup>

Surface roughness is critical surface and mechanical properties influencing the clinical performance and longevity of maxillofacial elastomeric materials.<sup>15</sup> Surface irregularities may act as nucleation sites for crack propagation, corrosion, plaque accumulation, and

bacterial colonization, thereby compromising prosthesis durability and hygiene.<sup>16,17</sup>

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

### Materials and Methods

A precise customized silicone putty mold with a disc-shaped cavity (25 mm diameter, 4 mm depth) and a flat lid was fabricated to ensure uniform thickness. Wax patterns were produced using modeling wax (Maarc Dental). The obtained wax discs (Fig. 1) were invested in a dental flask with Type III dental stone (Kalabhai Karson Pvt. Ltd.). After setting, dewaxing was performed to obtain standardized disc-shaped mold cavities.

Silicone samples were fabricated in this mould cavity. The sample size of 30 was divided into two groups, with each group having 15 specimens: Group A (control group) and Group B with the addition of titanium dioxide. 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. Mixed well until a homogeneous mixture was 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 deflashed. 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 (VITA Easyshade® V) and Profilometric analysis (Mitutoyo, Japan. Model : SJ 210) for initial readings . After 360 hours of artificial aging (QUV accelerated weathering tester), alteration in color change was analyzed using a spectrophotometer and roughness using profilometer (Fig 3,4). 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.<sup>4</sup>

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 3). 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.

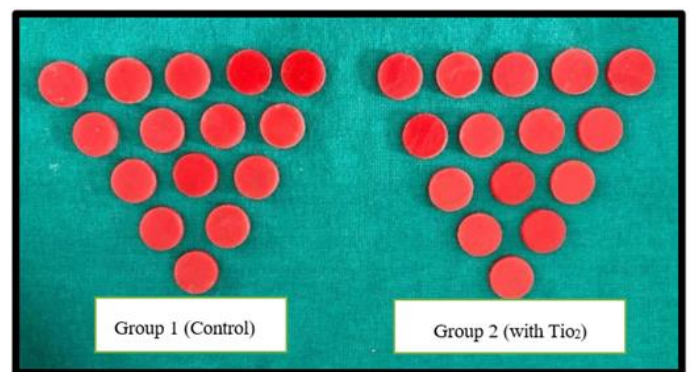


Figure 1: Wax models

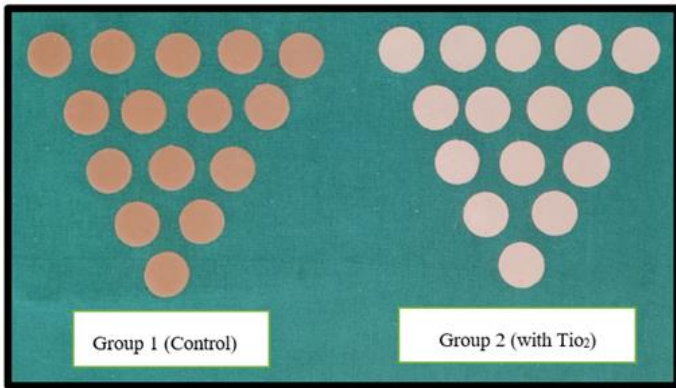


Figure 2: Silicone Samples



Figure 4: Profilometric readings



Figure 3: Spectrophotometric readings

Table 1: Results of (Independent samples t-test) for spectrophotometric color change ( $\Delta E$ ) after accelerated artificial aging.

Group	n	Mean $\Delta E \pm SD$	Mean difference	t value	p value	Significance
Without Titanium Dioxide (Group A)	15	$5.36 \pm 1.10$	0.11	0.24	0.81	Not significant
With Titanium Dioxide (Group B)	15	$5.47 \pm 1.34$				

Table 2: Comparison of the effect of Titanium Dioxide and Artificial aging on Surface roughness using two-way ANOVA test.

Source of Variation	df	SS	MS	F	P-value
Group	1	0.78	0.78	58.32	<0.001
With Titanium Dioxide					
Without Titanium Dioxide					
Time	1	1.52	1.52	113.74	<0.001
Before Artificial aging					
After Artificial aging					

Group × Time Titanium Dioxide * Artificial aging	1	1.21	1.21	90.41	<0.001
Error	56	0.75	0.013		
Total	59	4.26			

**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 Independent samples t-test and surface roughness was done using two-way ANOVA test. Statistical significance was set at  $p < 0.05$ .

**Result**

In group A (control), the mean  $\Delta E$  was  $5.36 \pm 1.10$ ; group B (titanium dioxide) was  $5.47 \pm 1.34$ . The maximum color change was seen in group B. However, A statistically Non significant difference was observed among the two groups. (Table 1)

In group A (control), Mean Surface Roughness before and after artificial aging was  $0.78 \pm 0.07$  and  $0.96 \pm 0.07$  respectively; group B (titanium dioxide) Mean Surface Roughness before and after artificial aging was  $0.97 \pm 0.10$  and  $1.50 \pm 0.14$  respectively. Two-Way ANOVA test, revealed statistical significant difference in Surface Roughness due to titanium dioxide and accelerated artificial aging at  $p \leq 0.01$ . (Table 2)

**Discussion**

The null hypothesis that the opacifier would protect maxillofacial silicone from surface roughness and colour stability was partially rejected, as the results of the present study revealed significant differences in surface roughness between the control and Titanium dioxide group. However, no significant difference was found between the control group and the Titanium dioxide group for colour stability.

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 determines how long maxillofacial prostheses last, and these factors can be directly linked to the prosthesis’ efficacy.<sup>12</sup>

Most maxillofacial prostheses must be refabricated about every 6 months because of the degradation of the color and physical properties of the prosthesis.<sup>3</sup> Polyzois affirmed that the exposure of facial silicone to the environment for 1 year resulted in visually detectable color changes.<sup>6</sup>

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.<sup>4</sup>

The CIE LAB color standard was used to analyze color change ( $\Delta E$ ). 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).<sup>13</sup>

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  $\Delta L$ ,  $\Delta a$ , and  $\Delta b$  are changes in  $L$ ,  $a$ , and  $b$ , respectively, between the interval of interest and baseline, and  $\Delta E$  is the color difference.<sup>6</sup> There is a

difference between observable and clinically acceptable values of  $\Delta E$  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.<sup>4,9</sup>

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  $\Delta E > 3$ .<sup>14</sup>

The total color change for these two groups of specimens in the current investigation is indicated by  $\Delta E$  values. Group 1 (control) with  $\Delta E = 5.36 \pm 1.10$  represents the color difference, which is clinically unacceptable and visually perceptible. Group 2 (titanium dioxide) with  $5.47 \pm 1.34$  represents the color difference, which is clinically unacceptable and visually perceptible.

The result of this color analysis suggests that the opacifiers used did not show clinically acceptable results. Mahale H2 and Haddad MF14 found similar results, where titanium dioxide was found to be least color stable among all the groups, which were consistent with the findings of the present study.

Physical sunshields, such as barium sulphate ( $\text{BaSO}_4$ ), Titanium dioxide ( $\text{TiO}_2$ ), and zinc oxide ( $\text{ZnO}$ ) 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.<sup>17</sup> As barium sulphate is composed of nanoparticles, it can

form strong union to the polymeric chain of the silicone.<sup>10,16</sup>

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.<sup>4</sup>

In this study a progressive increase in surface roughness following accelerated aging in both experimental groups. Specimens with Titanium dioxide exhibited significantly higher  $R_a$  values after aging compared to specimens without Titanium dioxide modification, suggesting increased surface degradation and potential clinical implications related to plaque retention and esthetic deterioration.

Faten K. Al-Kadi demonstrated that  $R_a \approx 0.20\text{--}0.80 \mu\text{m}$  represents the threshold surface roughness for bacterial plaque retention, beyond which microbial accumulation increases significantly.<sup>15</sup>

In present study Artificial aging significantly increased surface roughness in both groups. However, the titanium dioxide group exhibited higher baseline roughness and a more pronounced increase after aging, indicating reduced surface stability. Post-aging roughness values in both groups exceeded the clinically acceptable threshold, suggesting a higher susceptibility to microbial accumulation, particularly in the titanium dioxide group.

The findings of the present study are consistent with the observations reported by Ahmed Mushfiqur Rahman, who demonstrated that artificial aging significantly affects surface roughness (SR) in most maxillofacial silicones, with the exception of M-511, where the changes were not statistically significant.<sup>17</sup>

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 titanium dioxide opacifier exhibited similar results for color change after artificial aging, However the colour change was clinically unacceptable and visually perceptible for both the groups.
2. RTV maxillofacial silicone (without titanium dioxide) before artificial aging exhibited Ra value lower than clinical threshold for plaque retention, however after artificial aging its Ra value significantly increased above the threshold.
3. RTV maxillofacial silicone (with titanium dioxide) before artificial aging exhibited Ra value higher than clinical threshold for plaque retention and Ra value significantly increased after artificial aging.

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