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Effect of extraoral aging conditions on the color stability of high temperature vulcanizing and room temperature vulcanizing maxillofacial silicone elastomers: An *in vitro* study

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Abstract
Maxillofacial prostheses require enhancement or replacement due to deterioration in their color during their use. The major factors that affect the color of the prostheses are ultraviolet (UV) light exposure, temperature changes, and cleaning and handling by the patient. The aim of the study was to find the effect of extraoral aging conditions on the color stability of high temperature vulcanizing (HTV) and room temperature vulcanizing (RTV) maxillofacial silicone elastomers. Specimens of 25mm x3mm dimensions were fabricated in Techsil S25 HTV silicone and Factor II RTV silicones and processed according to the manufacturer's instructions. Eight groups with eleven specimens each were made. The color stability test was conducted with a Ultraviolet- visible (UV-VIS) spectrometer (Shimadzu) before and after exposure to outdoor weathering and disinfection. The results of the two groups were compared using independent t test. The results of the subgroups were compared with One way ANOVA test followed by Scheffe multiple comparison test. The average color change was found highest in subgroup 4(3.90) and least in subgroup 3(2.3) in HTV samples. The average color change was found highest in subgroup 1(2.70) and least in subgroup 2(1.78) in RTV samples. Color changes caused by HTV samples were significantly greater than that caused by RTV samples. Color changes caused in subgroups 2 and 4 between HTV and RTV samples were significantly greater than in the other groups. There were no significant differences in color change in other subgroups.

Keywords: Color stability, maxillofacial silicone, outdoor weathering, disinfection

1. Introduction
Color is considered a major criterion for evaluating facial prostheses. Any color change of the prosthesis observed over a short period calls for the need for a new prosthesis. Such color changes have been the main reason behind the failure of the facial prosthesis with respect to the durability of the prosthesis. These color changes are mainly due to UV light exposure in the environment, changes in humidity and temperature [1–3] air pollution, and daily handling and cleaning of prostheses by the patient. The service life of maxillofacial prosthesis is usually 6 months to 2 years, irrespective of the type of elastomer used in the fabrication [4]. The thresholds for the perceptible and acceptable color differences of fair-skin-colored silicone specimens were reported to be 0.8 and 1.8, respectively [5]. The Commission International de l'Eclairage, L∗, a∗, b∗ (CIELAB) perceptibility and acceptability thresholds for light-skin-colored maxillofacial silicone specimens are 1.1 and 3.0, respectively [6].
The longevity of prostheses has been a major concern for a very long time. Color is an integral part of a maxillofacial prosthesis. But there is no evidence of studies comparing the longevity of different silicones. There is no facial prosthetic material so far that meets all the ideal requirements but there have been improvements in the past few decades, and silicone rubbers have been established as the current state-of-art material [7]. Many studies have investigated the properties of silicone elastomers after storage in simulated sebum solution or acidic perspirations [8, 9], exposure to artificial daylight or radiation, [8–12] storage in silicone-cleaning

solutions, [15] or outdoor weathering [16, 17], However, direct comparisons between these treatments are not possible, as studies varied in silicone elastomers tested, conditioning treatments (composition and duration), and specimen fabrication and testing standards used. So the need to study the effect of the same sample on different aging conditions over some time was necessary to find out the duration in which the silicone material remains color stable and fit to use.
The study aims to investigate the color stability of TechSil S25 and Factor II maxillofacial silicone elastomer when exposed to different duration of extraoral aging conditions on the same sample.

2. Subjects and Methods

2.1 Fabrication of specimens

The specimens of dimensions 25 mm in diameter and 3 mm in height were made using a metallic cylindrical matrix. Two maxillofacial silicone materials are used for this study: 1 high-temperature vulcanized (HTV) (TechSil S25) material and 1 room-temperature vulcanized (RTV) (A-2186) material. The silicone and catalyst are mixed manually (HTV-9:1, RTV-10:1) recommended by the manufacturers. The powder pigments were added to silicone laid on a polypropylene cup. The silicone is then poured into the mold. HTV silicone specimens are polymerized at 100^0C for 2 hours in a dry oven whereas RTV silicone specimens are allowed to polymerize for 24 hours at room temperature. After polymerization, the specimens are removed from the mold and stored in a plastic box. Each specimen is evaluated for defects. Only specimens without visible defects are tested.
A total of 88 specimens were obtained. Group A denoted the HTV specimens. Group B denoted the RTV specimens. Based on the duration of exposure to extraoral aging conditions, these specimens were divided into subgroups A1, B1 (outdoor weathering-45 days, disinfection-15 hours), A2, B2 (outdoor weathering- 90 days, disinfection-30 hours), A3, B3 (outdoor weathering-135 days, disinfection-45 hours) and A4, B4 (outdoor weathering-180 days, disinfection-60 hours).
These samples were grouped neatly in plywood blocks at 450 angles to prevent stagnant water and increase the amount of sunlight on the samples. The whole setting was set on the roof for different periods. The disinfectant solution was prepared using Fittydent tablets. After exposure to outdoor weathering, the specimens were washed in distilled water and then immersed in beakers containing disinfectant solution and kept for a specified period. These specimens were washed, dried, and tested for color stability.

2.2 Testing of the specimens:

The prepared specimens were subjected to a color stability test which was carried out using a UV-VIS spectrometer (Shimadzu). All test specimens were washed with distilled water and subjected to initial chromatic analysis before outdoor weathering. The UV-VIS spectrometer was calibrated according to the manufacturer's instructions before each measurement. The color differences were evaluated using CIE L* a* b* [Commision Internationale de l'Eclairage (CIE)] colorimetric system. This system is based on 3 parameters for defining color: L*, a*, and b*. The "L" axis is known as brightness and extends from 0 (black) to 100 (perfect white). The coordinate "a" represents the amount of red (positive values) and green (negative values) while coordinate "b" represents the amount of yellow (positive values) and blue (negative values). It allows the calculation of the mean value of ΔE (color variation) between two readings by the formula:

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

After the initial color test, all specimens were stored in a plastic box. The specimens were exposed to outdoor weathering conditions and disinfection. Once the disinfection was complete, a new chromatic analysis was done using a UV-VIS spectrometer (Shimadzu) and the color alterations were measured using CIE L* a* b* method.

3. Results & Discussion:

Categorical and quantitative variables were expressed as frequency (percentage) and mean ± standard deviation (SD) respectively. Descriptive statistics such as mean ± SD, Median with Inter Quartile Range, and minimum and maximum were used to describe color change score. One-way ANOVA test and Scheffe Multiple Comparisons (post hoc test) were used to compare color change among different subgroups. An independent t test was used to compare color change between HTV and RTV groups. For all statistical interpretations, $p<0.05$ was considered the threshold for statistical significance. Statistical analyses were performed by using a statistical software package SPSS, version 20.0
Based on different durations, a comparison of color changes for different subgroups among HTV samples were given in Table 1. The average color change was found highest in subgroup 4 (3.9) followed by subgroup 2 (3.8), subgroup 1 (3.16), and least in subgroup 3 (2.3). The color changes between subgroups B & C and C & D was found to be statistically significant. There were no differences in color change between A & C, A & D, B & D, and C & D subgroups. (Table 1)
Based on different durations, a comparison of color changes or different subgroups among RTV samples were given in Table 2. The average color change was found highest in subgroup 1 (2.7) followed by subgroup 3 (2.68), subgroup 4 (2.05), and least in subgroup 2 (1.7). The color changes between subgroups A & B and B & C were found to be statistically significant. There were no differences in color change between A & C, A & D, B & D, and C & D subgroups. (Table 2)
A comparison of color changes of HTV and RTV samples was given in Table 3. The color changes between HTV and RTV samples were found to be statistically significant in subgroups 2 & 4 and as a whole. There were no significant differences in color changes in subgroups 1 and 3. (Table 3)
Incidence of maxillofacial defects either due to carcinoma, trauma, or congenital disease has gone up in the last few years and these patients seek qualitative and comprehensive prosthetic care so that they can improve their quality of life. An esthetic and functional prosthesis can help these patients adjust well to the circumstances, relieving them of fear and anxiety.
Silicone elastomers have been the material of choice for the fabrication of maxillofacial prostheses over the years. However, one of the main reasons for the failure of facial prostheses is color degradation [15–17]. During the evaluation of facial prosthesis, the most important parameter used is color [4, 18]. The prosthesis has to be refabricated almost every 1 to 1.5 years, mainly due to the discoloration it undergoes [19].
Surveys have reported color fading as the most common cause for patients not liking their prostheses. The environmental exposure to ultraviolet (UV) light, air pollution, and changes in humidity and temperature cause deterioration of the material. Various factors play a key role in changing the physical properties and the color stability of

the prosthesis material. Some of them are handling the prosthesis during cleaning and the application of adhesives.[20] Other than this, finished facial prostheses rest on living human skin for extended periods and may absorb perspiration and sebum. These absorbed secretions can cause changes in the deteriorating elastomer structure, leading to the final deterioration of the prosthesis.

Color stability of a material is the property of retaining color for some time in a certain environment. It indicates the resistance of the prosthesis to discoloration during service. The Munsell color system and the CIE L* a* b* color system are used to determine the chromatic differences. Cantor *et al* [21] determined various methods for evaluating facial prosthetic materials. The esthetics of the materials and color matching of skin and facial materials were evaluated by authors using reflectance spectrophotometry. Subsequently, color stability was determined by reflectance spectrophotometry and color and optical density.

The main factors that cause outdoor polymer degradation are sunlight, moisture, and temperature. The type and amount of these undesirable changes may vary depending on the geographic location, climatic conditions, and environment in which the prosthesis is worn [22].

Sweeney *et al.* [23] in 1972 reported the use of an accelerated aging chamber for the evaluation of maxillofacial material color stability. This device exposes specimens to radiation, temperature, and humidity similar to the atmosphere. However, this aging chamber does not simulate the conditions clinically experienced by the patients. The accelerated aging affects the mechanism of degradation of the polymer and leads to inaccurate estimates of color stability [24, 25]. Hatamleh *et al.* [25] investigated the effect of extraoral aging conditions on the mechanical properties of maxillofacial silicone elastomer and concluded that accelerated aging caused degradation of the silicone which adversely affected the properties of silicone. To simulate the natural daylight in this study, the specimens were directly exposed to the sunlight.

The conditioning periods are selected to simulate silicone prosthesis in service for 6-24 months. Considering that each day patients wear their prosthesis for 8-12 h, during which it is expected to be exposed to at least 6 h of daylight, normal environmental conditions, and continuous sebum and perspiration. Moreover, patients spend an average of 5 min in cleaning their prostheses before sleeping. Therefore, wearing the prosthesis for 1 month equals 180 h of daylight aging and 150 min of exposure to the cleansing solution. So 6 months of wear is equivalent to 45 days (1080 h) of daylight and 15 h (900 min) of exposure to the cleansing solution. Accordingly, 12 months of wear is equivalent to 90 days of daylight aging and 30 h of exposure to the cleansing solution. 18 months of wear is equivalent to 135 days of daylight aging and 45 h of exposure to the cleansing solution. 24 months of wear is equivalent to 180 days of daylight aging and 60 h of exposure to the cleansing solution.

The samples were subjected to outdoor weathering from May to October 2021. The maximum temperature that was recorded during this period was 33^0C in May and the lowest temperature recorded was 23^0C in July, September, and October. The highest amount of rainfall that was recorded was 262 mm in June.

Room temperature vulcanizing silicones are more widely used than high temperature vulcanizing silicones for the fabrication of maxillofacial prostheses due to the ease of processing. However, RTV material tends to discolor over time and this necessitates a new prosthesis. Although it has been stated that HTV silicones have the advantages of excellent thermal stability and physical properties along with color stability in comparison with RTV silicones 3, some recent studies have reported good color stability of RTV silicones[26]. Findings from studies on HTV silicones have been contradictory due to the difference in climate in different areas. Al Harbi *et al* [27] reported that TechSil S25 elastomer showed better mechanical durability and color stability when compared with A-2186 and MED-4210 materials. Also, the non-pigmented samples in his study did not show significant color changes when compared to pigmented samples. Intrinsic pigments in the form of powder were incorporated into the silicone samples to mimic the average skin color of people in India.

Many researchers have studied the color stability of maxillofacial silicones. However, direct comparisons between these treatments are not possible as there was no standardization (different silicone elastomers, conditioning treatments, specimen fabrication, and testing standards). Although many authors have studied the effects of extraoral aging conditions on different types of maxillofacial silicones, a review of the pertinent literature indicates that studies comparing the changes in HTV and RTV silicones as a result of exposure to outdoor weathering and disinfection on the same samples have not been reported.

The present in vitro study evaluated the effect of duration on the color stability of maxillofacial silicones exposed to extraoral aging conditions and compared the color stability of HTV and RTV samples. The extraoral aging conditions that were taken into consideration were outdoor weathering and disinfection. Color changes are mainly caused due to UV light and disinfection of the prosthesis was a mandatory step in the maintenance of the prosthesis. Keeping this in mind, the effects of these two factors were evaluated on the same sample, one after the other.

The color changes in the specimens before and after disinfection were assessed using a spectrometer with the CIE L* a* b* color system (UV-VIS spectrometer). The ADA recommends the use of the CIE L* a* b* color differential system. According to this system, all natural colors are acquired through the blending of three basic colors-red, blue, and green in various proportions.28 The use of the CIE L* a* b* colorimetric system is recommended for dental purposes in improving the quantifying process. The CIE L* a* b* color space is plotted in a cube form. L* denotes lightness. The maximum value of L* is 100. The minimum value for L* is zero. The a* and b* axes have no specific numerical limit. A positive a* value is represented by red and a negative value by green. A positive b* value is yellow and a negative b* value is blue. These coordinates, obtained from the spectrometer, provide a numerical description of the color position in a three-dimensional color space. The total color difference ΔE may also be calculated. The quantitative ΔE is calculated using the formula [29].

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

ΔE represents the relative color change in a specimen seen by an observer after treatment so ΔE value is more meaningful than individual L*, a*, b* values.30 CIE L*a*b* colorimetric system is a uniform 3-dimensional system that has been widely used for the determination of chromatic differences by converting the combinations of these differences into mathematical data. Color measurement by spectrophotometry is a reliable, sensitive, and repeatable method; however, some color changes detected by this method cannot be observed

visually. Only ΔE values higher than 3 can be detected by the human eye.

In the present study, the data were analyzed using Statistical Package for Social Sciences (SPSS) version 20.0. Data were expressed in mean and standard deviations. An independent t test was used to compare color change between groups. One-way ANOVA test and Scheffe Multiple Comparisons (post hoc test) were used to compare color change among different subgroups.

One way ANOVA test was used to compare the mean color changes among different subgroups. The F test value for HTV samples, 5.64 ($p<0.01$) showed that the variation in color change among the different subgroups of HTV samples was statistically significant at a 0.01 level. The F test value for RTV samples, 6.25 ($p<0.01$) showed that the variation in color change among the different subgroups of RTV samples was statistically significant at a 0.01 level. Scheffe multiple comparison test (Post hoc test) was used to compare the mean color change in the four different subgroups of HTV and RTV samples taken two at a time (pair-wise) to assess where a significant mean difference exists. The color changes in subgroups 2 & 3 and 3 & 4 of HTV samples were found to be clinically significant at $p<0.05$ and $p<0.01$ respectively. The color changes in subgroups 1 & 2 and 2 & 3 of RTV samples were found to be clinically significant at $p<0.05$. The color changes between all other groups were statistically not significant.

An independent t test was used to compare color changes between HTV and RTV groups. The color changes between HTV and RTV samples in subgroups 2 & 4 were found to be clinically significant. The total color change between the two groups was also found to be clinically significant.

Limitations of the study

Though the study was carried out following the standard protocols, it had some limitations:

1. The present study was an in vitro study that did not completely simulate the patient conditions.
2. The climate is a varying factor depending on the time of the year and location, hence the color change cannot be standardized.
3. Evaluation of color stability was done using intrinsic pigments only. Further studies are required for the evaluation of color stability based on extrinsic staining.
4. Manipulation of the maxillofacial silicone was done by manual mixing which caused porosity in the specimen and hence changes in density and color of the specimens.

3.1 Tables and Figures

Table 1: Comparison of color changes for different sub groups among HTV samples

Sub group	Mean	SD	N	F	p	Scheffe Multiple Comparisons		
						Pair	F`	p
Sub group 1 (A)	3.163	1.325	11	5.64**	0.003	A &B	0.71	0.550
Sub group 2 (B)	3.803	0.661	11			A & C	1.28	0.295
Sub group 3 (C)	2.305	0.951	11			A & D	0.95	0.427
Sub group 4 (D)	3.901	1.061	11			B & C	3.9*	0.016
						B & D	0.02	0.997
						C & D	4.42**	0.009

Table 2: Comparison of color changes for different sub groups among RTV samples

Sub group	Mean	SD	N	F	P	Scheffe Multiple Comparisons		
						Pair	F`	p
Sub group 1 (A)	2.702	0.569	11	6.25**	0.001	A &B	4.16*	0.012
Sub group 2 (B)	1.781	0.812	11			A & C	0	1.000
Sub group 3 (C)	2.680	0.552	11			A & D	2.07	0.119
Sub group 4 (D)	2.052	0.455	11			B & C	3.96*	0.015
						B & D	0.36	0.782
						C & D	1.94	0.139

Table 3: Comparison of color changes of HTV and RTV samples

Sub group	HTV			RTV			T	P
	Mean	SD	N	Mean	SD	N		
Sub group 1	3.163	1.325	11	2.702	0.569	11	1.06	0.302
Sub group 2	3.803	0.661	11	1.781	0.812	11	6.4	p<0.01
Sub group 3	2.305	0.951	11	2.680	0.552	11	1.13	0.271
Sub group 4	3.901	1.061	11	2.052	0.455	11	5.31	p<0.01
Total	3.293	1.182	44	2.304	0.715	44	4.75	p<0.01

5. Conclusion

Within the limitations of the study, the following conclusions were drawn:

1. Subjecting the specimens to outdoor weathering and disinfectant solution produced maximum color change in TechSil S25 Maxillofacial Silicone Elastomer.
2. The HTV samples when subjected to outdoor weathering and disinfectant solution for 90 days and 30 hours respectively, showed greater color change than the RTV samples subjected to the same conditions.
3. The HTV samples subjected to outdoor weathering and disinfectant solution for 180 days and 60 hours respectively, showed greater color change than the RTV samples subjected to the same conditions.
4. Color changes between HTV and RTV samples in all other groups were statistically not significant at 0.05 levels.

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