To Evaluate and Compare the Effect of Indoor and Outdoor Weathering on Mechanical Properties and Color Stability of High Temperature Vulcanized Maxillofacial Elastomer Material: An In Vitro Study

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Abstract

Background: Research in the dental material field is progressing to find the perfect material for maxillofacial prosthetics. This material must meet certain criteria such as functionality, biocompatibility, esthetics, and durability. Silicone is currently the most commonly used material, but it still has weaknesses that need to be addressed. This article explores how environmental factors, such as sunlight, rain, wind and cleaning, can affect auricular prostheses. The article also examines the areas where current materials fall short and need improvement to provide individuals with the best maxillofacial prostheses possible.

Aim: The purpose of this in vitro study was to evaluate and compare the effect of indoor and outdoor weathering on mechanical properties and color stability of high temperature Vulcanized silicone (HTV) maxillofacial elastomer material.

Objective: To evaluate and compare tear strength, tensile strength, hardness and color stability of HTV silicone before and after 6 months of indoor condition and outdoor weathering.

Materials and methods: In order to achieve the objective, mechanical properties of maxillofacial silicone material Technovent Z004 Platinum Silicone Rubber was investigated before and after natural outdoor weathering in comparison to indoor weathering. A total of 40 maxillofacial silicone samples were prepared in two different shapes and sizes using a standardized stainless steel die. The samples were divided into two groups, indoor and outdoor weathering of 20 samples each. Before weathering the samples were tested at baseline for hardness and color stability. About 20 samples were placed in a dry dark closed box and the other half samples were placed outdoor on a rooftop for 6 months. After 6 months, final testing for all the parameters was done using Universal Testing Machine, Shore A durometer and spectrophotometer. The mean values of all the readings of all the samples were statistically analyzed.

Result: The results obtained from this in vitro study conclusively showed that over time the tear strength, tensile strength, hardness and color stability ($\Delta E$) degraded more in outdoor samples (tear strength = 16.93 N/mm, tensile strength = 2.77 N/mm², Hardness = 39.50, $\Delta E = 1.81$) as compared to indoor samples (tear strength = 20.22 N/mm, tensile strength = 3.61 N/mm², Hardness = 37.25, $\Delta E = 0.72$). This showed that apart from aging, exposure to sunlight degrades the silicone even more and it needs to repeat a new prosthetic every 6 months.

Conclusion: Silicone elastomers are thus materials that have ideal physical properties suitable for making prostheses to replace lost facial structures. Though, esthetic quality still requires future studies, particularly long-term prospective clinical trials to determine the amount of distortion tolerable biologically and mechanically.

Keywords: Environmental factors, High temperature Vulcanized silicone, Maxillofacial prosthesis, Physical properties, Polyphosphazenes, Room temperature Vulcanized silicone, Silicone elastomer.

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Introduction

Maxillofacial prosthetics is the department of prosthodontics concerned with the rebuilding and/or substitution of stomatognathic and craniofacial structures with prosthesis which will or may not be expelled on a customary or elective premise.1

The evolution in surgical techniques and the increasing number of patients requiring service have presented new challenges to the management of these patients and principles of prosthodontic practice. Today, patients with defects that cannot be corrected surgically should be referred to a dentist for their oral defects. The profession’s knowledge and skills can help restore these defects along with cooperative effort with bioengineers and biochemists as part of the team that makes maxillofacial prosthetics successful.2

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Materials for maxillofacial applications should have sufficient strength while remaining flexible and soft enough to adapt to facial motion. The material’s strength is the most essential physical property in clinical practice. The tear and tensile strengths of maxillofacial prosthesis indicate the extent to which a material can stretch before failure in tension and to endure the development of facial muscles. The maxillofacial silicone’s hardness is also a measure of flexibility and it is essential because it is preferable to use as a material that is similar in texture to the missing facial tissue.

Color stability shows the resistance of the prosthesis to discoloration amid benefit. The mechanical and physical properties of facial prosthetic materials have progressed over a course of time but the color instability of the facial prosthesis still limits the serviceability and is frequently the reason for changing the prosthesis.

In order to produce a prosthesis with all the above-mentioned properties, it should be made with an ideal maxillofacial prosthesis material. Maxillofacial prosthesis is fabricated by variety of materials, namely, polyvinyl chloride, polyurethanes, polymethylmethacrylate, chlorinated polyethylene and silicones are examples of these materials. Out of these, silicones till date outruns other materials. Barnhart first used silicones in the year 1960 for extraoral prosthesis, which were introduced in 1946. Nowadays, medical grade silicones are perhaps the most commonly utilized materials for facial reconstruction.

Silicones have sufficient tear and tensile strengths, high elongation, ease of production, chemical inertness and suitable bonding to underlying materials, among other characteristics. Fillers are used to boost the polymer’s strength especially elastomers made of polydimethyl siloxane (PDMS) are commonly used for that purpose.

Overtime maxillofacial material is subjected to primary environmental characteristics that cause degradation, such as daylight, temperature, dampness, wind, dust, and toxins. The optical and mechanical qualities of the maxillofacial silicone are degraded by environmental variables, such as weathering, normal aging, and cleaning solvents. Therefore, to maintain the efficacy of prosthesis, silicone-based maxillofacial prosthesis requires replacement in every 6–12 months. Moreover, scientific evidence on the physical properties of maxillofacial material in Asian nations is very constrained, where climatic conditions are exceptionally diverse than the climatic condition where these materials are fabricated.

**Materials and Methods**

This *in vitro* study was conducted at the Department of Prosthodontics Crown & Bridge and Implantology, Sudha Rustagi College of Dental Sciences and Research, Faridabad, Haryana, India. Data were collected and were analyzed statistically to obtain the result.

**Materials**

- Technovent Z004 Platinum Silicone Rubber Part-A and B, Bridgend UK (Fig. 1).
- Functional intrinsic pigment – Dark brown color (Fig. 2).

![Fig. 1: Technovent Z004 platinum silicone rubber Part-A and B](image1)

![Fig. 2: Functional intrinsic pigment – Dark brown color](image2)

**Methodology**

**Sampling**

For conducting this *in vitro* study, a total of 40 samples were taken and each subgroup had 10 samples. The groups were represented in the following flowchart as follows (Flowchart 1):

- Since, tear and tensile strengths would destroy the samples on testing, therefore, hardness and color stability tests were carried out first followed by mechanical strength testing.
- Baseline testing for hardness and color stability was done before exposing.

**Preparation of the Study Die**

Computer Numerical Controlled machine (CNC machine) fabricated three-piece standardized Stainless steel die (International Standards Organization 34 and 37) was used for this study, the three-piece assembly comprised of an upper member, lower member, and a center member which comprised of two different shapes and sized plates (Fig. 3).
Indoor vs Outdoor Weathering Effects on Maxillofacial Elastomer

Center Piece

Trouser-shaped (for hardness and tear strength)
- 20 trouser-shaped samples were made according to ISO specification no. 34 with thickness of 2 mm (Fig. 4).^{10}

Dumbbell-shaped (for color stability and tensile strength):
- 20 dumbbell-shaped samples were made according to ISO specification 37 with thickness of 3 mm (Fig. 5).^{11}

Preparation of Samples

- About 10 gm of Part A and 10 gm of Part B in ratio 1:1 as recommended by the manufacturers of the silicone elastomer were manually mixed on a glass slab in single direction to avoid the incorporation of air bubble, followed by the addition of dark brown intrinsic pigment (1 drop = 0.05 gm) to the mix until uniform color was obtained (Fig. 6).
- The lower and the center member of the die were assembled together over the vibrator and mixed silicone was poured into it and kept for 10–15 minutes. The upper member was placed over this assembly following the right alignment and this was placed under 2000 psi pressure in hydraulic press for 1 hour.
- Keeping the pressure maintained, the die was tightened by four metal clamps for uniform pressure and the whole assembly was placed in a hot air oven for 2 hours for polymerization (Fig. 7).
The samples were carefully retrieved from the die and samples without visible defects were used for the study (Figs 8 and 9).

**Weathering**

*For Control Group (Indoor Weathering)*
- About 10 trouser-shaped and 10 dumbbell-shaped samples were kept at room temperature in a closed black cardboard box in dry and dark environment for 6 months.

*For Experimental Group (Outdoor Weathering)*
- About 10 trouser-shaped and 10 dumbbell-shaped samples were aged outdoor by suspending them from a wooden rack with stainless steel ligature wire and set on the roof of the building for 6 months (June 2021–December 2021). The rack was a customized box which was adjusted at an incline of 45° from the horizontal plane so as to expose the samples to maximum amount of daylight.

**For Testing**
- After weathering, the samples were removed from their respective boxes and cleaned by immersing them for 15 minutes in distilled water and incubating them for 1 full day at 37°C before testing.

**For Tensile Strength and Tear Strength**
- The aged samples were placed in Universal Testing Machine fitted at 25 N load cell linked to an IBM compatible computer at a machine speed of 10 mm/minute (Figs 10 and 11). The software automatically calculated the tensile strength in megapascals (MPa) and it was calculated according to the formula:

\[
\text{Tensile strength} = \frac{F}{A},
\]

where \( F \) = Force recorded at fracture (N)
\( A \) = original cross-sectional area of the specimen (mm)\(^2\)

The tear strength was expressed in kN/m and was calculated according to the formula:

\[
\text{Tear strength} = \frac{F}{d},
\]

where \( F \) = Median Force (N) calculated
\( d \) = Median thickness (mm) of the test sample.

**For Hardness**

Hardness for each sample was tested based on needle penetration on the material surface with manual pressure using Shore A durometer (Fig. 12).

**For Color Stability**
- The color stability of the samples was tested using a Spectrophotometer at 0 and 6 months interval (Figs 13 and 14).
- The values were carried out according to the CIELAB (Commission Internationale de l’Eclairage) color system. The color difference
Indoor vs Outdoor Weathering Effects on Maxillofacial Elastomer

**Results**

Indoor weathering master chart (Table 1). Reading of samples for all four parameters before and after 6 months in indoor dark box.

Outdoor weathering master chart (Table 2). Reading of samples for all four parameters before and after 6 months in outdoor box.

The data were analyzed utilizing Statistical Package for Social Sciences (SPSS) version 21, IBM Inc. Descriptive information (Frequency distribution) was detailed for each variable. Summarized information was displayed utilizing tables. Data were not normally distributed as tested using the Shapiro–Wilk W test ($p$-value $< 0.05$). Mann–Whitney $U$ test (two independent groups) was used for inter-group comparison for tear strength, tensile strength, hardness, and color stability (Table 3). $p$-value $< 0.05$ was considered statistically significant.

**A. Tear Strength**

**B. Tensile Strength**

For both indoor and outdoor weathering, lower tear and tensile strengths were noted after 6 months as compared with baseline with more difference noted in outdoor weathering (Tables 4 and 5).

**C. Hardness**

For both indoor and outdoor weathering, higher hardness was noted after 6 months as compared with baseline with more difference noted in outdoor weathering (Table 6).

**D. Color Stability**

For both indoor and outdoor weathering, lower color stability was noted after 6 months as compared with baseline with more color instability noted in outdoor weathering (Table 7).

**Discussion**

Maxillofacial silicone’s physical properties and esthetics are possible signs of general strength, flexibility, durability, marginal integrity, and longevity in clinical service. The primary goal of maxillofacial prostheses is to enhance the patient’s quality of life by reducing their morbidity and suffering. To achieve these objectives, the tear strength and tensile strength of silicone is the most crucial physical characteristics from a clinical standpoint, especially at the delicate edges of extraoral silicone prosthesis. The thin borders of the facial prosthesis are gently peeled away from the facial tissue. When it is taken off, typically during the night or for cleaning, as a result, the prosthesis is irreparably damaged and needs to be changed. Therefore, these prostheses should be made of a material that has high resistance to tearing.12

Similarly, the silicone elastomer’s tensile strength reflects the material’s overall strength, and the consequent elongation shows how flexible is the prosthesis. When removing nose or ocular prosthesis from facial tissue, when it comes to prosthesis, it is preferred to use a material with high elongation at break. This can be achieved through cross-linking a high molecular weight polymer, which results in a highly elastic material and increases the overall strength of the base polymer.4

Color and surface changes in maxillofacial silicones overtime, is the most common reasons for replacing a prosthesis, especially changes in appearance that patients can notice with their eyes.13 Silicones in comparison with other maxillofacial materials are color stable, durable and resilient while also being soft and flexible (low Shore A Hardness) and more lifelike.
During use, the color and mechanical properties of silicone prosthetics may deteriorate due to the material’s reaction to sunlight, humidity, and temperature, resulting in patient’s dissatisfaction. These changes occur due to photooxidative degradation.

The following events may take place during a photooxidative degradation:

- **Initiation:** Free radicals are formed through a radical chain process that can be initiated by the dissociation caused by the collision of a photon with sufficient energy with a polymer.
Table 6: Comparison of hardness (Shore A) baseline (manufacturer recommended) and after 6 months being exposed to different weathering conditions

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Mean</th>
<th>Std. Dev.</th>
<th>Mean difference</th>
<th>p-value</th>
</tr>
</thead>
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<td>Control</td>
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<tr>
<td>Baseline</td>
<td>10</td>
<td>35.00</td>
<td>1.15</td>
<td>-2.25</td>
<td>0.001*, sig</td>
</tr>
<tr>
<td>After 6 months</td>
<td>10</td>
<td>37.25</td>
<td>1.11</td>
<td></td>
<td></td>
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<tr>
<td>Experimental</td>
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<tr>
<td>Baseline</td>
<td>10</td>
<td>35.00</td>
<td>0.92</td>
<td>-4.50</td>
<td>0.001*, sig</td>
</tr>
<tr>
<td>After 6 months</td>
<td>10</td>
<td>39.50</td>
<td>1.18</td>
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</tbody>
</table>

Sig: * Statistically significant. Mann–Whitney U test, Level of significance set at p < 0.05

Table 7: Comparison of color stability at baseline (manufacturer recommended) and after 6 months being exposed to different weathering conditions

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Mean</th>
<th>Std. Dev.</th>
<th>Mean difference</th>
<th>p-value</th>
</tr>
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<tr>
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<td></td>
<td></td>
<td></td>
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<tr>
<td>Baseline</td>
<td>10</td>
<td>0.59</td>
<td>0.012</td>
<td>-0.13</td>
<td>0.001*, sig</td>
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<tr>
<td>After 6 months</td>
<td>10</td>
<td>0.72</td>
<td>0.03</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Experimental</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>10</td>
<td>0.59</td>
<td>0.012</td>
<td>-1.22</td>
<td>0.001*, sig</td>
</tr>
<tr>
<td>After 6 months</td>
<td>10</td>
<td>1.81</td>
<td>0.08</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Sig: * Statistically significant. Mann–Whitney U test, Level of significance set at p < 0.05

In the current study, difference in tear strength, tensile strength, hardness, and color stability of maxillofacial silicone (Technovent, UK) were evaluated and compared before and after outdoor and indoor weathering conditions. According to the ISO, standard tear strength of silicone material used in current study must be 18–53 N/mm and tensile strength 2.0–7 N/mm². For hardness, Castleberry and Lewis in 1980 stated that 25–35 Shore A units were ideal but values within 10–45 range were considered acceptable. Conroy et al. in 1979 considered 25–55 Shore A units as the correct range for hardness. For color stability, the perceptible thresholds is ∆E = 0.7, as demonstrated by Paravina et al. in 2015, >1 by Lemon et al., Kiat-Amnuay et al., Haug et al., 2 by Beatty et al., Polyzois et al., and 3 by Kantola et al. has been considered perceptible to the human eye. Therefore, ∆E values less than equal to 3 can be considered as acceptable for evaluating color stability.

The findings of the current study showed the mean value of tear strength at baseline as recommended by manufacturer was 21.57 N/mm and after 6 months values decreased to 20.22 N/mm for indoor weathering and 16.93 N/mm for outdoor weathering. In the case of tensile strength, the mean value at baseline as per manufacturer was 4.24 N/mm² and after 6 months of weathering it showed decrease in values for indoor to 3.61 N/mm² and outdoor to 2.77 N/mm². Additionally, the mean value of hardness at baseline was 35 SHA and after 6 months of weathering, it showed increase in values, with 37.25 SHA for indoor weathering and 39.5 SHA for outdoor weathering. As per the results, the mean value of ∆E in color stability at baseline was 0.59, and after 6 months, the values increased to 0.72 for indoor weathering and 1.81 for outdoor weathering. The values for all parameters were calculated with level of significance of p < 0.05 was set to be statistically significant.

It was also observed that after 6 months of outdoor weathering, values for tear strength, tensile strength, and color stability were decreased, with an increase in the hardness values as compared with samples kept indoor. Maxillofacial silicone elastomer therefore with time becomes less elastic, less resistant to tear, changes color visible to naked eye (i.e., darker over time) and becomes harder. This may be due to post-polymerization cross-linking from photoirradiation energy causing changes in the polymer network structure. These modifications will include the number of polymer electronic devices, the connectivity between them, and their position in space, likely altering the light transmitted by the maxillofacial device and the degradation of the polymer’s shade.

In addition to this, the mechanical, physical, and optical properties degraded after 6 months of outdoor and indoor weathering but still remained within acceptable range showing that the material used has good mechanical and optical properties. The variations in characteristics were influenced by the type of materials used. These changes could be attributed to modifications in the chemicals present, which include dispersed fumed silica particles in platinum-catalyzed silicone fluid with vinyl termination. Using a silica filler that has a high surface area can enhance the interactions between the polymer and filler leading to more flexible network which ultimately increases mechanical strength.

The findings of the present research were consistent with other researchers like Hatamleh et al, in 2011 who evaluated the effect of outdoor weathering on physical properties of Techsil high temperature vulcanized silicone (HTV) silicone and concluded that while hardness increased, tear strength and tensile strength dropped. Authors concluded that human and environmental factors have a negative impact on the mechanical characteristics.
of maxillofacial elastomers. In 1972, Sweeney et al. discovered that the weatherometer-induced artificial weathering of several maxillofacial silicone results in considerable changes in the material's tensile strength, percent elongation, tear resistance, hardness, and elastic modulus. Similarly, Eleni et al. in 2009, carried out a study with the same parameters but different silicone material was taken and determined that all properties of the maxillofacial materials deteriorated over time in the outdoor weathering in a year. Similar results were put forward by Haug et al. in the year 1992. M K Kheuer et al. in 2012 compared the hardness of room temperature vulcanized silicone (RTV) and HTV silicone after 9 months of outdoor weathering and concluded that hardness increased after 9 months for both the silicones but more so in HTV silicone owing to more complete polymerization in HTV as compared with RTV with time and as it progressed, the hardness also increased in the same proportionality.

The results for color stability showed that all samples became darker over time in both indoor and outdoor weathering expressed in terms of ΔE. The mean ΔE values of outdoor and indoor samples were more after 6 months as compared with baseline readings. The color stability of the samples decreased drastically over 6 months of weathering with more instability noted in outdoor weathering suggesting that the prosthesis needs to be replaced after 6 months of use. This outcome could be the result of post-polymerization cross-linking brought by the energy from light irradiation, altering the structure of the polymer network affecting the transmission of light through maxillofacial material, thus resulting in unacceptable color change over time. These changes may have involved the quantity of units in the polymer chains, their connection to one another, and their angular arrangement in space.

The results of this study were followed by other researchers, such as Al-Harbi et al. found that pigmented Techsil s25, a-2186, and med-210 silicone elastomers have poor color change due to weather conditions. Kantola et al., in 2013, examined the color stability of maxillofacial elastomer over time and reported a significant shift and concluded that polymeric materials often have poor thermal stability and minimal solar radiation protection. The UVA-UVB irradiation (sunlight), moisture, wind, dust, temperature, and pollution are some of the elements that have an impact on color stability. Babu et al., in 2020, evaluated the effects of chemical disinfection and accelerated aging on two types of maxillofacial silicone: A2186 and Cosmesil. They measured the changes in color stability, Shore A hardness, and surface roughness and found that both types of silicone experienced deterioration in their overall properties.

In contrast to favoring studies, many authors gave different conclusions. Takamata et al. reported that when maxillofacial silicone elastomer (RTV and HTV) is kept in dry and dark environment for 1 year, the silicone elastomer shows a change in the color and concluded that aging rather than exposure to daylight leads to most of the color change observed in the RTV and HTV polymers which could be due to the chemistry of the elastomers and no further detailed reasoning of the result was done by the authors. GL Polyzois et al. in a study presented that when silicone specimens were aged for a period, that is, 1.5 years of clinical service (perspiration and simulated sebum at 37°C), it showed clinically insignificant results with respect to the tear strength, tensile strength, hardness, weight, and color change, the authors concluded that this could be due to the propagation of the cross-linking reaction of the silicone elastomer which does not alter the internal chemistry of elastomer on aging and on exposure to sebum or perspiration.

Considering statistical analysis and facts proposed by various authors, this study revealed that the mechanical elements of the maxillofacial prosthetic material were negatively impacted by 6 months of indoor and outdoor weathering, with more degradation observed in outdoor weathering. In pigmented HTV, weathering also brought about undesirable color changes which is visible to the naked eye. This could be because of continued polymerization as a function of aging process which increases even more when subjected to exposure of light, and can result in changes to the structure of the polymer network.

### Conclusion

Within the realm and preview of the current study, the following conclusions were made for maxillofacial silicone:

- The tear strength decreased after 6 months of indoor and outdoor weathering with more significant results on exposure to sunlight, rain, wind, and dust. The values were in acceptable range.
- The tensile strength decreased after 6 months of indoor and outdoor weathering with more significant results on exposure to sunlight, rain, wind, and dust. The values obtained were still in acceptable range.
- The hardness increased after 6 months of indoor and outdoor weathering with more visually detectable results on exposure to sunlight, rain, wind, and dust. The pigmented samples became dark in color over time.

Silicone elastomers are thus materials that have ideal physical properties suitable for making prosthesis to replace lost facial structures. But the esthetic quality still requires further research, especially long-term clinical trials, to determine the amount of biological and mechanical deformation.

### References

8. Al-Harbi FA, Ayad NM, Saber MA, et al. Mechanical behavior and colour change of facial prosthetic elastomers after outdoor weathering in


