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Comparative Evaluation of Color Stability of Maxillofacial Silicones Following Accelerated Aging Conditions

[1]Dr. Abha Nair, Assistant Professor, Dept. of Prosthodontics & Crown & Bridge, PMS College of Dental Sciences & Research, Golden Hills, Vattappara, Trivandrum, Kerala – 695028, India

[2]Dr. Sudeep Saratchandran, Professor & Head of Department, Dept. of Prosthodontics & Crown & Bridge, PMS College of Dental Sciences & Research, Golden Hills, Vattappara, Trivandrum, Kerala – 695028, India

[3]Dr. Dinesh Nair, Professor, Dept. of Prosthodontics & Crown & Bridge, PMS College of Dental Sciences & Research, Golden Hills, Vattappara, Trivandrum, Kerala – 695028, India

[4]Dr. Sapna Bhaskaran, Professor, Dept. of Prosthodontics & Crown & Bridge, PMS College of Dental Sciences & Research, Golden Hills, Vattappara, Trivandrum, Kerala – 695028, India

Corresponding Author: Dr. Abha Nair, Assistant Professor, Dept. of Prosthodontics & Crown & Bridge, PMS College Of Dental Sciences & Research, Golden Hills, Vattappara, Trivandrum, Kerala – 695028, India

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Abstract

This study has evaluated the effect of natural and artificial weathering on the color stability of two maxillofacial silicone elastomers using UV Visible spectrophotometry in order to provide a scientific basis for aging induced changes in the Maxillofacial silicone materials. Seventy Two samples of two different silicones were made for the study and divided into three groups of conditioning; Dark storage, accelerated aging and outdoor weathering. Color measurements were recorded by Commission Internationale de l'Eclairage–CIE L*a*b* colour system before and after conditioning using spectrophotometer. The data was analyzed with one way ANOVA for multiple Group comparisons, followed by Post hoc Scheffe's Multiple comparison test for Group wise calculation at the 0.05 significance level. All groups exhibited variation in color over time. The color change (ΔE) of the pigmented specimens of all the tested High Temperature Vulcanization - HTV & Room Temperature Vulcanization - RTV silicone elastomers were greater than the acceptable value (ΔE >3.0). Within non pigmented HTV specimens, none of the tested silicone elastomers showed significant color changes. Within non pigmented RTV specimens, all of the tested silicone elastomers showed significant color changes ($P<0.05$). Comparing the ΔE of pigmented M511 and pigmented A-2186, a statistically significant difference was found. The high vulcanized M511 elastomer showed better color stability compared with the room temperature vulcanized A-2186 material. Furthermore, accelerated aging condition was more detrimental and showed significant deterioration of the color properties of both HTV and RTV specimens. Within the limitations of the study, it could be concluded that all groups exhibited great color change regardless of the aging conditions. HTV maxillofacial silicone elastomer consistently showed least color change as compared to the RTV maxillofacial silicone elastomer with all three methods of conditioning. Among the methods of conditioning, accelerated aging in an accelerated aging chamber showed the maximum change. Weathering also caused unacceptablecolor changes in pigmented Cosmesil M511 and A-2186, silicone elastomers.

Keywords: Maxillofacial Prosthetic Rehabilitation, Dental Materials, Material Science, Maxillofacial Silicones, Accelerated Aging, Color Stability.

Introduction

Facial disfigurement resulting from cancer surgery or trauma can severely debilitate patients, preventing them from leading a normal life in our society. Maxillofacial prosthetics plays a key role in the overall rehabilitation of patients. Maxillofacial prostheses can provide an acceptable appearance and restore the function by transforming congenital, developmental, and acquired defects of the head and neck region into natural-appearing reproductions of the missing parts. [1]

Silicone materials have over taken conventional acrylic resins and have become the materials of choice for the fabrication of extra oral maxillofacial prosthesis. However, silica fillers, the polymer chains and the interactions between them, and the surrounding environment may affect their performance during service, necessitating frequent replacement of the prosthesis. Hence, maxillofacial prosthesis needs to be periodically replaced between 6 months to 1 year. [2] Degradation in appearance due to change in color and physical properties are reasons for re-fabrication of a facial prosthesis. Measurements made with a spectrophotometer yield accurate and highly reproducible results under standard conditions. [3-4]

The main factors that cause outdoor polymer degradation are sunlight, moisture, and temperature. To engineer a combination of material components that will produce a color stable prosthesis, it is cardinal that the effects of individual environmental variables be better appreciated. Although, accelerated aging can indicate the polymers' outdoor performance as well as an estimate of the in-service lifetime of polymers, [5] it could also affect the mechanism of degradation and could lead to inaccurate estimates of the polymers' lifetime. [5-6] There has been no report regarding the effect of an exceptionally hot and humid climate on the degradation of maxillofacial silicone polymers. Hence, the prospect of this research is to study ultraviolet exposure, temperature and humidity as individual variables and measure its effect in an exceptionally hot and humid climate on the color stability occurring in two different types of maxillofacial silicone elastomers, Room temperature Vulcanization (RTV) and High temperature Vulcanization (HTV) silicones subjected to accelerated aging process.

Materials & Methods

The two different maxillofacial silicone materials chosen in this study for comparison are popular silicone materials that are widely used in maxillofacial prostheses, High-temperature vulcanized (HTV) (Cosmesil M 511) (Technovent Co - UK) material and Room-temperature vulcanized (RTV) (A-2186) (Factor II) material.

Standard specimens of dimension 25mm diameter and 4mm thickness were used for the study to evaluate color change. Standard custom fabricated nickel chromium molds (dimension 25mm diameter and 4mm thickness) were used to prepare the wax specimens. The Nickel Chromium mold was used to custom fabricate a silicone mold of dimensions 25mm diameter and 4mm thickness. For each type of maxillofacial silicone elastomer, thirty six wax disks were prepared with Hard wax (Cavex Set up Hard Modeling Wax.) using the custom fabricated silicone mold.

The specimens were prepared by weighing the silicone elastomer (Base A) to a catalyst B using digital weight scale (Greggs Professional Digital Scale, Amazon, India). To achieve a ratio of 10 : 1, that is, 10 g part A to 1 g part B = 11 g totally. They were mixed with the help of a stainless steel spatula in a glass plate for two minutes until a homogenous mixture was obtained, then pigment (colorants intrinsic pigments-coloring agents, Red FI 204, Functional Intrinsic II silicone coloring system, Factor II) was added in amounts of 0.2% by weight to half the specimens of each type of maxillofacial silicone elastomer and mixed until a homogenous color was obtained. This produced both pigmented and non-pigmented silicone samples of both HTV and RTV.

72 maxillofacial silicone discs were tested. Specimens were exposed to three different conditionings, including Group A- Dark storage, Group B - Aging in an accelerated aging chamber and Group C - Outdoor weathering in a hot and humid environment for a period of 8 months.

In Group A – Dark Storage, the test specimens immediately after processing without subjecting to any aging condition were stored in the dark in a stainless steel sealed container at room temperature (23 ± 2$^{\circ c}$) and 50 ± 5% relative humidity for 8 months.

In Group B – Accelerated aging, accelerated aging chamber [Binder Photo ageing chamber – model KBF 240] was used & provided an ultraviolet light exposure which was equivalent to 720KJ/m2/hr. This exposure reflected the average daily exposure from natural sunlight measured with an UVB detector (Indian Meteorological Society) at noon in Trivandrum, Kerala, between March and October, 2017.The aging chamber also provided a temperature of 60^{0C} and relative humidity of 80%. The conditioning periods were selected to simulate silicone prosthesis in service for 8 months. Each day, patients wear their prostheses for 8 to 12 hours, during which it is expected to be exposed to at least 3 hours of daylight in normal environmental conditions. Therefore, 1 month of service equals 90 hours of daylight aging and 8 months of service is equivalent to 720 hours of aging.

In Group C – Outdoor Weathering, the specimens were weathered outdoors by suspending them from stainless steel racks & placed outside.

Color changes were evaluated using CIELAB system by recording L*, a*, and b* values at base line and after the conditioning period with a UV -Visible spectrophotometer. The ΔE, ΔL*, Δa*, and Δb* of the specimens were calculated. One-way ANOVA was applied to compare the mean values of the individual silicone elastomers(pigmented & non pigmented) and the post hoc Scheffe's multiple comparison test was carried out to compare between two groups of silicone elastomers.

Results & Discussion

All the silicone specimens exhibited variation in color over an exposure period of 8 months. The color change (ΔE) of the pigmented specimens of all the tested HTV silicone elastomers were greater than the acceptable value (ΔE >3.0) after exposure to dark storage, accelerated aging chamber and outdoor weathering. The value of ΔE ranged from 4.30 to 5.90 units. Within non pigmented HTV specimens, none of the tested silicone elastomers showed significant color changes.[Table 1]

The color change (ΔE) of the pigmented specimens of all the tested RTV silicone elastomers were greater than the acceptable value (ΔE >3.0) after exposure to dark storage, accelerated aging chamber and outdoor weathering. The ΔE value ranged from 3.2 to 7.1 units. Within non pigmented RTV specimens, all of the tested silicone elastomers showed significant color changes (P<0.05), with the color change, ΔE value ranging from 4.9 to 9.5. [Table 2]

Comparing the ΔE of pigmented M511 (HTV) and pigmented A-2186 (RTV), a statistically significant difference was found. [Tables 3 & 4]

The high vulcanized Cosmesil M511 elastomer showed better color stability compared with the room temperature vulcanized A-2186 material. Furthermore, accelerated aging condition was more detrimental and showed significant deterioration of the color properties of both HTV and RTV specimens when they were exposed for 8 months.

Poly-dimethylsiloxane (PDMS), often referred to simply as silicone, is an important class of organo-silicon synthetic material based on molecular chains of alternate silicon and oxygen atoms. It is a combination of organic and inorganic components.[7] It was first applied to maxillofacial prosthetics by Barnhart in the 1960's. [8-9] Till date, it is the most widely used maxillofacial material for extra oral prosthetic devices. This is because its physical properties makes it suitable for use when adaptability and accommodation of soft tissue movement is required during contact between the device and the patient's soft tissues, such as excellent tear and tensile strength over a range of temperature, easier to manipulate, high degree of chemical inertness, low degree of toxicity, and high degree of thermal and oxidative stability. Silicones have good thermal and color stability along with physical properties comparable to human tissues when compared with other maxillofacial materials. [10]

Polysiloxanes must be cross-linked to form solid elastomer materials. Antioxidants and vulcanizing agents are added to change the raw mass into rubbery resins during processing and the process of cross linking is known as vulcanizing. Depending on whether the vulcanizing process uses heat or not, silicones are available as high temperature vulcanized (HTV) or room temperature vulcanized (RTV) and both exhibits their own advantages and disadvantages.

The perceptible color changes may compromise the clinical acceptability of maxillofacial restoration. [11] Discoloration of facial prosthesis observed clinically is a complex phenomenon comprising of several contributing factors that include intrinsic color stability of silicone elastomer, pigments and flocking, loss of extrinsic coloration, personal habits and environmental staining. [12-13] The most serious problems associated with facial prosthesis are poor durability and loss of esthetics, which have been verified by clinical studies. In a study conducted to evaluate the reaction of 138 patients to their facial prosthesis, color fading was the most frequent response given for disliking their prosthesis. [14]

The color stability has been thoroughly investigated as a part of the primary physical property studies of maxillofacial elastomers. Aging and environmental factors cause a general degradation of polymers, color changes of the silicone elastomer itself, and in some cases, color changes of the pigments. The weathering of polymers can cause changes in physical and chemical characteristics, which result in alterations in their mechanical properties. Climate characteristics, including solar radiation, temperature, and moisture, can affect properties of silicone elastomers by inducing changes in their chemical nature, resulting in alterations in their functional properties. [15] The actual performance of silicone elastomers under extraoral factors can be determined by tests that simulate real conditions involving outdoor exposure. [16]

As polymeric biomaterials cannot withstand high thermal changes and show little resistance to sunlight, [17] they become susceptible to deterioration on exposure to weather conditions. For most polymeric materials the primary cause of deterioration is a photo-oxidative attack, the combined action of oxygen and sunlight, on their chemical structure. In outdoor exposure experiments, the degradation of polymers is not always explained on the basis of meteorological data on factors that are generally held responsible for polymer degradation (solar radiation, temperature and moisture) [18-20]

Researchers began evaluating the color stability of maxillofacial prosthetic materials in an artificial weathering environment. Since then, reflectance spectrophotometry, color and optical density have been used to evaluate the color stability of maxillofacial elastomers. [21-22]

Studies investigated the color changes of different samples after artificial and outdoor weathering. The conclusion was that the amount of UV energy had a significant effect in color change (ΔE). [23] In the present study, the artificial accelerated aging was represented by a combination of UV irradiation exposure, a raised temperature of 60℃ and 85% humidity.

The clinician tries his best to obtain a color as close to the patient's skin color as possible with intrinsic pigments. Hence, the intrinsic coloring of the silicone is critical in obtaining prosthesis with a perfect color match. While some clinicians prefer to choose colors manually, the use of devices like the Spectrophotometer is popular for color formulations and limiting effects of metamerism. [24]

Cosmesil M511 silicone was chosen for the present study as a recently introduced high-vulcanized silicone elastomer that has been shown to possess adequate properties. [25] Room-temperature vulcanized silicone elastomers, A-2186 was chosen for the present study because it is commonly used facial elastomer. [26-27] Comparing the ΔE of pigmented Cosmesil M511 and pigmented A-2186, a statistically significant difference was found. The high vulcanized Cosmesil M511 elastomer showed better color stability compared with the room temperature vulcanized A-2186 material.

The results of the present study are in agreement with that of a recent study that concluded that heat-polymerized TechSil S25 elastomer showed better mechanical durability and color stability compared with the room-temperature polymerized A-2186 and MED-4210 materials. [28] But in comparison to the present study, they evaluated the effect of a single factor, outdoor weathering, which is a major setback. [28]

The findings of the present study are contradictory to the results obtained by a research study according to whom following the exposure to sunlight for 6 months, HTV silicone showed a larger difference than RTV silicone against the three backgrounds. [29]

During service, color changes of silicone prostheses may occur over time because of the material's response to solar radiation, moisture, and temperature, leading to patient dissatisfaction. In agreement with other studies, [30 - 32] the present study revealed that pigmented specimens exposed to outdoor weathering exhibited significant color changes ($P<.05$) when compared with their equivalent non pigmented specimens. This result might be caused by post polymerization cross-linking as a result of energy from light irradiation, [29] causing modifications in the polymer network structure. These modifications might have included the number of units of polymer chains, their bonding to each other, and their angular arrangement in space, most probably followed by changes in the extent of light transmission through the maxillofacial material along with degradation of the polymer color shade.

Artificial aging is a useful, effective and fast method to evaluate the color stability of maxillofacial materials. Another study concluded that the materials showed significantly perceptible changes after accelerated aging using UV radiation. [24] Several research studies have evaluated the color differences of maxillofacial materials after accelerating aging. The changes in ΔE were greater for the artificially aged than for the outdoor weathered samples. The outdoor weathering exposes the samples to natural weathering conditions, but it is an un-controlled subjective method of testing. There is no control over the amount of each factor causing the deterioration which include, geographic location, season, weathering condition, time of day, and length of exposure. [33]

The accelerated weathering condition is a controlled method of testing the effect of the most deteriorating factors on the SP. Thus, they do condense the process in a shorter time frame. However, it does expose the samples to extreme and aggressive weathering condition. It is still not clear how effective the artificial weathering process simulates the natural process and it may well present an incorrect estimation about the service life of the materials used for the fabrication of these prostheses. [34]

In the present study accelerated aging was used, which include three different aging conditions to test the materials: sunlight exposure, ultraviolet exposure and relative humidity. Each of these aging conditions affected the materials differently. It has been suggested that 1000 hours of exposure to UV light and other weathering conditions using accelerated weathering chambers is equivalent to one year of natural outdoors exposure.[25] Thus, one hour exposure to artificial weathering corresponds to 8.76 hours of natural weathering conditions. Therefore, the 4 weeks time frame exposure to accelerated weathering that has been applied in this study should be equivalent to 8 months of natural weathering conditions.

It appears that the accelerated aging is responsible for the highest amount of color changes in both silicone groups (Table 1,2,3 & 4). Most polymers contain aromatic rings and C = C bonds in their structures, which can absorb ultraviolet light during accelerated aging. [35] When the polymer molecule absorbs ultraviolet light, this energy creates instability in the molecular structure. The excess of energy can be dissipated through several pathways, for instance transfer of the excitation to another molecule. These functional groups may return to their ground state in steps, re-emitting the excess of energy at longer wavelengths such as visible or infrared light. If not dissipated, the excess energy may lead to bond cleavage (photochemical degradation). This degradation contributes to deterioration of the molecule, causing dimensional changes, color and brightness changes, loss of opacity, crack formation, and hardening. [35]

The results of the present study revealed that pigmented silicone specimens underwent more color change after the aging conditions. Red and yellow pigments are commonly used in color formulations to obtain skin colors. Intrinsic red pigment was used in this study that caused color degradation. This could be due to the organic nature of the red pigment being affected more by irradiation. [13,36] Organic colorants rely on the placement of double and triple bonds to impart color to the molecule. Since, these bonds tend to be relatively reactive these colorants are considered to be unstable. [37] Inorganic pigments are generally more color stable but are often not considered as these pigments are not as bright as organic pigments making it difficult to achieve a good color match. [38]

A study evaluated the color stability of polydimethyl siloxane (HTV silicone and RTV silicone) by comparing the effects of 6 months of aging at room temperature in a dry and dark room to the effects of aging through exposure to outside conditions, especially sunlight. They concluded that color changes as a result of exposure to sunlight for both HTV and RTV were quite small compared to the effects of 6 months of aging. [29]

According to the National Bureau of Standards, a color change is considered to be very low when ΔE is less than 1, clinically acceptable when ΔE is between 1 and 3, and clinically noticeable when ΔE exceeds 3. [39]

Comparing the ΔE of HTV silicone M511 and RTV Silicone A-2186, a statistically significant difference was found. The heat polymerized M511 elastomer showed better color stability compared to the room temperature polymerized A-2186 materials irrespective of whether pigmented or not.

The limitation of the present study relies on the mechanism of artificial aging used which differs from the natural aging mechanism to which medical silicones are normally subjected. During normal function, most elastomers used in facial prostheses are not exposed to the wet environments or thermal cycling procedures used during the artificial aging process. Although artificial weathering causes a greater change than natural weathering, [40] there is no definitive research examining the correlation between the aging chamber used in the present study and clinical changes in physical properties of silicones. Future research is warranted to investigate this correlation.

Although this study examined two different maxillofacial silicone elastomer materials under conditions of accelerated ultraviolet light exposure, the results clearly indicate that pigment and elastomer color stability may vary considerably. Color changes occurring soon after a maxillofacial prosthesis is fabricated may be caused by inherent chemical change occurring within the elastomer or by color loss occurring with certain pigments that are not UV-resistant. Hence, future studies can be directed towards prolonging the longevity of the facial prosthesis by incorporating UV absorbers and hindered amine light stabilizers.

With the results of the present study, it is safe to conclude that the maximum duration for which a prosthesis remains color stable is 8-12 months and needs to be periodically changed once in every 10 months for better patient acceptance. The results of the study also gives an insight into how different maxillofacial silicone elastomers may behave when exposed to different aging conditions, thus affecting the clinician's choice of material and the patient's concern towards the prosthesis.

Conclusion

Within the limitations of the study, the present study could derive following conclusion:

- Both groups of maxillofacial silicone elastomers exhibited significant color change regardless of aging conditions.
- HTV maxillofacial silicone elatomer consistently showed least color change as compared to the RTV maxillofacial silicone elastomer with all three methods of conditioning, revealing superior color stability.
- Among the methods of conditioning, accelerated aging in an accelerated aging chamber showed the maximum color change.
- Outdoor Weathering also caused unacceptable color changes in pigmented M511 and A-2186, silicone elastomers.
- Addition of pigments to the base elastomer in both HTV and RTV resulted in significant (ΔE) color changes after exposure to accelerated aging.

- Both Pigmented HTV and RTV silicone elastomers showed greater color variation than the non-pigmented category.

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Table Legends

Table 1: Comparison of color variation (ΔE) in pigmented and non-pigmented HTV maxillofacial silicone material

Group	Pigmented			Non Pigmented			t	p
	Mean	SD	N	Mean	SD	N		
Dark Storage	4.3	0.5	6	1.0	0.4	6	13.67**	0.000
Accelerated Aging Chamber	5.9	0.7	6	1.1	0.5	6	14.67**	0.000
Outdoor Weathering	5.5	0.5	6	1.3	0.4	6	16.4**	0.000

**: - Significant at 0.01 level

Table 2: Comparison of color variation (ΔE) in pigmented and non-pigmented RTV maxillofacial silicone material

Group	Pigmented			Non Pigmented			t	p
	Mean	SD	N	Mean	SD	N		
Dark Storage	4.9	0.4	6	3.2	0.3	6	8.27**	0.000
Accelerated Aging Chamber	9.5	1.4	6	7.1	0.7	6	3.83**	0.000
Outdoor Weathering	6.2	0.5	6	5.9	0.7	6	0.935	0.372

**: - Significant at 0.01 level

Table 3: Comparison of color variation (ΔE) in pigmented HTV and RTV maxillofacial silicone material.

Group	HTV			RTV			t	p
	Mean	SD	N	Mean	SD	N		
Dark Storage	4.3	0.5	6	4.9	0.4	6	2.51*	0.031
Accelerated Aging Chamber	5.9	0.7	6	9.5	1.4	6	5.7**	0.000
Outdoor Weathering	5.5	0.5	6	6.2	0.5	6	2.28*	0.045

**: - Significant at 0.01 level

Table 4: Comparison of color variation (ΔE) in non-pigmented HTV and RTV maxillofacial silicone material.

Group	HTV			RTV			t	p
	Mean	SD	N	Mean	SD	N		
Dark Storage	1.0	0.4	6	3.2	0.3	6	11.95**	0.000
Accelerated Aging Chamber	1.1	0.5	6	7.1	0.7	6	17.87**	0.000
Outdoor Weathering	1.3	0.4	6	5.9	0.7	6	14.62**	0.000

**: - Significant at 0.01 level