Effect of Chemical Disinfectants and Accelerated Aging on Maxillofacial Silicone Elastomers: An In vitro Study

Abstract

Context: Maxillofacial prostheses need frequent refabrication due to degradation of color and deterioration of physical properties of the elastomer. Aims: This study attempted to evaluate the change in color stability, Shore A hardness, and surface roughness of two maxillofacial silicones, A-2186 and Cosmesil M511, when submitted to chemical disinfection and accelerated aging. Settings and Design: This was a comparative in vitro study. Subjects and Methods: The materials included two silicone elastomers – A-2186 and Cosmesil M511 (Factor II Incorporated) – functional intrinsic red pigment and three disinfectants – Fittydent tablet, chlorhexidine gluconate 4%, and neutral soap. The specimens in each group of elastomer were evaluated initially for color, hardness, and surface roughness, which were further divided into subgroups and subjected to disinfection and accelerated aging. The evaluation of color was performed with the help of an ultraviolet reflectance spectrophotometer. Shore A hardness was evaluated using a durometer and surface roughness, with a digital roughness tester followed by scanning electron microscopy analysis. Statistical Analysis Used: Analysis of variance and Tukey’s multiple comparison test were used for statistical analysis. Results: Accelerated aging caused a significant decrease in color, increase in Shore A hardness, and variation in surface roughness in both silicone elastomer groups. Chemical disinfection presented significant changes in color and surface roughness whereas no significant effect on Shore hardness, irrespective of the disinfectant used. Conclusions: The maxillofacial silicone elastomers presented deterioration in color, hardening, and significant variations in surface roughness when subjected to chemical disinfection and accelerated aging, which provides a valid baseline for future research.

Keywords: Accelerated aging, chemical disinfection, color stability, maxillofacial silicone elastomer, shore a hardness, surface roughness

Introduction

Maxillofacial prosthetics has revolutionized the field of prosthodontics rendering solutions to restore facial mutilations associated with congenital malformations, acquired surgical defects, and trauma. The final esthetic result of the facial prosthesis depends on the knowledge concerning principles of facial harmony, color mixture, adaptation, retention, durability, prosthesis weight, and biocompatibility. Among the various contributing factors, properties of the prosthetic material play a crucial role in the final result of the prosthetic treatment. The main challenge encountered in the performance of an ideal facial prosthesis is the degradation in appearance, either due to changes in color or deterioration of physical properties.

The history of prosthetic materials dates back to around 1900s when vulcanite rubber was used for the fabrication of nasal and auricular prosthesis. A review on evolution of prosthetic materials by Lewis and Castleberry in 1980 accounts the use of polyvinyl chlorides, polymethyl methacrylate, polyurethanes, polyethylene, and silicones in the fabrication of facial prosthesis.[1] Barnhart is credited with introducing elastomeric silicone for facial prosthesis in 1960.[2] Since then, silicone elastomers chemically termed as polydimethyl siloxane have been the material of choice. These are of two types: room temperature vulcanizing (RTV) silicone and heat temperature vulcanizing silicone.[3] Medical grade silicone has been widely reported as better serviceable material for maxillofacial applications. According to Feldman, several primary factors of weathering including...
ultraviolet (UV) rays, temperature, moisture, and secondary factors such as deposition of microscopic residues in the porosities of the material’s surface and use of disinfecting agents, contributed to the color instability. Many authors in their reviews also affirmed the effect of pigments, UV light absorbers, and opacifiers on the maxillofacial materials.\[^{[4-7]}\] Physical properties such as hardness, surface roughness, and tensile strength were also evaluated extensively.\[^{[8,9]}\] Polyzois et al. suggested that the wear time of facial silicones exposed to environment averages from 3 months to 1 year of use. Sweeney et al. in 1972 recommended the use of an accelerated aging chamber in the evaluation of the color stability and other physical properties of maxillofacial materials where specimens can be exposed to conditions similar to outdoor atmosphere, radiation, temperature, and humidity.\[^{[10]}\] Disinfecting solutions comprising alkaline peroxides, chlorhexidine solutions, and neutral soap are frequently used to clean the prosthesis and prevent accumulation of bacteria on the prosthesis. Research studies are still scarce regarding the effect of these disinfecting solutions on the properties of maxillofacial silicone elastomer.

In the view of these findings, the objective of this study was to evaluate the change in three physical properties—color stability, Shore A hardness, and surface roughness of two maxillofacial silicones, A-2186 and Cosmesil M511, when submitted to chemical disinfection and accelerated aging.

**Subjects and Methods**

Two commercially available silicone elastomers A-2186 silicon elastomer, Factor II Inc., 5642 White mountain Avenue, lakeside, AZ, USA and Cosmesil M511 silicon elastomer, Factor II Inc., 5642 White mountain Avenue, lakeside AZ 85929 USA were evaluated in this study [Figure 1]. Functional intrinsic red (FI-204) was used for intrinsic pigmentation of the silicone elastomers.

**Preparation of the test specimen**

Thirty specimens each of A-2186 maxillofacial silicone elastomer (Group A) and Cosmesil M511 (Group C) were prepared in the shape of a disc (30 mm × 3 mm) using round metallic flask. The silicones were handled according to the manufacturer’s instructions. A volume of 11 g of the material was prepared in a ratio of 10 g (Part A) of silicone elastomer to 1 g catalyst (Part B) into a homogenous mix after weighing with a precision digital scale. Red pigment (FI-204) of 0.2% by weight was mixed with the silicone. The silicones were then inserted into the cavities in the master mold and heat polymerized in a dry heat oven at 100°C for 1 h. After preparation of all the specimens, they were numbered and stored in a dark black box.

The control specimens of Groups A and C were then submitted for initial analysis of color, Shore A hardness, and surface roughness. Color stability was determined from spectral reflectance measurements in the visible range of wavelength 200–800 nm with a double-beam, UV-visible spectrophotometer (UV-Vis-NIR Varian Cary 5000 spectrophotometer).\[^{[8,11]}\] Shore A hardness is an indicative measure of a material’s texture and flexibility. The test was performed on all samples using a digital durometer according to ASTM D 2240 procedures. The potency of the measurement was established between 0 and 100 Shore A, with 1% of tolerance.\[^{[12]}\] Surface roughness average (Ra) is rated as the arithmetic average deviation of the surface valleys and peaks expressed in micro inches or micrometers. A portable digital roughness tester was used with 0.01 μm accuracy and 6 mm measurement course.\[^{[13]}\] Scanning electron microscopy (SEM) analysis of samples was done at ×250 and ×500 magnifications.\[^{[14]}\] The specimens were then divided into subgroups according to the study design [Figure 2].

The disinfectants evaluated in this study were Fittydent tablet (sodium perborate monohydrate - 480 mg), 4% chlorhexidine gluconate (Microshield 4), and neutral soap (Johnson and Johnsons Ltd). Thirty specimens of each silicone group were subdivided into three groups, with each group treated with either of the disinfectants. The process of chemical disinfection was accomplished three times a week for 60 days.\[^{[15-18]}\] For disinfection with Fittydent, specimens were immersed in a container containing the effervescent tablet dissolved for 15 min and then rinsed in running water.\[^{[13-17]}\] Specimens washed with neutral soap.
were thoroughly scrubbed with it by hand friction for 30 s and rinsed in running water. Specimens disinfected with 4% chlorhexidine gluconate were immersed in the solution for 10 min and then rinsed in running water. After simulated disinfection period, a new chromatic analysis was done to record the parameters.

After the second chromatic analysis, five specimens of each subgroup were subjected to accelerated aging while the rest were placed in the dark box. For artificial aging, specimens were positioned in the accelerated aging chamber (ASTM–Norma 53) and subjected to alternated periods of UV light and darkness with condensation of distilled water saturated in oxygen. Each aging cycle was accomplished in 12 h. In the first 8 h, UV light irradiance was set to a temperature of 60°C ± 3°C. In the following 4 h, a dark condensation period was carried out at a temperature of 45°C ± 3°C [Figure 3].[21] A total of 1008 artificial aging hours were accomplished simulating deterioration caused by rain, dew, and UV light followed by third chromatic analysis.

Statistical analysis of the data was done by one-way analysis of variance for comparing the color reflectance, Shore A hardness, and surface roughness (Ra) between the silicone groups before and after chemical disinfection and accelerated aging. Mean ± standard deviation values were analyzed. Post hoc comparisons between different disinfected groups were made using Tukey's multiple comparison test. The P values for all the comparisons were calculated using Student's t-test. The level of significance was set at P < 0.05. The data were statistically analyzed using GraphPad prism (version 5.03), GraphPad Software Inc., California corporation, USA.

Results

There was a significant difference in color between the specimens of control Groups A and C, with Group C presenting more color reflectance (P < 0.05). After disinfection of the samples in Group A, samples treated with neutral soap showed a significant difference in color when compared to the control group A (P < 0.01). However, there was no significant change in color among the samples in Group C (P > 0.05). There was no significant difference in color between the two silicone groups when color stability was assessed after disinfection and accelerated aging (P > 0.05). However, there was a significant change in color after accelerated aging when each individual group was compared with the respective control group [Tables 1, 2 and Figure 4].

When the Shore A hardness of two silicone groups was compared, there was a highly significant change among the

| Table 1: Comparison of color stability (R%), Shore A hardness (units), and surface roughness (Ra) of two silicone groups (A-2186 and C-M511) after chemical disinfection and accelerated aging using one-way analysis of variance |
|--------------------------------------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|
| Type of disinfectant with aging                  | Mean±SD          | P                |                  |                  |                  |                  |                  |
|                                                  | Group A           | Group C          |                  |                  |                  |                  |
| Color values (R%)                                |                  |                  |                  |                  |                  |                  |
| Fittydent (F)                                    | 35.6±3.48        | 35.21±6.75       | 0.908            |                  |                  |                  |
| Chlorhexidine (Ch)                               | 34.08±8.19       | 40.04±4.47       | 0.191            |                  |                  |                  |
| Neutral soap (N)                                 | 35.85±1.86       | 35.87±7.19       | 0.996            |                  |                  |                  |
| Control                                          | 43.60±5.19       | 47.12±4.46       | 0.0478*          |                  |                  |                  |
| Shore A hardness (units)                         |                  |                  |                  |                  |                  |                  |                  |
| Fittydent (F)                                    | 35.4±7.92        | 17.2±4.91        | 0.0024**         |                  |                  |                  |
| Chlorhexidine (Ch)                               | 32.6±8.61        | 27.6±9.04        | 0.397            |                  |                  |                  |
| Neutral soap (N)                                 | 28±6             | 32.8±5.21        | 0.213            |                  |                  |                  |
| Control                                          | 30.44±5.45       | 6.77±5.01        | <0.0001***       |                  |                  |                  |
| Surface roughness (Ra)                           |                  |                  |                  |                  |                  |                  |                  |
| Fittydent (F)                                    | 0.68±0.41        | 0.76±0.17        | 0.70             |                  |                  |                  |
| Chlorhexidine (Ch)                               | 0.86±0.13        | 0.72±0.11        | 0.12             |                  |                  |                  |
| Neutral soap (N)                                 | 0.78±0.13        | 0.69±0.15        | 0.36             |                  |                  |                  |
| Control                                          | 0.85±0.42        | 0.82±0.34        | 0.97             |                  |                  |                  |

*P<0.05, **P<0.01, ***P<0.001
two control specimens of Groups A and C, with Group C showing a decreased Shore A hardness (P < 0.0001). After disinfection, when compared with their respective control group, only Group A samples disinfected with neutral soap presented a significant change in hardness (P < 0.05). There was no significant change in hardness among Group A samples before and after accelerated aging and within the disinfectant groups (P > 0.05), whereas there was variation in Group C samples with a highly significant variation in hardness before and after accelerated aging in samples treated with neutral soap (P < 0.001) and least variation with Fittydent (P < 0.0001) [Tables 1, 3 and Figure 5].

The results of the surface roughness test [Tables 1, 4 and Figure 6] and SEM analysis showed a significant decrease in roughness after the disinfection period and then an increase in roughness after accelerated aging [Figures 7 and 8].

**Discussion**

This study investigated the change in properties of two commercially available silicone elastomers, A-2186 and Cosmesil M511, following disinfection and accelerated aging. These materials were selected in our study because of their texture, strength, durability and ease in handling, coloring, and patient comfort. Kiat-amnuay et al. and Beatty et al. in their studies evaluated the color stability of pigmented maxillofacial silicone and stated that red pigments had the most adverse effect on color stability compared with the effect of cosmetic yellow, burnt sienna, and no cosmetic pigment.[11,22] Therefore, red pigment was preferred for this study.

In the present study, the two groups of silicone elastomers were subjected to 60 days of chemical disinfection as they were reported to result in property alterations of the maxillofacial prosthesis. The choice of chemical disinfectants should be based on its antimicrobial properties, compatibility to preserve the physical properties of surface of the material. The disinfectant Fittydent selected in the study work through an oxygen-liberating mechanism that purportedly loosens debris and removes light stain.[23] The 4% chlorhexidine solution is biocompatible, and the immersion disinfection technique treatment acts through saturation. The disinfection of specimens with neutral soap is done through digital friction.

**Table 2: Post hoc analysis of color values (R%) using Tukey’s multiple comparison test**

| Disinfected specimen groups undergoing accelerated aging | Control group | P     |
|---------------------------------------------------------|---------------|-------|
| Group A with disinfectant                                |               |       |
| AFAg=Samples of A-2186 disinfected with Fittydent undergoing accelerated aging | Control       | 0.018* |
| AChAg=Samples of A-2186 disinfected with 4% gluconate chlorhexidine undergoing accelerated aging | Control       | 0.026* |
| ANAg=Samples of A-2186 disinfected with neutral pH soap undergoing accelerated aging | Control       | 0.016* |
| Group C with disinfectant                                |               |       |
| CFAg=Samples of Cosmesil M511 disinfected with Fittydent undergoing accelerated aging | Control       | 0.0009*** |
| CChAg=Samples Cosmesil M511 were disinfected with 4% gluconate chlorhexidine undergoing accelerated aging | Control       | 0.008** |
| CNAg=Samples Cosmesil M511 disinfected with neutral pH soap undergoing accelerated aging | Control       | 0.001** |

*P<0.05, **P<0.01, ***P<0.001. AFAg=Samples of A-2186 disinfected with Fittydent undergoing accelerated aging, AChAg=Samples of A-2186 disinfected with 4% gluconate chlorhexidine undergoing accelerated aging, ANAg=Samples of A-2186 disinfected with neutral pH soap undergoing accelerated aging, CFAg=Samples of Cosmesil M511 disinfected with Fittydent undergoing accelerated aging, CChAg=Samples Cosmesil M511 were disinfected with 4% gluconate chlorhexidine undergoing accelerated aging, CNAg=Samples Cosmesil M511 disinfected with neutral pH soap undergoing accelerated aging.
The weathering of polymers can produce changes in physical and chemical characteristics through a photo oxidative degradation mechanism that causes a significant loss in important mechanical properties. The factors of weathering (temperature, irradiation, rain, and moisture) were artificially induced in Promt Engineering works, Edapally, Kochi, Kerala and samples were exposed for 1008 h, which was equivalent to 1 year of patient use in natural environment.

Color stability is one of the most important parameters when evaluating the performance of a facial prosthesis from a patient’s perspective. The initial chromatic analysis in this study presented a slightly high color reflectance for Cosmesil M 511 when compared to A-2186. It is likely that the continuous release of subproducts during the continuous polymerization of silicones causes alteration in dimension and chromatic pattern of the silicone. After disinfection, there was a significant difference in color in A-2186 samples treated with neutral soap.

Accelerated aging presented a significant decrease in color in both silicone samples. A study by Langwell employing a spectrophotometer concluded that alkaline peroxides such as Efferdent or Fittydent through an oxygen-liberating mechanism also cause bleaching of the prosthesis. Others have claimed that neutral soap can also remove nanoparticles (pigments) from superficial layer of silicone since this technique is based on mechanical methods such as finger friction and brushing. This fact can justify the highest color change presented in specimens of group

**Table 3: Post hoc analysis of Shore A hardness (units) using Tukey’s multiple comparison test**

| Disinfected specimen groups undergoing accelerated aging | Control group | P     |
|----------------------------------------------------------|---------------|-------|
| Group A with disinfectant                                |               |       |
| AFAg = Samples of A-2186 disinfected with Fittydent undergoing accelerated aging | Control       | 0.17  |
| AChAg = Samples of A-2186 disinfected with 4% gluconate chlorhexidine undergoing accelerated aging | Control       | 0.5   |
| ANAg = Samples of A-2186 disinfected with neutral pH soap undergoing accelerated aging | Control       | 0.39  |
| Group C with disinfectant                                |               |       |
| CFAg = Samples of Cosmesil M511 disinfected with Fittydent undergoing accelerated aging | Control       | 0.72  |
| CChAg = Samples Cosmesil M511 were disinfected with 4% gluconate chlorhexidine undergoing accelerated aging | Control       | 0.0073** |
| CNAg = Samples Cosmesil M511 disinfected with neutral pH soap undergoing accelerated aging | Control       | <0.0001*** |

**P<0.01, ***P<0.001.**

**Table 4: Post hoc analysis of surface roughness (Ra) using Tukey’s multiple comparison test**

| Disinfected specimen groups undergoing accelerated aging | Control group | P     |
|----------------------------------------------------------|---------------|-------|
| Group A with disinfectant                                |               |       |
| AFAg = Samples of A-2186 disinfected with Fittydent undergoing accelerated aging | Control       | 0.40  |
| AChAg = Samples of A-2186 disinfected with 4% gluconate chlorhexidine undergoing accelerated aging | Control       | 0.92  |
| ANAg = Samples of A-2186 disinfected with neutral pH soap undergoing accelerated aging | Control       | 0.60  |
| Group C with disinfectant                                |               |       |
| CFAg = Samples of Cosmesil M511 disinfected with Fittydent undergoing accelerated aging | Control       | 0.53  |
| CChAg = Samples Cosmesil M511 were disinfected with 4% gluconate chlorhexidine undergoing accelerated aging | Control       | 0.37  |
| CNAg = Samples Cosmesil M511 disinfected with neutral pH soap undergoing accelerated aging | Control       | 0.30  |

**P<0.01, ***P<0.001.**

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disinfected with neutral soap. The results of our study demonstrated that silicone can display color alteration after aging due to intrinsic and extrinsic factors. The intrinsic factors involve proper material discoloration with matrix alteration, which is a frequent occurrence after aging because of some physical-chemical conditions such as thermal and humidity variations. Extrinsic factors such as absorption and adsorption of substances may also generate discoloration. In addition, silicone facial prosthetics are often associated with color changes owing to their porous and irregular surface, which allows collection of microscopic debris in the pores.26,27

According to Lewis and Castleberry, the hardness of commercially available silicone material ranges from 16 to 45 Shore A, whereas Goiato et al. and Polyzois et al. presented the acceptable ranges as between 25 and 35 units.1,17,28 In this study, Cosmesil M511 showed significantly less Shore A hardness values (16 units) when compared to A-2186 (30 units), regardless of disinfection and accelerated aging. The difference in hardness readings between the two silicone groups may be due to differences in crosslinking systems, crosslinking density, molecular weight of the polymer, and differences in the grade and concentration of silica filler. Bell et al., Wolfardt et al., and Sanchez et al. concluded that greater softness of maxillofacial silicone is desirable for facial prostheses as they are more similar to the human skin.29‑31 After the disinfection period, there was a general decrease in hardness values which can be attributed to absorption of the disinfection solution. According to the literature, long-term storage of silicone materials can promote water absorption leading to reduced hardness. The analysis after accelerated aging showed a significant increase in Shore hardness after accelerated aging. This may be attributed to the continuous polymerization of the materials and evaporation of acetic acid and formaldehyde, which occurs during the aging process.32 Among the disinfectant groups, neutral soap showed the most significant increase in hardness after the aging process. Yu et al. and Goiato et al. have reported similar findings in their studies on physical properties of maxillofacial silicone and suggested that accelerated aging did cause a significant increase in Shore A hardness.17,33

Surface roughness was tested in this study as roughness is often a good predictor of the performance of a mechanical component; irregularities in the surface may form nucleation sites for cracks or corrosion. The initial testing showed no significant difference between the two control groups. After 60 days of storage, the roughness values showed a significant decrease in all samples, irrespective of the material and the chemical disinfection. This can be explained by the continuous polymerization process, which promotes a more complete polymeric chain, making the silicone surface smoother with time. A study conducted by Goiato et al. to evaluate the surface roughness of two silicones reported decreased roughness value under the influence of chemical disinfection which substantiated the results of this study.17 The final analysis after accelerated aging for 1008 h presented a generalized increase in surface roughness in both groups, irrespective of the disinfectants. The SEM examination was done to correlate the microstructure finding to the physical properties of the material. It gives a magnified micro-image of a surface of analyzed material which resembles viewing an object by electron microscope.34 The results were similar to those obtained using roughness tester machine. The surface became significantly smooth after disinfection when compared to the control group and surface roughness increased after accelerated aging.

Conclusion

Within the limitations of the study, it can be concluded that comparison of control groups of silicone not subjected to chemical disinfection and accelerated aging showed that Cosmesil M511 has more color reflectance and significantly less hardness when compared to silicone A-2186.

After accelerated aging, there was a highly significant decrease in color stability in both the silicone elastomer groups. Increase in hardness (Shore A) was more significant in Cosmesil M511 whereas variation in surface roughness was more evident in silicone A-2186. Chemical disinfection caused a significant decrease in color stability in both the silicone groups after disinfection but did not have a significant change in hardness. Surface roughness decreased significantly after disinfection, irrespective of the disinfectants used.

Silicone elastomers are thus materials that have ideal optical and physical properties suitable for making prostheses to replace lost facial structures. Some of their inherent drawbacks such as their loss of color, hardening, and change in surface roughness are topics of the current cutting edge for research in this field.

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Conflicts of interest

There are no conflicts of interest.

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