BASIC SCIENCE RESEARCH

Color Stability of Dry Earth Pigmented Maxillofacial Silicone A-2186 Subjected to Microwave Energy Exposure

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Purpose: **The purpose of this study was to measure spectrophotometrically the color stability of pigmented A-2186 silicone maxillofacial elastomer with 10% by volume of titanium white dry earth opacifier before and after exposure to microwave energy over a simulated 1.5-year period of microwave sterilization.**

Materials and Methods: **A-2186 silicone elastomer opacified with titanium white dry earth pigment, pigmented with 5 cosmetic dry earth pigment colors [no pigment (control) group (Pc), red (Pr), yellow ochre (Py), burnt sienna (Po), and a mixture of Pr + Py + Po color group (P3)], was used in this study. Each of the 5 experimental groups consisted of 5 specimens. All specimens were placed in a 250 ml glass beaker filled with 150 ml of water (replenished for each microwave exposure). An exposure of 6 minutes was used 18 times (simulating 1.5 years of microwave sterilization with one 6 minute exposure monthly). Reflectance values were measured by spectrophotometer. Three- and two-way analyses of variance with repeated measures were performed for the color difference (ΔE^*) with the factors of group/color/months, and group/months, respectively. Means were compared by Tukey Honest Significant Difference (HSD) multiple range test calculated at the 0.05 level of significance using SPSS.**

Results: **The trained human eye can detect color changes (ΔE^*) greater than 1.0. Most ΔE^* values of the red pigment group at all intervals and the mixed pigment group at 15- and 18- month intervals increased significantly greater than 1.0 ($p < 0.001$) compared with the control group. Yellow and burnt sienna groups remained the most color stable over time with ΔE^* values below 0.35.**

Conclusions: **Lack of color stability of red dry earth pigmented A-2186 silicone maxillofacial elastomers was clinically significant after 12-month exposure to microwave energy as compared with yellow, burnt sienna, and opacified A-2186 dry earth pigments**

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INDEX WORDS: maxillofacial prostheses, maxillofacial elastomer, polymer, spectrophotometric analysis, color differences (ΔE^*), microwave, color stability

ELASTOMERS HAVE been used for over 50 years to fabricate facial prostheses for individuals missing facial anatomy due to resection, trauma, or congenital anomalies. To approximate human skin color, the prostheses are colored with various pigments often suspended in various solutions. Color stability of the prosthesis is an important factor in patient acceptance. Evaluation of color stability using combinations of pigments, opacifiers, and elastomeric materials allows an understanding of the effects and interactions of each component and aids in identification of the

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combination of these ingredients that could be used to produce the most color stable prosthesis.

Commercial grade silicone A-2186 was developed for facial prosthetics in the early 1990s and was claimed as an alternative to the medical grade silicone MDX4-4210, offering lower cost and improved physical and mechanical properties.[1] Although Haug et al[2] reported that compared with MDX4-4210, silicone A-2186 did not retain its superior physical and mechanical properties after being subjected to environmental variables, many clinicians continue to use silicone A-2186 in the clinical setting. Beatty et al[3] in 1995 studied the color changes produced in unpigmented and pigmented silicone A-2186 and in 1999[4] studied color changes produced in oil-pigmented maxillofacial elastomer after exposure to ultraviolet light. Haug et al[5] evaluated the effects of weathering on the color stability of 3 elastomers (including silicone A-2186) with Georgia kaolin, and 6 dry earth pigments. Recent research published by Kiat-amnuay et al[6] studied effects of 5%, 10%, and 15% of 4 dry earth opacifiers on color stability of pigmented silicone A-2186 subjected to artificial aging.

Microwave sterilization has been used extensively for urinary catheters,[7-9] contact lenses,[10] infant bottles, nitrous oxide nasal hoods,[11] plastic tissue culture vessels,[12] laboratory equipment,[13,14] culture media,[15] reusable tissue culture vessels,[16] and bacterial strains.[17-20] Recently, this sterilization method has been used in dentistry for cleaning dental instruments,[21-23] acrylic resin dentures,[24-26] and maxillofacial silicone prostheses.[27]

The primary materials for facial prostheses are silicone elastomers. Facial prostheses exposed to the oro/nasal secretions can harbor microorganisms within the porous silicone (Fig 1), leading to discoloration and offensive odors. Other medical devices made of silicone are either discarded after onetime use, or are sterilized by various methods. Microwave energy has been used to sterilize medical devices made of plastic, silicone, and rubber. Even acrylic resin dental prostheses have been disinfected and sterilized with microwave energy. Because washing the prostheses does not remove the organisms deep within the pores of maxillofacial prostheses, preliminary research in the use of microwave energy as an alternative method of prosthesis sterilization has begun. Since color stability, or lack thereof, could alter the durability of a facial prosthesis, determination of the effects of microwave radiation on color stability is critical.

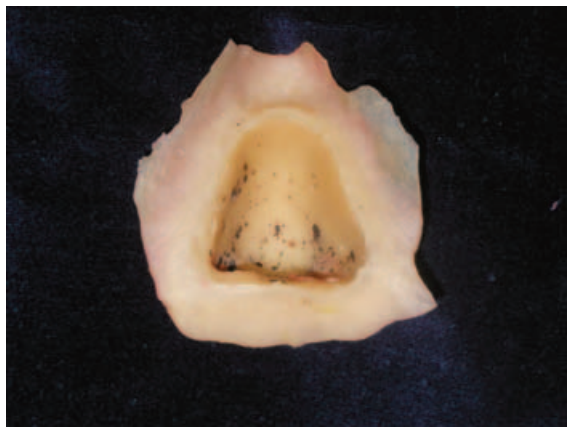

Figure 1. Tissue surface of silicone nasal prosthesis with black stain of microbial growth.

It has long been recognized that exposure to cleaning methods and solvents, sunlight, and oils of human skin has altered the color stability of silicone facial prostheses. Since 1969, reflectance spectrophotometry[3,4,28-36] and color and optical density[2,5,37,38] have been used to evaluate the color stability of maxillofacial prosthetic materials subjected to natural weathering, artificial aging, passage of time, ultraviolet light exposure, etc; however, no studies have evaluated microwave energy and its effect on the color stability of facial elastomers.

The purpose of the present investigation was to measure spectrophotometrically the color stability of pigmented A-2186 silicone maxillofacial elastomer after exposure to microwave energy over a simulated 1.5-year period of microwave sterilization.

Materials and Methods

Specimen Preparation

Five experimental groups of A-2186 silicone elastomers (Factor II, Inc., Lakeside, AZ, Batch no. 2208806), opacified 10% by volume with titanium white dry earth pigment (Factor II, Inc., Batch no. 85929), were pigmented with cosmetic dry earth pigment colors [no pigment (control) group (Pc), red (Pr), yellow ochre (Py), burnt sienna (Po), and a mixture of Pr + Py + Po color group (P3) (all from Factor II, Inc., no batch no. indicated)]. Each experimental group consisted of 5 specimens. The specimens (22 mm in diameter × 2 mm thick) were processed into 3-sided gypsum molds using A-2186 room temperature vulcanizing silicone.

A 9:1 volume ratio of base to catalyst was used to prepare the specimens. Preliminary mixing trials determined that 10 cc of silicone A was needed for each pigment group. First, 9 cc of base plus 0.03 g of each pigment and 10% (1.0 cc) of opacifier was mixed to ensure consistency among the specimens. Then, 1 cc of catalyst was added to the first mix. The 5 pigment groups consisted of (1) no pigment (control), (2) 0.03 g of red, (3) 0.03 g of yellow ochre, (4) 0.03 g of burnt sienna, and (5) 0.03 g of a mixture of 0.01 g each of red, yellow ochre, and burnt sienna. Each pigment was measured using a Denver Instrument AA-160 balancing machine (Denver Instrument Co., Denver, CO) that was calibrated each day. Each combination of silicone A-2186 base, catalyst, opacifier, and pigment was mixed by hand with a spatula on a glass slab until the color was evenly distributed.

Gypsum mold flasks were made using the methods previously described by Kiat-amnuay et al.[6] Mixtures were loaded into a plastic syringe (Sherwood Medical Company, St. Louis, MO) and injected into each gypsum mold flask. All flasks were placed in a vacuum chamber (Factor II, Inc.), set at at least 30 psi, for 30 minutes. All 5 flasks were then placed and tightened in a regular denture flask press. The material was allowed to set at room temperature for 24 hours. The press was then placed in a circulating hot air oven (Stabil-therm, Blue M Electric Company, Blue Island, IL), set at 80°C, for 30 minutes. The specimens were removed and placed in the same oven for another 30 minutes to ensure complete vulcanization. All specimens were then trimmed and marked with small notches to classify the number and group.

Microwave Exposure

The microwave used in this study was an unmodified domestic oven with a rotating table (model no. 565.8902090, serial no. 1P6Y38022, power consumption 120 V, 60 Hz, 1300 W, output 720 W, frequency 2450 MHz; Sears, Roebuck and Co., Chicago, IL). The microwave oven power and timer calibration was carried out by a method described by Thomas et al[24] and Webb et al.[26] Preliminary experiments were performed with only 1 per specimen to establish the efficacy of the procedure and to determine that color changes did occur within the simulated 18 month (1 sterilization session per month in an 18-exposure period). Acceptable results were obtained from the pilot study. Specimens in each group were placed in a 250 ml glass beaker (Kimax USA no. 26500 and Pyrex USA no. 4980) filled with 150 ml of tap water (replenished for each run).[22,24,25] An exposure of 6 minutes was used[27] for 18 times (simulating 1.5 years of service at 6 minutes monthly). After each run, specimens were removed from the water, dried, and cooled for at least 10 minutes prior to spectrophotometer reading.

Spectrophotometry readings (MacBeth Color Eye 7000, Newburgh, NY) and reflectance measurements (CIELAB $L^*a^*b^*$ color computed version 1.2 KA, Macbeth Optiview, Newburgh, NY) were recorded. The position of the specimens was the same for each data collecting interval. The values of L^*, a^*, and b^* were entered on a spreadsheet program (Microsoft Excel, Redmond, WA) for calculation of color change (ΔE^*) using the standard formula:[39]

$\Delta E^* = [(\Delta L^*)^2 + (\Delta a^*)^2 + (\Delta b^*)^2]$.
ΔE^* = color difference.
ΔL^* = changes in L^* between the interval of interest and baseline.
Δa^* = changes in a^* between the interval of interest and baseline.
Δb^* = changes in b^* between the interval of interest and baseline.

One person (SK) fabricated and measured the specimens. Spectrophotometer values were recorded for each specimen. The investigator was not blind to the microwave exposure times, but the independent spectrophotometer values were not indicative of color stability until ΔE was calculated. Calculations and statistical analysis were performed by a statistician.

Means and standard deviations of L^*, a^*, b^*, and ΔE^* were calculated. A 3-way analysis of variance (3-factor ANOVA) with repeated measures was performed for the color difference (ΔE^*) with the factors of group, color, and months by SPSS program (Version 11.5, SPSS, Inc, Chicago, IL). Means were compared by Tukey Honest Significant Difference (HSD) multiple range test calculated with significance at the 0.05 level of significance. Differences between means greater than the HSD were considered statistically significant. Then, a 2-way analysis of variance (2-factor ANOVA) with repeated measures was used to confirm the lack of significant interaction between group and months.

Results

The means and standard deviations in bold in Table 1 show ΔE^* greater than 1.0. All ΔE^* values of the red pigment group at all intervals (ΔE^* range = 0.74 to 3.14) and the mixed pigment group at 15 ($\Delta E^* = 1.19$) and 18 month ($\Delta E^* = 1.32$) intervals increased significantly greater than 1.0 ($p < 0.001$) compared with the no pigment (control) group (Fig 2). The yellow and burnt sienna groups remained the most color stable over time with ΔE^* values below 0.35. The 2-factor analysis of variance for this trial shows there is a significant color difference ($p < 0.001$), time difference ($p < 0.001$), and interaction between

Table 1. Mean Values and Standard Deviations of ΔE^* of A-2186 with Dry Earth Pigments over Time (18 months). $N = 5$

10% Opacifier/ ΔE^*	ΔE^* *3 Months*	ΔE^* *6 Months*	ΔE^* *9 Months*	ΔE^* *12 Months*	ΔE^* *15 Months*	ΔE^* *18 Months*
Control (no pigment)	0.05 ± 0.03	0.12 ± 0.04	0.15 ± 0.07	0.17 ± 0.07	0.30 ± 0.10	0.35 ± 0.08
Red (Pr)	**1.05 ± 0.32**	0.74 ± 0.41	**1.16 ± 0.23**	**1.88 ± 0.54**	**2.72 ± 0.57**	**3.14 ± 0.43**
Yellow (Py)	0.07 ± 0.02	0.09 ± 0.03	0.17 ± 0.04	0.19 ± 0.04	0.21 ± 0.06	0.23 ± 0.07
Burnt sienna (Po)	0.03 ± 0.03	0.05 ± 0.02	0.12 ± 0.03	0.21 ± 0.02	0.15 ± 0.02	0.16 ± 0.03
Mixed (P3 = Pr + Py + Po)	0.32 ± 0.15	0.22 ± 0.10	0.51 ± 0.19	0.86 ± 0.16	**1.19 ± 0.14**	**1.32 ± 0.13**

†Values of ΔE^* greater than 1.0 are shown in boldface type.

time and color ($p = 0.005$). As the interaction is quantitative, the HSD will represent the overall changes in color and time that may not have accurate p-values for certain combinations of color and months. As expected, the ΔE^* increases over time. Overall, red has significantly higher ($p = 0.001$) ΔE^* values than the mixed pigment group, which is significantly higher than the other 3 pigments ($p < 0.001$), which are not significantly different ($p = 0.501$). To verify the pigment differences at each time point, months 3 and 6 still show significant difference in color ($p < 0.001$), but only red is significantly above the other 4 ($p < 0.001$), which are not different ($p = 0.063$ at month 3, and $p = 0.621$ at month 6). Beyond month 6, the overall pattern was observed at each month.

Discussion

Due to the nature of silicone A-2186, the setting of the material is easily disturbed by organic material, such as oil, petrolatum, or clay.[6] Therefore, only cosmetic dry earth pigments were used in this study. Our team found in previous silicone A-2186 color stability investigations[6] that use of opacifiers 10% artskin and 10% titanium white dry earth pigment represented the best color stability of all test groups, but were not different from each other. We chose to use 10% titanium white dry earth pigment in this investigation.

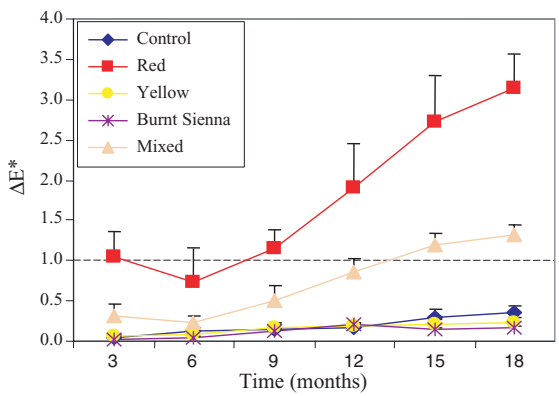

Figure 2. Mean values of ΔE^* of A-2186 with dry earth pigments over time (18 months).

The trained human eye can detect color changes (ΔE^*) greater than 1.0,[12,13,18] but an untrained eye usually cannot distinguish ΔE^* values below 2.0. This method demonstrates that red pigment underwent color changes after exposure to microwave energy by increased ΔE^* values up to 3.14 after 18 exposures, and that yellow ochre and burnt sienna were the most color stable pigments over multiple exposures. Beatty et al[3] studied color changes of silicone A-2186 exposed to ultraviolet light. Consistent with our results, red pigment underwent significant color changes and cosmetic yellow ochre remained color stable. Haug et al[5] evaluated the effect of different kaolin opacifiers (Georgia kaolin) and different dry earth pigments (dark buff, medium brown, red brown, blue) separately on the color stability of silicone A-2186 after exposure to simulated weathering. Therefore, the results of the study cannot be compared.

In a previous study, the authors[6] investigated the effects of dry earth opacifiers on color stability of pigmented silicone A-2186 subjected to artificial aging and determined that mixing cosmetic pigments with different ratios (5%, 10%, and 15%) of 4 different types of dry earth opacifiers did not protect silicone A-2186 from color degradation over time, especially in the case of red pigment. When comparing the color stability of 10% titanium white dry earth pigment in the previous study [artificial aging (AA)] and the present study [microwave energy exposure (MW)], we found that ΔE^* values of the red pigment group in AA (150 to 450 kJ/m^2) ranged from 18.41 to 18.69,

and from 0.74 to 3.14 using MW. The explanation of these differences is likely due to specimens exposed to only microwave radiant energy in this study but exposed to ultraviolet light, water spray, fluctuating temperatures, and humidity in the artificial aging study. In addition, the average exposure time to the artificial aging machine (150 kJ/m^2 cycle) was about 7 days compared with microwave exposure for only 108 minutes (6 minutes for 18 months); however, both investigations showed consistently that red pigment underwent significant color changes, and that cosmetic yellow ochre and burnt sienna remained color stable.

Patients requiring significant amounts of red pigments in their prostheses may experience greater color changes than patients requiring less red colorant in their prostheses. The longevity of the prosthesis for these patients may be shorter, and patients may require more visits to the maxillofacial prosthetics clinic for color touch up, adjustment, or a remake of their prostheses over time.

Tap water, rather than distilled water, was selected in an effort to make the study more clinically relevant as this is thought to be the water used by most patients for cleaning prostheses. All pigments but the red remained stable in tap water; therefore, the tap water in this study does not seem to be a variable affecting color stability. It is possible, however, that water obtained in different locations could contain different chemical and mineral proportions that could affect color stability.

The change in red pigments, as opposed to no change in the other dry earth pigments, is consistent with previous findings using various silicones and various other methods of stressing color stability.[3,6] The authors are currently analyzing data on the effects of dry earth and silicone opacifiers and multiple pigments (cosmetic pigments, artists' oil colors, silicone pigments) on color stability of multiple maxillofacial silicone elastomers (MDX4-4210/Type A, A-2186, A-2000, VST-20A, and VST-50) subjected to microwave energy exposure.

Conclusions

Under conditions of this investigation, testing dry earth pigmented silicone A-2186 maxillofacial elastomer exposed to microwave energy, cosmetic red pigments had the most adverse effect on color stability compared with the effect of cosmetic yellow, burnt sienna, and A-2186 with no cosmetic pigment. Lack of color stability of red dry earth pigmented A-2186 silicone maxillofacial elastomers was clinically significant after 12-month exposure to microwave energy.

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