Color Stability of Facial Silicone Prosthetic Elastomers

after Artificial Weathering

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ABSTRACT

Background: External prostheses exhibit an unwanted color change over time. Color deterioration of prosthetic elastomers affects the life expectancy of facial prostheses in a service environment. The effect of different pigmentation and irradiation duration on color stability of four silicone elastomers after artificial weathering was investigated in this study.

Methods: The materials used included four different pigmented industrially synthesized RTV (room temperature vulcanizing) silicones. The materials chosen in this study were representative silicone prosthetics that are widely used in the last decade in maxillofacial prostheses. Artificial weathering was performed in a weatherometer of total radiant energy 1.35 W/m^2 (UVA – UVB). The samples were exposed in eight different periods (8, 24, 48, 72, 96, 120, 144, 168 hours). L, a, b readings were obtained before and after weathering from a spectrophotometer to define color changes. Color changes were calculated from the following equation: $\Delta E = (\Delta L^2 + \Delta a^2 + \Delta b^2)^{1/2}$. The data were subjected to two-way analysis of variance at a significance level of $\alpha = 0.05$. Also, simple mathematical models were developed for color changes.

Results: The results showed that color changes depend on irradiation time and initial color of samples. Episil Europe 1 and Episil Africa 3 were identified as the most stable materials since their color changes were not eye detectable. Contrary to materials Episil Europe 2, 3 that showed significant color changes.

Conclusion: Artificial weathering caused significant, eye detectable, but yet still clinically acceptable color changes in the examined prosthetic silicone elastomers due to deterioration that occurs through irradiation.

Keywords: Color, degradation, elastomers, prostheses, silicones.

Introduction

Medical materials for facial prostheses have been widely used over the past decades to replace missing or damaged facial parts, which have been lost or changed due to genetic disorder or because of disease or trauma. Although the elastomers used in facial prostheses have the required physical and mechanical properties, they still experience serious problems that can be grouped into two major categories: gradual discoloration of prostheses in a service environment and degradation of physical, static, and dynamic mechanical properties.[1-3]

One of the most desirable performance characteristics of an ideal facial prosthetic is the ability to withstand color change when exposed to sunlight over an extended period.[4,5] Degradation in appearance, due to changes in color or physical properties, is the main reason for replacing a facial prostheses.[6] Clinical studies demonstrated that the

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average life span of maxillofacial prostheses is 1.5 to 2 years,[7,8] mostly because of discoloration and decreased patient satisfaction with external prostheses within the first 3 years of service.[9] Weathering is the adverse response of a material to climate, often causing unwanted discoloration.[10] The three primary factors of weathering are solar radiation, temperature, and water (moisture).[10,11] The amount of each factor as well as different types of solar radiation, different type phases of moisture and temperature cycling all have an effect on materials. Other factors that also act to cause color changes in the prostheses are air pollutants, routine cleaning and patient mishandling.[12,13] Photo degradation that occurs primarily due to UV-radiation appears to cause the most serious and observable changes in these materials, so the research has focused on irradiation effects.[11,14] Over the past decades, several research studies were conducted to evaluate the color stability of maxillofacial prosthetic materials.[1,5,6,15-18] Lemon et al.[17] investigated the efficacy of a UV light absorber on the color stability of a facial elastomer. Spectrophotometric analysis was performed to assess color changes and to determine the effects of artificial weathering and outdoor weathering on color stability. Sweeney et al.[5] evaluated the color stability of maxillofacial prosthetic materials under artificial weathering. Since then, reflectance spectrophotometry[1,17,19-22] and optical density[6,16,23] have been used to evaluate the color stability of maxillofacial elastomers. Other factors that affected the color of facial prosthetics were investigated in the literature.[23-27] Discoloration in those materials incur primarily due to ultraviolet light but the surface and marginal deterioration is more likely due to use of adhesives and the subsequent patient cleaning and handling. Some of these problems such as deterioration of the margins, do not occur in implant-retained prostheses.[28] In addition, silicone facial prosthetics reveal color changes because their surface is porous and irregular, which allows collection of microscopic debris in the pores. It has also been known to harbor bacteria and fungi that have inherent color.[27] Skin secretions, mouth rinse and other solutions are also responsible for the observed color changes.[23,26] Materials for facial prostheses over the years include latex, polymethacrylates, polyvinylchlorides, chlorinated polyethylene, polyurethanes silphenylene and silicone elastomers.[29] Most of these materials were improved and used as facial prosthetics

despite the fact that still exhibit some undesirable characteristics. The materials most often used are the new silicone elastomers, which have achieved wide clinical acceptance. Silicone elastomer became commercially available in the late 1950s, however this material remains the most commonly used to the present day.[30] There are many advantageous characteristics of silicone prosthetics that consecrate silicone as the most suitable material for facial prostheses such as good biocompatibility and biodurability, wide service temperature range, non-adhesive properties, low toxicity, possible optical transparency, low chemical reactivity and excellent resistance to attack by oxygen, ozone and sunlight.[31]

Silicone elastomers are more color stable[1] than other materials used in maxillofacial prostheses thus many authors investigated the color stability of those materials under weathering conditions.[6,8,17,32,33] Although they are widely used, these materials too, are far from ideal. The main aim of this study was to evaluate the color stability of four different pigmented silicone prosthetics after exposure to UV radiation.

Materials and Methods

Episil silicone prosthetic elastomers (Dreve-Dentamid GmbH, Unna, Germany), an addition-type RTV (room temperature vulcanizing) elastomers, were examined in the current study. Their basic structure unit is siloxane. Those silicone facial prosthetics were selected as they are commonly used for maxillofacial prostheses. The material is provided in a disposable twin-cartridge system with a platinum hardener and a mixing ratio of 1:1. It is processed in dental stone molds using a dry heat oven for 1 hour at 100°C. The four different pigmented silicone materials are listed in Table 1. The composition of the four silicone elastomers and their basic structure is the same. The difference between them appears in their color agent as it is shown in figure 1. Ten rectangular specimens (2 X 1.5 X 0.33 cm) from each material were fabricated.

Artificial Weathering – Irradiation

Polymeric materials that are used for external maxillofacial applications are subjected to attack typically by ultraviolet light, oxygen, and water. No single light exposure apparatus can exactly simulate natural exposure but it is a good approximation.

Table 1. Silicone facial prosthetics used.

Material	Type	Manufacturer	Coding
Episil Europe 1	Addition reaction	Dreve-Dentamid GmbH, Unna, Germany	epeu1
Episil Europe 2	Addition reaction	Dreve-Dentamid GmbH, Unna, Germany	epeu2
Episil Europe 3	Addition reaction	Dreve-Dentamid GmbH, Unna, Germany	epeu3
Episil Africa 3	Addition reaction	Dreve-Dentamid GmbH, Unna, Germany	epaf3

*All tested materials contained color pigments, but that the manufactures did not provide details about the pigments used.

Figure 1. The four different pigmented silicone facial materials used.

The specimens from each color were artificially aged in a weatherometer (Rayonet photo reactor, Southern New England Ultraviolet Company, Brandford, CT) and exposed to ultraviolet light (UVA-UVB). The test was run for a total radiant energy of 1.35 W/m^2, and the conditions of humidity and temperature were 20% and 40-45°c, respectively. The total exposure time was 168 hours (eight different measurement moments - 8, 24, 48, 72, 96, 120, 144 and finally, 168 hours). Ultraviolet radiation induced radical formation mechanisms, which involve either permanent chain scission or radical recombination to form structural irregularities in the specimens' chains.

Evaluation of color
Color changes were evaluated with a MiniScan XE spectrophotometer (Hunter Associates Laboratory Inc, Reston, Virginia), with a measuring head aperture of 4 mm in diameter. It is a reflectance measurement spectrophotometer with laboratory instrument performance. Diffuse/8° geometry is available. The spectrophotometer was calibrated according to the manufacturer instructions, using the supplied black and white calibration standard. For each sample, three repeated measurements were taken to determine the colorimetric measurements L, a, b. Values were carried out according to

the CIELAB color system. The CIELAB system uses the three dimensionless colorimetric parameters L, a, b whereby "L" indicates the brightness, "a" describes the red-green content and "b" the yellow-blue content. Figure 2 is defined graphically the CIE LAB system. The samples were able to serve as their controls, as they were not damaged or otherwise affected by the measurements and could be measured before and after test conditions. Color difference (ΔE) was calculated according to equation 1.

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

Where ΔL, Δa and Δb are changes in L, a and b, respectively, between the interval of interest and baseline, and ΔE* is the color difference.[23]
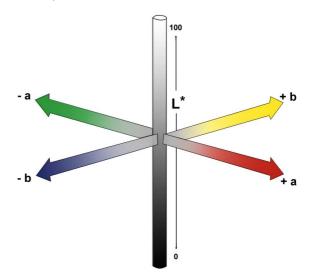

Figure 2. CIELAB color system.

ΔE values indicate the total color changes. As it resulted from equation 1, an increment of ΔE indicates greater color changes. There is a difference

between observable and clinically acceptable values of ΔE concerning to facial prosthetics. The relationship between perceptibility and acceptability was detected because color differences that are only just visually perceptible under experimental conditions are not necessarily clinically unacceptable.[34] In the present study a color change, ΔE, greater than 2 was considered as eye detectable and a ΔE greater than or equal to 3.3 was considered as clinically unacceptable.[33-35] A 2-way analysis of variance (ANOVA) was performed for the color changes (ΔE) with the factors of exposure period (eight different periods - 8, 24, 48, 72, 96, 120, 144 and finally, 168 hours at 1.35 W/m^2) and initial color (four different pigmented silicone elastomers). Then, 2-way ANOVA and the Duncan's multiple range tests were used to detect significant differences between the groups. All analyses were computed with SPSS for Windows software (SPSS 16.0, SPSS Inc, Chicago, Ill.). A significance level of α = 0.05 was selected.

Mathematical Modeling
Several mathematical models were used in order to predict the value of ΔE according to irradiation time. As the irradiation time was increasing, ΔE seemed to increases too. The following equation depicts well this behavior:

$$\Delta E = \Delta E_0 * (t_{ir} / t_0)^{k_{1-4}} \qquad (2)$$

Where ΔE_0, k_{1-4} are constants
  t_{ir} is the irradiation time
  t_0 is the reference time ($t_0 = 85$)

Regression of the mathematical model
The parameters were estimated by fitting the mathematical model to the experimental data using direct nonlinear regression. This procedure presents several advantages over indirect nonlinear regression. Linear regression on the other hand, can give highly erroneous results and should be avoided.[36] The method of direct nonlinear regression estimates the parameters ΔE and k_{1-4} by fitting equation 2 to all experimental data. The parameters are estimated by minimization of the residual sum of squares SST:[37]

$$SST = \sum_{i=1}^{N} \sum_{j=1}^{n_i} (\psi_{ij} - y_i)^2 \qquad (3)$$

where ψ_{ij} is the experimental value of the dependent variable (ΔE) of the jth replicate of the ith

experiment, y_i is the predicted value of the model for the ith experiment, n_i is the number of replicates in the ith experiment, and N is the total number of experiments. The residual sum of squares, SST, consists of the lack of fit sum of squares, SSR, and the pure error sum of squares, SSE:

$$SST = SSR + SSE \qquad (4)$$

where:

$$SSR = \sum_{i=1}^{N} n_i (\psi_i - y_i)^2 \qquad (5)$$

$$SSE = \sum_{i=1}^{N} \sum_{j=1}^{n_i} (\psi_{ij} - \psi_i)^2 \qquad (6)$$

$$\text{and} \quad \psi_i = \sum_{j=1}^{n_i} \psi_{ij} \qquad (7)$$

The standard deviation between experimental and predicted values, S_R and the standard experimental error, S_E, can then be calculated from the following equations:

$$S_R^2 = SSR / (N - p) \qquad (8)$$
$$S_E^2 = SSE / (M - N) \qquad (9)$$

$$M = \sum_{i=1}^{N} n_i \qquad (10)$$

where p is the number of parameters. A model is considered acceptable if the standard deviation, SR, between experimental and predicted values is close to the standard experimental error, S_E.

Results
The ΔE for color change of the four pigmented silicone elastomer after different irradiation times are presented in table 2. The ANOVA for the effects of irradiation time and materials on color change, ΔE, is shown in table 3. The analysis revealed that both irradiation time and type of material are statistically significant (P < 0.001) and had a significant influence on color changes. The irradiation time factor seems to have the strongest effect (F = 161.05). F value is critical to decide which factor may have the greatest effect on ΔE.

Table 2. ΔE (SD) for color changes of the four different pigmented silicone elastomers after irradiation in eight periods.

Irradiation time	Materials			
	epeu1	epeu2	epeu3	epaf3
8	0.29 [a] (0.035)	2.51 [b] (0.019)	2.16 [b] (0.045)	0.63 [a] (0.032)
24	0.69 [a] (0.003)	2.90 [b] (0.029)	2.60 [b] (0.040)	0.94 [a] (0.043)
48	0.96 [a] (0.033)	3.12 [b] (0.091)	2.86 [b] (0.016)	1.13 [a] (0.067)
72	1.19 [a, x] (0.021)	3.20 [b, x] (0.042)	2.91 [b, x] (0.040)	1.40 [a, x] (0.036)
96	1.26 [a, x] (0.064)	3.23 [b, x] (0.081)	2.93 [b, x] (0.018)	1.52 [a, x] (0.052)
120	1.43 [a, x] (0.058)	3.25 [b, y] (0.039)	2.95 [b, y] (0.017)	1.66 [a, y] (0.034)
144	1.46 [a, x] (0.016)	3.22 [b, y] (0.030)	2.95 [b, y] (0.014)	1.82 [a, y] (0.089)
168	1.69 [a] (0.012)	3.21 [b] (0.023)	2.90 [b] (0.090)	1.99 [a] (0.008)

a - b: Means with the same letter in rows for respective material were not significantly different (α = 0.05).
x - y: Means with the same letter in columns for respective irradiation time were not significantly different (α = 0.05).

The interaction between them was investigated using Duncan's multiple range tests that also identified differences between groups and are clearly shown in table 2. As it shows, the initial color affect differently ΔE but some of the irradiation times have similar effect on the color changes. ΔE curves obtained from equation 2 presented in Figure 3 as a function of irradiation time. The curves indicate that the color changes are significant for all the materials and increase while the irradiation time increases too. The materials with the lighter and darkest initial color, Episil Europe 1 and Episil Africa 3, respectively, have the less color changes contrary to the middle colored samples, Episil Europe 2 and 3. The mathematical model was fitted to the experimental data, which were received from equation 1 using the colorimetric measurements L, a, b. The results of parameter estimation of the ma-

thematical model for ΔE (equation 2) that was used are summarized on table 4. The standard deviation S_R, was found to be about 1.5 times greater than the pure error standard deviation S_E, and the mathematical model predicted well the discoloration that occurred due to irradiation. According to the defined criterion above, for perceptible color change, ΔE, the color changes of Episil Europe 1 and Episil Africa 3 samples were not even eye detectable as it is shown in figure 4. Whereas Episil Europe 2, 3 samples presented visible eye color differences but not clinically unexpected changes. Nevertheless, according to CIELAB color system, all the samples had color changes since all values of ΔE were above 1 for all the irradiation periods except Episil Europe 1 and Episil Africa 3 samples that endorse the conclusion that these samples are the most color stable.

Table 3. Two-way ANOVA of color changes ΔE.

Source	Df	Sum of squares	Mean square	F value	P value
Irradiation time	3	6.858	0.98	161.050	0.000
Material	7	46.492	15.497	2.548	0.000
Interaction	21	0.996	0.047	7.796	0.000

Table 4. Parameter estimation for color changes ΔE, and standard deviations.

Type of material	Mathematical model constants		Standard deviations	
	ΔE_0	k_{1-4}	S_R	S_E
epeu1	1.22	0.45	0.48	0.35
epeu2	3.16	0.07	0.50	0.43
epeu3	2.83	0.07	0.51	0.42
epaf3	1.49	0.40	0.46	0.29

Discussion

The color changes of tested silicone materials after UV artificial aging was investigated. The perceptible color changes may compromise the clinical acceptability of maxillofacial restoration.[38] The materials tested showed that irradiation has significantly affected their colors. The different pigments seemed to wield on their behavior to irradiation since the lightest and the darkest samples were more stable than the others.

Poor durability and loss of esthetics are the most serious problems associated with facial prostheses, which have been verified by clinical studies. As it has been reported that among patients who had their prostheses remade within one year, 29% had returned for new prostheses due to color changes.[2] As indicated in a clinical research, the patients are really anxious about their facial prostheses and one of the really important reasons was the appearance of their prostheses.[25] Chen et al.[39] studied the reaction of 138 patients to their facial prostheses. The most frequent response given by the patients for disliking their prostheses was color fading. Visser et al.[7] have reported the treatment outcome of a clinical study performed in consecutively treated patients with implant-retained craniofacial prostheses. And, concluded that irrespective of the craniofacial defect, every 1.5 to 2 years,
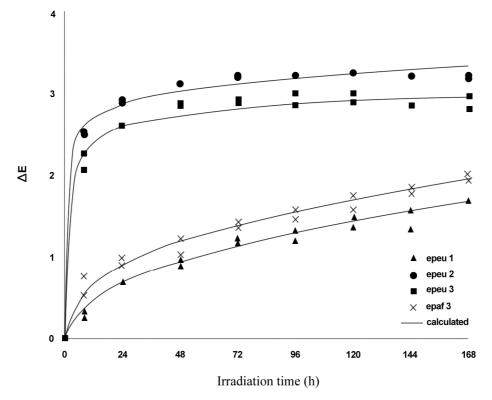

Figure 3. ΔE curves for different times of irradiation of the four silicone elastomers.
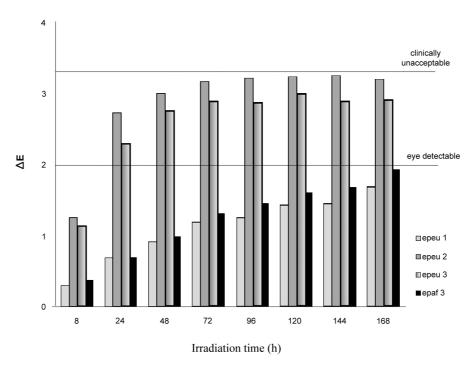
Figure 4. ΔE color changes of the four silicone elastomers during irradiation times.

approximately a new facial prosthesis was made, due to discoloration (31.2%), problems with attachment of the acrylic resin clip carrier to the silicone (25.3%), rupture of the silicone (13.3%), or bad fit (10.9%). McKinstry[9] has found that patients' satisfaction with external prostheses declined within the first 3 years of service. This phenomenon may be attributed to the fact that from a patient's perspective, color change is one of the most important parameters when evaluating the performance of an external prosthesis.[40] Therefore, the ability to withstand color changes over an extended period in services environment is one of the most desirable performance characteristics of facial prosthetic elastomers.[8, 5] Several research studies have evaluated the color differences of maxillofacial materials after accelerating aging. Lemon et al.[17] 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). Schulze et al.[32] concluded that the materials showed significantly perceptible changes after accelerated aging using UV radiation. Many authors[6,10,18,19,33,41] have been investigated the effect of weathering on pigmented silicon elastomers and showed that samples with red pigments discolor at a higher rate than the ones with yellow pigments and the un-pigmented samples.[33] The weathering

of polymers can produce changes in physical and chemical characteristics that cause a significant loss in important mechanical properties that also affect the color of the samples. When a photo oxidative degradation occurs the following steps can be considered:

Initiation step: formation of free radicals.

Propagation step: reaction of free polymer radicals with oxygen, production of polymer oxy and peroxy radicals and secondary polymer radicals, resulting in chain scission.

Termination step: reaction of different free radicals with each other resulting in cross linking.[42] So, the main structural modifications in irradiated polymers are changes in molecular weight distribution - due to main chain scission, cross linking and end linking - and the production of volatile degradation products.[31,43,44] All of these phenomena tend to modify the materials' physical properties such as their color. The deterioration that occurs in polymers due to UV irradiation, as described above, seems also to affect their color. There is a doubt whether the measured color differences (ΔE) represent a perceptible color change. The range of values of ΔE had related in previous reports to perceptible color differences. A value of 1 unit for ΔE is approximately equivalent to a color difference that is just visually perceptible to 50% of observers under controlled conditions.[45,46] Values of ΔE be-

tween 0 and 2 represent imperceptible color differences, whereas values between 2 and 3 represent color differences that are just perceptible.[47] When values of ΔE are greater than or equal to 3.3, the color difference is visually perceptible and clinically unacceptable to 50% of trained observers.[48] Considering all these information, we accepted in the present study a color change, ΔE, greater than 2 as eye detectable and a ΔE grater than or equal to 3.3 as clinically unacceptable.

Conclusions

The nil hypothesis of this study was rejected since the results showed significant differences observed in the color between the control (unirradiated samples) and irradiated samples as a result of the degradation caused by the UV radiation. Artificial weathering caused significant eye detectable color changes in Episil Europe 2 and Episil Europe 3 samples that approached clinically unacceptable changes. Contrary, color changes in Episil Europe 1 and Episil Africa 3 were below detection limits for the naked eye.

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