



Evaluation of Color Change and Hardness of Different Maxillofacial Silicone Elastomers after Natural Daylight Aging

Ceyda Başak İnal¹, Merve Bankoğlu Güngör¹, Meral Bağkur²,
Seçil Karakoca Nemli¹

¹ Gazi University, Faculty of Dentistry, Department of Prosthodontics, Ankara, Turkey

² Cyprus Health and Social Sciences University, Department of Prosthodontics, Güzelyurt, Turkish Republic of Northern Cyprus

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Abstract

Facial prostheses used in aesthetic rehabilitation of facial defects contribute to socialization of patients and increase quality of life. Nowadays, maxillofacial silicone is the most widely used material for facial prosthesis. Maxillofacial silicone can be naturally colored to match with the skin but time-dependent discoloration occurs. Among various factors that cause discoloration, the importance of solar radiation has been revealed. The aim of this study was to evaluate color change and hardness of silicones with different physical properties. Three maxillofacial silicones (M511, Derma-sil 10, and Derma-sil 30) with different physical properties were used in the study. Disc-shaped specimens (n=10) were prepared in 15 mm in diameter and 2 mm in thickness from orange-brown and red colors. Then the specimens exposed to natural daylight. Color coordinates (L*, a*, b*) were determined using spectrophotometer and Shore A hardness values detected using hardness device before and after aging. The color change (ΔE) and hardness of the specimens were calculated and statistically analyzed ($\alpha=0.05$). Color change of red specimens were significantly higher in M511 group and color change of orange-brown specimens were significantly higher in Derma-sil 30 group. Also aging significantly decreased the hardness values of M511 red and orange-brown groups than other groups. The color and hardness of the maxillofacial silicones are affected by daylight. It was observed that the color changes of 3 different maxillofacial silicones were in acceptable limits ($\Delta E < 3$) at the end of aging period.

1. Introduction

Maxillofacial defects are generally resulted from trauma, surgical resection of malignant tumors, and congenital disorders. These defects may affect patient's speech and psychology besides quality of life and social behavior. Rehabilitation of these defects with maxillofacial prostheses can improve quality of life of the patients (Akash, & Guttal 2015; Nobrega, Andreotti, Moreno, Sinhoreti, Dos Santos, & Goiato 2016).

Polymethyl methacrylate, polyvinyl chloride, chlorinated polyethylene, polyurethane, and silicones are the commonly used polymers in maxillofacial prostheses (Bal, Yılmaz, Aydın, Karakoca, & Yılmaz 2009; Eleni, Katsavou, Krokida, Polyzois, & Gettleman 2009). Silicones are the most popular among these materials with adequate mechanical and optical properties along with ease of handling for over 50 years. Currently used maxillofacial silicones have good mechanical properties as high tear strength, tensile strength, and hardness. Also, they have durability, chemical inertness, strong bonding potential with polymethyl methacrylate substructures, and compatibility with medical adhesives (Bal et al., 2009; Hatamleh, Polyzois, Silikas, & Watts 2010). Optical properties of silicones give the maxillofacial prosthodontists to fabricate natural looking and life like maxillofacial prostheses. Uncolored and uncured polymer form of the material is translucent. During fabrication, the prosthodontist arranges the color and the translucency of the material individually for each patient by using intrinsic and extrinsic colorants. Using traditional coloration methods or computerized color matching systems, an experienced maxillofacial

prosthodontist may achieve good color matched silicone prostheses with the patients' skin. (Nemli, Güngör, Bağkur, Bal, & Arıcı 2018). With these properties, maxillofacial silicones perform well initially; however, rapid deterioration of the prostheses have been reported by clinicians (Anderson, & Szalai 2003; Chang, Garrett, Roumanas, & Beumer III 2005). Clinical studies showed that silicone prostheses change color during daily service and the patients could wear them up to 2 years (Cifter, Ozdemir-Karatas, Cinarli, Sancakli, Balik, & Evlioglu 2019; Haddad, Goiato, Dos Santos, Moreno, Pesqueira, & D'almeida 2011; Hatamleh et al., 2010). Studies reported that outdoor conditions such as ultraviolet (UV) radiation, rain, humidity, air pollutants, human body secretions, staining of the prosthesis due to daily habits, and using disinfectants caused color change of maxillofacial silicones (Cifter et al., 2019; Haddad et al., 2011). Among these factors, the UV played an important role in discoloration of maxillofacial prostheses (Beatty, Mahanna, & Jia 1999; Dos Santos et al., 2020; Kiat-Amnuay, Lemon, & Powers 2002).

The materials used in maxillofacial and body prostheses should have the necessary mechanical properties to meet clinical requirements (Eleni, Katsavou, Krokida, & Polyzois 2008; Yeh 2014). Properties and functions of the replaced tissues are the determinants for the prosthetic material selection. For example; soft and flexible materials would be compatible with movements of resilient and removable tissues as earlobes, cheeks, and lips. On the other hand, bone and cartilage supported tissues

as nose, large facial structures, fingers, and toes are required to be replaced with hard and strong prosthetic materials to restore their function. The physical and mechanical properties of prosthetic silicones are determined by the concentration and type of fillers, additives, and pigments used (Eleni et al., 2008; Yeh 2014). Currently, a wide variety of materials differing in mechanical properties are available for face and body prostheses. In the literature, the effects of pigments and additives on the color stability of silicone elastomers have been widely studied. According to these studies, pigment type significantly affects the color stability of the prostheses (Haddad et al., 2011; Kiat-Amnuay et al., 2002; Rashid, Barman, Farook, Jamayet, Yhaya, & Alam 2020). Also, additives namely opacifiers or UV protective agents may affect color stability of maxillofacial silicones. In particular, adding nano-sized titanium oxide (TiO₂) and zinc oxide (ZnO) into silicone elastomers have improved color stability of silicones under different aging conditions (Akash, & Guttal 2015; Bangera, & Guttal 2014; Dos Santos, Goiato, Moreno, Pesqueira, & Haddad 2011).

The aim of this study was to evaluate the color change and hardness of different maxillofacial silicones after natural sunlight aging. The null hypothesis of the study is aging would not generate change in color and hardness of silicone materials.

2. Materials and Methods

2.1. Preparation of Specimens

Three maxillofacial silicones were used in the study: an additional curing heat-temperature-vulcanized silicone elastomer (M511, Technovent Ltd., Newport, UK), additional curing room-temperature-

vulcanized (RTV) Derma-sil 10 (Spectromatch Ltd., Bath, England), and Derma-sil 30 (Table 1). Disc shaped stone molds with dimension of 2 mm in thickness and 15 mm in diameter were prepared using Type III dental stone (Alston, Ata Alçı Sanayi ve Ticaret AŞ, Ankara, Turkey).

Two components of M511 silicone (Part A and Part B) were combined at a 10:1 ratio by weight as recommended by the manufacturer. The silicone was combined with 2 different pigments as orange-brown and red (Spectromatch Ltd., Bath, England) in concentration of totally 0.2% by weight. The colored silicone was poured into the molds and the molds were placed into an oven (Mikrotek, Ankara, Turkey), held at 100 °C for 1 hour for vulcanization, and then allowed to cool at room temperature.

Base and catalyst components and pigments of Derma-sil 10 and Derma-sil 30 silicones were mixed by using two roll mill machine (Servitec Maschinenservice GmbH, Bremer, Germany) at a 10:1 ratio as recommended by the manufacturers, then placed into stone molds. The molds were stored under pressure at room temperature for 24 hours.

The vulcanized silicone discs were separated from the molds and inspected for porosity under a magnifying glass (Loupe opt-on, Orange Dental, Biberach, Germany). Excess material at the edges of disc-shaped specimens were trimmed by using scissors and cleaned in an ultrasonic cleaner (Erosonic Energy, Euronda, Vincenza, Italy) in distilled water for 10 minutes to remove dental stone residue. Only the specimens without visible porosity were included in the study. A total of 60 disc-shaped specimens for 3 silicone types and 2 color groups of each (n=10) were prepared.

Table 1. Materials used in the study

Material	Brand Name	Manufacturer
Heat-vulcanized silicone	Technovent Ltd.	Principality Medical Ltd., Newport, England
- M511		
Room-temperature-vulcanized silicone		
- Derma-sil 10	Spectromatch	Spectromatch Ltd, Bath, UK
- Derma-sil 30		
Coloring Pigment		
- Orange-brown	QuickWeigh LSR	Spectromatch Ltd, Bath, UK
- Red		

2.2. Aging Process

The specimens were subjected to natural sunlight aging by being placed near a window in Ankara for three months (1st June – 30th August).

2.3. Color Measurements

Color parameters were measured twice; before and after aging process. The L^* , a^* , and b^* values of each specimen were measured with a spectrophotometer (Konica Minolta CM-2300d, Minolta Konica, Tokyo, Japan). Standard D65 illuminant with illumination geometry d/8 degree, 100 colorimetric standard observer, and measurement region of 8 mm in diameter were the spectrophotometer's measuring characteristics. Measurements of each specimen were performed on a standard white (L : 97.17, a : -0.11, b : 0.16) background. L^* , a^* , and b^* values of the specimens where L = darkness (0 to 100, 100 is lightest), a = green/red (+ is red, – is green), and b = blue/yellow (+ is yellow, – is blue) were recorded. The spectrophotometer was calibrated using its own white calibration tile according to the manufacturer's standard procedure.

The color change (DeltaE: ΔE) of each specimen between two measurements was calculated by the following equation:

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

(ΔL^* : lightness difference, Δa^* : a value difference, and Δb^* : b value difference)

2.4. Hardness Test

Hardness test was performed according to ASTM D2240 (Standard Test Method for Rubber Property-Durometer Hardness, 2005). Accordingly, 3 specimens placed on the top of the other to provide minimum 6 mm in thickness for hardness test and ten measurements were taken by placing each specimen on top. Shore type A digital durometer used for hardness measurements (Durotech Digital M202 Series; Ray-Ran Test Equipment LTD, UK). The tests were performed at room temperature (23 ± 1 °C).

3. Statistical Analysis

The normality of the ΔE data was assessed and confirmed using the Shapiro-Wilk test ($P > .05$).

Table 2. Means and standard deviations of color changes (ΔE^*) of each group

Material	Color (n=10)	Red mean (\pm SD)	Orange-brown mean (\pm SD)
M511		3.42 (\pm 0.70) A a	3.27 (\pm 0.90) A a
Derma-sil 10		1.61 (\pm 0.68) B b	2.61 (\pm 0.83) A a
Derma-sil 30		2.09 (\pm 0.52) B a	1.74 (\pm 1.18) B a

Same uppercase letters in same color (vertically) indicate that mean ΔE^ values not significantly different ($P > .05$).

**Same lowercase letters in same material (horizontally) indicate that mean ΔE^* values not significantly different ($P > .05$).

The homogeneity of the variances of the experimental groups was tested using Levene test. The mean and standard deviation values of the data were calculated as descriptive statistics. To evaluate the effects of silicone type and color factors on the ΔE , the data were statistically analyzed by two-way Analysis of Variance (ANOVA). The Shore A hardness values of each group were statistically compared by Paired-t test. All statistical analyses were performed using the statistical software SPSS v.20 (IBM Inc., USA).

4. Results

Color change values of groups evaluated with two-way ANOVA and it has been found that there was an interaction between color and material types ($P = .028$, $P < .05$). Color change values of groups and standard deviations (SD) are shown in Table 2. The mean color change values of the experimental groups were found to be in visually perceptible and clinically acceptable limits $3.3 > \Delta E^* > 1$ (Dos Santos et. al, 2020) except red colored M511 group. The color change of red color M511 maxillofacial silicone was $3.42 (\pm 0.70)$.

When the color changes of the materials were compared in the red color group, it was found to be the most in the M511, Derma-sil 30, and Derma-sil 10 silicone materials, respectively. Although there was no significant difference in color change values between the Derma-sil 10 and Derma-sil 30 groups, the color change in the M511 group was significantly higher than the other two groups ($P < .05$).

When comparing the color change between materials in the orange-brown color group, the mean color change values were higher in M511 and Derma-sil 30 silicone groups, respectively. Although there is no significant difference in color change values between the M511 and Derma-sil 10 group, the color change in the Derma-sil 30 group was significantly lower than the other two groups ($P < .05$). However, there was no significant difference in color change values between the red and orange-brown specimens of M511 and Derma-sil 30 silicones, the color change of the orange-brown specimens of the Derma-sil 10 group was significantly higher than the red specimens ($P < .05$).

Table 3. Hardness values of each material in same color group before and after artificial aging

Material (n=10)	Before aging mean (\pm SD)	After aging mean (\pm SD)
M511 red	22.90 (\pm 1.05) a	21.90 (\pm 1.10) b
M511 orange-brown	21.95 (\pm 1.01) a	19.60 (\pm 1.66) b
Derma-sil10 red	9.15 (\pm 1.08) a	8.70 (\pm 0.82) a
Derma-sil10 orange-brown	7.65 (\pm 1.00) a	7.90 (\pm 1.2) a
Derma-sil30 red	19.95 (\pm 6.40) a	21.65 (\pm 0.78) a
Derma-sil30 orange-brown	19.75 (\pm 1.18) a	19.65 (\pm 0.85) a

*Same lowercase letters in same material group (horizontally), indicate that difference of hardness values between before and after aging not significantly different ($P>.05$).

Hardness values of each group before and after aging are shown in Table 3. When the hardness values of the groups were examined, aging influenced the hardness values. However, it only had a significant effect on the M511 silicone group ($P<.05$). In the M511 red and orange-brown groups, it was revealed that aging significantly decreased the hardness values ($P<.05$). The hardness values for both colors were similar in the Derma-sil 10 and Derma-sil 30 groups.

5. Discussion

In the present study, changes in the color and hardness of different maxillofacial silicones after daylight aging were evaluated. The null hypothesis was rejected as significant color and hardness changes were observed in silicone groups.

Maxillofacial silicones are desired to mimic skin color, to be flexible as facial tissues, and to have adequate strength to withstand rupture during daily use.

These properties are objectively measured by laboratory tests namely color measurements, hardness, tensile strength, elongation at rupture, and tear strength tests. Color and hardness are the prominent physical properties which visually affect clinical performance of the maxillofacial silicones (Dos Santos et. al, 2020). Therefore, changes in these properties of different maxillofacial silicones in two frequently used color groups after aging were evaluated in the present study.

During daily use, environmental factors such as moisture, dust, sunlight, temperature, and pollutants cause changes in the physical properties of maxillofacial silicones (Eleni et al., 2008; Farah, Sherriff, & Coward 2018; Tetteh, Bibb, & Martin 2018). Previous studies showed that sunlight which contain wavelengths as UV light, visible light, and infrared light have the most dramatical effects on the maxillofacial silicones (Beatty et al., 1999; Eleni et al., 2008). When maxillofacial prostheses are exposed to the sunlight, the silicone material absorbs the photons which cause photodegradation.

Photodegradation generate the breakup of molecules into smaller pieces as well as the shape of molecule to be changed by photons in irreversible manner (Meszároš, Schmidt, Pospíšil, & Nešpůrek 2006). While most of the research on the effect of sunlight on properties of maxillofacial silicones used artificial aging, limited information on the effect of natural sunlight. Furthermore, sunlight of each geographic region is typical and unique properties and results observed in each region would be beneficial for the habitants. Therefore, the tested maxillofacial silicones were subjected to natural sunlight in the present study.

Silicone rubbers are crosslinked polymers with a low surface energy that can be used as a variety of biomaterials. Poly (dimethyl siloxane) (PDMS) which is the most widely used silicone material in the field of maxillofacial prosthetics is composed of polymer (PDMS), filler (surface treated silica), cross linker, and catalyst. The material is also colored with appropriate pigments. These are the modifications of poly (siloxanes) differing in characteristics of base polymer, characteristics and quantity of filler, and degree of cross-linking. Comparing stability and durability of materials with different contents and properties under standardized conditions is required for clinical use. In the present study, color and hardness change of three maxillofacial silicones were evaluated under natural aging conditions. One of those, M511, has a wide clinical use and color stability and mechanical properties was tested in several research (Bankoglu, Oral, Gül, & Yilmaz 2013; Cifter et al., 2019; Eleni et al., 2008).

Derma-sil 10 and Derma-sil 30 are two materials of a manufacturer. These silicones composed of compounds with different filler content which, when cured, produce Shore A hardness of 10 and 30, respectively. To the best of authors' knowledge, no recent research is available on physical properties of these silicones.

Studies showed that both accelerated aging in a weathering chamber (Eleni et al., 2008; Kiat-Amnuay et al., 2002; Mancuso, Goiato, & Santos 2009) and natural outdoor weathering (Al-Harbi, Ayad, Saber, ArRejaie, & Morgano 2015; Hatamleh et al., 2010; Haug, Andres, & Moore 1999; Polyzois 1999) caused color changes in maxillofacial silicones. Although accelerated aging has been reported to cause higher color changes than natural aging (Farah et al., 2018; Hatamleh et al., 2010), natural aging has been applied in a fewer number of studies (Al-Harbi et al., 2015; Hatamleh et al., 2010; Haug et al., 1999; Polyzois 1999). Farah et al. (2018) reported that outdoor weathering method may better to imitate the natural environmental factors. Nevertheless, the reason for limited application of natural aging might be that the process is the time consuming and lack of standardization according to climate conditions of different geographic regions. Previous studies revealed that 6-months (Al-Harbi et al., 2015; Haug et al., 1999) and 1-year (Eleni et al., 2009) of natural weathering aging generated alteration in physical properties. Dos Santos et al. (2012) tested color change of maxillofacial prosthetic materials after 90 and 180 days of natural weathering.

They reported color change (ΔE) ranging between 3.10 and 10.13 after 90 days differing between materials; however, no statistically significant difference was observed between ΔE values of 90 and 180 days. This finding can be interpreted as significant color change of the prostheses may occur within 3 months of use as performed in the present study.

Chemical changes on polymeric chains or the loss of pigments sensitive to ultraviolet light can cause discoloration of maxillofacial prostheses after fabrication (Beatty et al., 1999). Dos Santos et al. (2012) reported that pigmented materials underwent greater color changes than nonpigmented colorless materials, which indicates the loss of pigments is the main cause of color change. In the present study, pigmented silicones showed color change (ΔE) ranging between 1.61 and 3.72 which is in accordance with previous findings (Akash, & Guttal 2015; Bangera, & Guttal 2014; Dos Santos et al., 2011; Farah et al., 2018). When the ΔE values of the present study is elucidated regarding perceptibility and acceptability threshold values specially determined for maxillofacial prostheses (Leow, Ow, Lee, Huak, & Pho 2006; McHutchion, Zhao, Dixon, & Seelaus 2020; Paravina, Majkic, del Mar Perez, & Kiat-Amnuay 2009), tested silicone materials represented clinically acceptable color stability after 90 days of natural sunlight aging.

The structural properties of the silicone elastomer and pigment type incorporated into the silicone are known factors affecting the color change of maxillofacial silicones (Dos Santos et al., 2011; Rashid et al., 2020).

In the present study, two different brands of maxillofacial silicones were tested. The widely used maxillofacial prosthetic material M511 is in a viscous consistency before curing and reaches to approximately 25 Shore A hardness. Derma-sil includes a series of gum silicone providing different Shore A hardness values after curing. Derma-sil 10 and Derma-sil 30 provide cured silicones in Shore A 10 and Shore A 30 hardness, respectively. In the present study, gum silicones showed lower color change compared with M511. The higher filler content of the base compound of gum silicones may contribute to color stability compared with viscous silicone. Another factor may be the vulcanization method for the color stability of tested silicone materials. M511 is a heat vulcanized maxillofacial silicone and the other types of the tested silicones are vulcanized by keeping at room temperature. Al-Harbi et al. (2015) reported that heat-vulcanized TechSil S25 elastomer showed better mechanical durability and color stability compared with the room-temperature vulcanized A-2186 and MED-4210 materials. Rahman et al. (2021) tested the surface roughness and mechanical properties of room-temperature vulcanized (A-2000, A-2006, and A-103) and heat-temperature vulcanized (M-511) silicones subjected to outdoor weathering. It was stated that A-2000 showed the least tensile strength changes, while A-2006 demonstrated significant changes in percentage elongation after outdoor weathering. And also, M-511 exhibited the highest mean value for surface roughness. It was observed that the properties of the vulcanization type of the silicone alter the behavior of the material against outdoor weathering.

Two frequently used colors, red and orange-brown, for color matching of maxillofacial silicone to the human skin color were used in the study. Previous studies represented that pigment type has an influence on the color change of maxillofacial silicone (Bankoglu et al., 2013; Dos Santos et al., 2011; Rashid et al., 2020). Unpigmented silicones generally showed lower color changes after aging which may indicate as the UV light has damaging effects primarily on pigment component of the pigmented silicone (Rahman, Jamayet, Nizami, Johari, Husein, & Alam 2019). However, exposing silicones with different pigments to the same UV light causes different amount of color change (Bal et al., 2009; Nobrega et al., 2016). In the previous studies, red pigment showed the highest color change after aging procedure (Beatty et al., 1999; Kiat-Amnuay et al., 2002) as observed for M511 and Derma-sil 30 groups of our study. The Derma-sil 10 which is the softest material after curing represented better stability for red color. This may be resulted from interaction between cross-linking of the polymer structure and pigment material. Further research should be conducted on color stability of different silicones and pigments, thereby clinicians may predict lifetime of prostheses and also prosthodontist can look for alternative pigments during color matching procedure.

Hardness of maxillofacial material indicates the flexibility and strength of a material's surface. In clinical use, maxillofacial silicones are desired to be flexible as close as that of the anatomic facial tissues and to have adequate strength to withstand rupture, also they should maintain these properties during lifetime of the prosthesis (Eleni et al., 2008; Hatamleh et al., 2010).

In the present study, there was a significant reduction in the hardness of the M511 silicone after aging ($P<.05$) while no significant difference observed in Derma-sil silicones ($P>.05$) (Table 2). This may indicate durability of gum silicones compared with conventional viscous maxillofacial silicones.

The study has some limitations. Pigmented maxillofacial silicones are translucent specimens and edge loss may occur in the spectrophotometric measurements (Johnston 2009). Edge loss effects were not measured and considered in this study. Less color and hardness changes were observed for Derma-sil silicones for 3 months of aging; however, studies including longer aging periods, both artificial and natural aging, should be performed to predict long term performance of the material. Several types of pigments are available for coloring maxillofacial prostheses. Materials used in the study colored with colorants recommended by manufacturers. Therefore, differences might be arising from colorants. Two color groups (red and orange-brown) were generated in this study; however, more different colors are used to simulate human skin color. Color and hardness are considered as two extremely important properties for maxillofacial silicone prostheses; however, other mechanical properties namely tensile strength, elongation at rupture, and tear strength should be evaluated in further studies.

6. Conclusion

The following conclusions can be drawn within the limitations of the study:

1. Derma-sil 10 and Derma-sil 30 silicones showed less color change than M511 silicone.

2. Color change values of each group were in visually perceptible and clinically acceptable limits (1-3.3) except red color of M511 maxillofacial silicone group (3.42 ± 0.70).

3. Hardness value of M511 was reduced after aging and that of both Derma-sil silicones did not significantly change after aging.

Acknowledgements-Remarks

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Conflicts of interest

The authors declare no conflicts of interest.

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