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Effects of pigment, disinfection, and accelerated aging on the hardness and deterioration of a facial silicone elastomer

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ABSTRACT

The failure of facial prostheses is caused by limitations in their flexibility and durability. Therefore, we evaluated the effects of disinfection and aging on Shore A hardness and deterioration of a facial silicone with different pigmentations. Twenty samples with addition of each pigment (ceramic (*C*), make-up (*M*)) and without pigment (*L*) were made. For each pigment type and no pigment, 10 samples were subjected to two types of disinfectant solution (soap (*S*) and Efferdent (*E*)), totaling sixty samples. The specimens were disinfected three times per week for 60 days, and subjected to accelerated aging for 1008 h. The hardness of the facial silicone was measured with a durometer, and its deterioration was evaluated by obtaining the weight difference over time. Both the hardness and weight of the samples were measured at baseline, after chemical disinfection, and periodically during accelerated aging (252, 504, and 1008 h). Deterioration was calculated during the periods between baseline and chemical disinfection, and between baseline and each aging period. The results were analyzed using three-way repeated measures ANOVA and the Tukey's HSD Post-hoc test ($\alpha = 0.05$). Specifically, samples containing pigment exhibited significantly higher hardness and deterioration values than those lacking pigment ($P < 0.05$). In addition, period of time (disinfection and accelerated aging) statistically increased the hardness and deterioration values of the silicone ($P < 0.05$). It can be concluded that both pigment and time statistically affected the hardness and deterioration of the silicone elastomer.

1. Introduction

Patients with facial mutilations due to congenital malformation, oncologic surgery, or trauma are often marginalized. Facial prosthetic rehabilitation aims to restore anatomic function, aesthetics, self-esteem, and quality of life [1–3]. However, facial prostheses present limited longevity (six months to one year) due to rapid deterioration, lack of retention, changes in intrinsic material [4], increases in hardness, color instability, and decreases in resistance. Several studies [5,6] have shown alterations in the optical, mechanical, and physical properties of facial silicone with changes in temperature and humidity, pigment incorporation [5–7], and chemical disinfection [4,8–10].

The hardness of maxillofacial material is important for the resistance and durability of facial prosthetics. At the same time, the material should be soft and flexible enough to allow movements of the patient's facial musculature [4]. Deterioration is directly linked to the aesthetics of the prosthesis [4,11]. Furthermore, both hardness and deterioration properties are important for esthetic appeal, and are also necessary for the proper fitting of the prosthesis over time as well as the protection of the surrounding soft tissues. Guiotti et al. [11] used scanning electron microscopy (5000× magnification) to investigate the deterioration of the MDX4-4210 facial silicone under the influence of different pigmentations, accelerated aging, and disinfection. Visual analysis of the photomicrographs showed that all groups presented deterioration over time. Disinfection did not affect silicone deterioration, regardless of pigmentation and accelerated aging.

The literature lacks studies concerning the effects of chemical disinfection, using either alkaline peroxide effervescent tablets or soap, on Shore A hardness and deterioration properties of pigmented facial silicone. Therefore, the aim of this study was to investigate Shore A hardness and deterioration of a facial silicone prosthesis fabricated with or without the incorporation of pigments, and to determine the effects of disinfection and accelerated aging on these parameters. We hypothesize that the effects of disinfection and accelerated aging on the hardness and

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deterioration of the Silastic MDX4-4210 facial silicone will be the same for the different pigments and disinfectants used, and will also be consistent over time.

2. Experimental

2.1. Specimen preparation

The samples were fabricated using Silastic MDX4-4210. Make-up and ceramic powder were used as intrinsic pigments. Afterward, specimens were submitted to two different types of disinfectants (effervescent tablets or neutral soap) (Table 1).

A total of 60 samples were made by simulating facial prosthetics. Twenty samples with added pigment; namely ceramic (*C*) and make-up (*M*), and 20 samples without pigment (*L*) were made. Ten samples of each pigment type and no pigment were subjected to two types of disinfectant solution: soap (*S*) and Efferdent (*E*). A cylindrical metal mold, 30 mm in diameter and 6 mm in thickness, was used to cast the samples [12]. The materials were weighed using a precision digital scale (BEL Equipamentos Analítico, Piracicaba, SP, Brazil). The pigments were added at a concentration of 0.2 wt% of silicone [1,5,6]. Silicone was manipulated according to the manufacturer's instructions at 23 $\pm$ 2 °C. The pigments were added to the silicone using a stainless steel spatula on a glass plate to obtain a homogenous mass. After manipulation, the mixture was placed in the mold and cured at room temperature for three days according to the manufacturer's instructions. The samples were then carefully removed from the mold to avoid distortion [4,6,8,9].

2.2. Hardness test and deterioration analysis

The hardness test and deterioration analysis were performed at baseline, after chemical disinfection, and periodically during each accelerated aging period (252 (A_1), 504 (A_2), and 1008 (A_3) hours). For the Shore A hardness test, a digital durometer (GSD 709, Teclock, Osaka, Japan) was used according to the American Society for Testing and Material specification ASTM D2240 [13]. This method is based on the penetration of a needle on the surface of the material with a constant load of 10 N. Deterioration was calculated during the periods between baseline and chemical disinfection, baseline and A_1, baseline and A_2, and baseline and A_3 to assess the material's weight loss over time. The deterioration values obtained during each period of time are expressed in grams.

2.3. Disinfection and accelerated aging

Samples were disinfected three times per week for 60 days. Ten samples of each pigment type and no pigment were disinfected with neutral soap and ten were disinfected with Efferdent (Naturativa, Araçatuba, SP, Brazil). Samples that were disinfected with water and neutral pH soap (Johnson & Johnson, São José dos Campos, SP, Brazil) were rubbed with the fingertips for 30 s, and then rinsed with water [9,10]. Samples that were disinfected with Efferdent (Pfizer Consumer Health, Morris Plains, NJ, USA) were immersed in a solution containing Efferdent tablets dissolved in 250 mL of warm water for 15 min [4,8,9]. Accelerated aging treatments were carried out using an aging chamber (Equilam, Diadema, SP, Brazil) [5,6]. Each aging cycle lasted 12 h. During the first 8 h, the samples were exposed to ultraviolet light at a temperature of 60 $\pm$ 3 °C. In the remaining 4 h, the samples were subjected to oxygen-saturated distilled water condensate in the absence of light at a temperature of 45 $\pm$ 3 °C [5,6]. The samples underwent 1008 h of accelerated aging. Both disinfection and accelerated aging simulated one year of clinical use of silicone [5,6].

Table 1
Materials used in this study.

Product	Color	Manufacturer	Lot number
MDX4-4210 (facial silicone)	Colorless	Dow Corning Corporation, Midland, Michigan, USA	0001798623
Ceramic powder (inorganic pigment)	Caramel	Clarart, Brasília, Distrito Federal, Brazil	171062
Make-up powder (organic pigment)	Beige	Avon, São Paulo, São Paulo, Brazil	250781
Efferdent original denture cleanser (disinfectant)	Blue	Pfizer Consumer Health, Morris Plains, NJ, USA	BH03D2V
Neutral soap (disinfectant)	Colorless	Johnson & Johnson, São José dos Campos, São Paulo, Brazil)	1180B01

2.4. Statistical analysis

The effects of pigment, disinfectant, and period of time on hardness and deterioration (interaction among these factors) were analyzed by three-way repeated measures analysis of variance (ANOVA). The means were compared using the Tukey's HSD Post-hoc test ($\alpha = 0.05$).

3. Results

Table 2 lists the mean and standard deviation of the hardness values of silicone for each period of analysis. All samples exhibited higher hardness values over time (Table 2). The results of the three-way repeated measures ANOVA test for the hardness values are shown in Table 3. Both pigment and period of time statistically affected the Shore A hardness of the silicone ($P < 0.01$, ANOVA Table 3). However, there were no statistically significant differences between the interactions among these three factors (pigment × disinfectant × time period) ($P > 0.05$, ANOVA Table 3). The period of time (disinfection and accelerated aging) statistically increased the hardness values of all samples (Tables 2 and 3). In addition, regardless of the period of time or the type of disinfectant, the pigmented samples exhibited significantly higher hardness values ($C = 31.61$; $M = 31.50$) than non-pigmented samples ($L = 31.15$) ($P < 0.01$). However, no differences among the pigmented samples were observed, regardless of the time period or disinfectant ($P > 0.05$).

The mean and standard deviation of deterioration values (in grams) of the silicone for each period of time are presented in Table 4. The pigmented samples with make-up that were disinfected with Efferdent displayed the greatest deterioration value (0.15) in the period between baseline and A_3 (Table 4). Table 5 shows that the pigment, time period, and interaction between

Table 2
Mean Shore A hardness values (SDs) for the silicone.

Pigment	Disinfectant	Periods				
		B	*D*	A_1	A_2	A_3
L	*S*	27.10 (0.42)	27.90 (0.57)	31.30 (0.95)	33.40 (0.84)	34.80 (0.63)
	E	27.40 (0.38)	28.80 (1.03)	32.10 (1.10)	33.70 (0.67)	35.00 (0.67)
C	*S*	27.53 (0.42)	29.30 (0.67)	32.40 (0.70)	33.80 (0.92)	35.20 (0.63)
	E	27.40 (0.38)	28.80 (1.03)	32.10 (0.74)	34.10 (0.74)	35.50 (0.53)
M	*S*	27.23 (0.52)	28.50 (0.71)	31.60 (1.58)	34.00 (0.82)	35.40 (0.70)
	E	27.83 (0.39)	29.10 (0.74)	32.10 (1.79)	34.00 (1.05)	35.20 (0.63)