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RESEARCH AND EDUCATION

Comparison of conventional and plant-extract disinfectant solutions on the hardness and color stability of a maxillofacial elastomer after artificial aging

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ABSTRACT

Statement of problem. Silicone elastomers undergo physical and chemical degradation with disinfecting solutions. Phytotherapy may be a suitable solution for disinfection. However, its effect on the properties of the silicone material is unknown.

Purpose. The purpose of this in vitro study was to evaluate the effect of disinfection with conventional and plant-extract solutions and of artificial aging on the hardness and color stability of a facial silicone associated with pigments and an opacifier.

Material and methods. Four hundred specimens of silicone (MDX4-4210) were fabricated (5×6 mm). Two pigment shades and 1 dry opacifier were combined in the tested material, and 4 groups (n=10) were obtained: colorless (GI), colorless with opacifier (GII), medium pigment with opacifier (GIII), and black pigment with opacifier (GIV). Specimens were subjected to disinfection (30 days) using saline solution, water, and neutral soap (digital friction, 30 seconds), chlorhexidine 4%, *Hydrastis canadensis*, and *Cymbopogon nardus* extracts (immersion, 10 minutes). Shore A hardness (ASTM D2240) and color analyses were performed before and after disinfection. Specimens were then exposed to 1008 hours of artificial aging (ASTM 53) and subjected to final hardness and color readings. The results were analyzed with ANOVA and the Tukey significant difference test (α=.05).

Results. The opacifier increased the hardness (GII). For GII, the *H. canadensis* solution and the friction with water and soap promoted significantly reduced hardness; the friction also promoted a reduction in this property for GIV. The GIII was not affected after disinfection. A significant difference was found between the ΔE values of the specimens disinfected with *H. canadensis*, *C. nardus*, and chlorhexidine, and specimens subjected to saline solution and neutral soap.

Conclusion. The hardness of MDX4-4210 after the experimental procedure was considered clinically acceptable for facial prostheses. All groups showed clinically unacceptable color alterations regardless of the disinfecting solution. (J Prosthet Dent 2016;115:501-508)

Maxillofacial prostheses should restore the esthetics of patients with facial deformities and improve their quality of life.[1] However, one of the most distressing and limiting aspects of this rehabilitation is that after a few months of clinical performance, these prostheses are unsatisfactory because of alterations in the silicone elastomer color and hardness, the distortion of the prosthesis margins, and a reduction in their tear resistance.[2,3] The degradation of maxillofacial silicone elastomers is caused by ultraviolet rays and by handling, cleaning, and removal when the prosthesis is glued to the skin with medical adhesive.[4-12]

Pigmentation is important in fabricating a successful

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Clinical Implications

Phytotherapy solutions may be suitable for disinfecting silicone for facial prostheses, in that the elastomers' Shore A hardness was preserved. However, these solutions also promoted color alteration of the silicone material. Thus, modifications of their composition are needed to prevent prosthetic complications.

maxillofacial prosthesis. Intrinsic and extrinsic colorings are often used to match a prosthesis to human tissue in clinical practice. Intrinsic coloring is less vulnerable to environmental conditions and handling but more likely to affect the structure and properties of the mixture.[13-15] Some studies have shown that the incorporation of nano-oxides (such as, ZnO, TiO_2, and CeO_2) as dry opacifiers improved the overall mechanical properties of silicone elastomers and that they may increase the lifetime of prostheses.[15-19] However, even with this strategy, silicone elastomers are far from ideal.[6]

Some unavoidable situations, such as cleaning, may also promote the degradation of the properties of silicone material.[18,20] Although the disinfection of maxillofacial prostheses is essential in providing healthy surroundings, some authors have suggested that digital friction, even when gently performed, induces the detachment of the compounds incorporated into the elastomer matrix for the characterization of maxillofacial silicone prostheses.[18,21] Chemical disinfection through immersion is a proposed alternative for cleaning silicone prostheses.[18] However, a plethora of disinfecting solutions (neutral soap, sodium hypochlorite 1%, cleansing tablets, commercial antimicrobial solutions, and chlorhexidine 2% to 4%), concentrations, and methods of handling are available, but all of them seem to affect the properties of an elastomer material.[18,21-24] According to some recent studies, the optimal disinfecting solution is still a matter of discussion.[21-23]

Phytotherapy may be a promising alternative for infections mainly because of its low cost and satisfactory antimicrobial properties.[25] *Cymbopogon nardus* and *Hydrastis canadensis* are plants that provide extracts with antimicrobial and antifungal properties. This action is produced by deleterious morphologic changes in cellular structures and on surfaces.[26,27] They may also be useful for a wide range of microorganisms because such plant compounds kill both yeast and filamentous fungi formations,[28] suggesting that these solutions might be useful as topical agents for silicone elastomers. However, to the best of the authors' knowledge, no studies have evaluated whether those disinfecting solutions can be used for facial silicone without affecting its properties.

The silicone elastomer Silastic MDX4-4210 is the most commonly used material for maxillofacial prosthesis fabrication.[16,17,29,30] It has good flexibility, its texture is closest to the ideal, and it is comfortable for the patient.[7,9] To evaluate in vitro the clinical performance of silicone elastomers, some studies have proposed artificial aging, allowing the analysis of environmental conditions that may degrade maxillofacial prostheses and reduce their lifetime.[18,24,31] Still, the effect of artificial aging on previously disinfected silicone elastomers has not been clearly investigated.

The purpose of this study was to evaluate the effect of disinfection with conventional and phytotherapy solutions and artificial aging on the Shore A hardness and color stability (ΔE) of a maxillofacial silicone elastomer associated with a dry opacifier or oil pigments. The null hypothesis was that the pigments and opacifier used, the disinfecting solutions, and artificial aging would not affect the hardness or the color stability of the tested silicone elastomer.

MATERIAL AND METHODS

The materials used in the present study are listed in Table 1. Four hundred disk-shaped specimens (5 mm in diameter, 6 mm in thickness) of 1 maxillofacial silicone elastomer were fabricated using a metallic matrix.[9] The specimens were distributed into 4 groups (GI, GII, GIII, GIV), each of which was divided into 5 subgroups. The factors evaluated were pigmentation (pigments/opacifier) at 4 levels, disinfecting solutions at 5 levels, and periods at 3 levels. The factorial design of this study was 4×5×3 (repeated measure) for the experimental groups, resulting in 20 subgroups (n=10), containing all combinations formed from the different levels of factors. For the specimen's fabrication, the colorless silicone elastomer and the pigments were weighed in a digital precision balance (Mark M214Ai; BEL Engineering). The quantity of the pigment was 0.2 wt%, whereas the opacifier was 2.0 wt%.[9,19] The silicone elastomer was manually mixed in a ratio of 10:1 (base:catalyst), according to the manufacturer's instructions.[8] The pigments and opacifier were mixed in the silicone elastomer matrix with a stainless steel spatula on a glass plate until a homogenous mixture was obtained. After handling, the silicone elastomer was poured into a metallic matrix, and the surface was exposed to the room environment for 3 days until polymerization was complete.

Specimens were submitted to initial hardness evaluation. A digital Shore A durometer (GSD 709, Teclock) was used to test the hardness of the specimens, according to ASTM specification D2240.[32] The hardness values are expressed in Shore units (range 0 to 100). For all specimens, 3 readings were made, and the average value calculated.[7,33,34] The hardness was considered

Table 1. Materials used

Material	Manufacturer	Color/number	Batch No.
MDX4-4210 (poly (dimethylsiloxane))	Dow Corning Corporation	Colorless	0007491879
Functional Intrinsic II - Silicone Coloring System	Factor II Inc	Medium shade (Tan FI – 215)	B042811
Functional Intrinsic II - Silicone Coloring System	Factor II Inc	Black shade (Black FI – 205)	SB041411
Dry opacifier (Zinc oxide - ZnO)	Pharmacotecnica	Colorless	XZY120901Y
Saline solution	Tayuyna Laboratory	_	252731
Neutral soap	Johnson & Johnson	_	0854B01
Chlorhexidine 4%	Pharmacotecnica	_	12082486 A
Hydrastis canadensis (Hydrastis)	Schraiber Homeopatia	_	5475
Cymbopogon nardus (Cytronella)	Pharmaspecial Espec	_	PS-002545/F01

clinically acceptable when specimens showed a Shore A result from 25 to 35. This range has been established for maxillofacial prostheses used for 6 months to 1 year.[35]

The color was analyzed with an ultraviolet-visible reflection spectrophotometer (UV-2450; Shimadzu Corp).[18,36-38] Color changes were calculated according to CIELab[39] with the formula $\Delta E=[(\Delta L)^2 + (\Delta a)^2 + (\Delta b)^2]^{½}$. The ΔE means were classified into 3 clinically relevant intervals[40-43] as follows: ΔE<1 (undetectable color alteration); 1<ΔE<3.3 (clinically acceptable color alteration); and ΔE>3.3 (clinically unacceptable color alteration).

Next, specimens were disinfected daily for 30 days with different disinfecting solutions in the following cleaning cycles: saline solution (SS); digital friction for 30 seconds with water and neutral soap (WN); chlorhexidine 4% (CHX), immersion for 10 minutes; *Hydrastis canadensis* extract (HC), immersion for 10 minutes; and *Cymbopogon nardus* extract (CN), immersion for 10 minutes.

Artificial aging was conducted in an aging chamber for nonmetallic specimens (EQUV; Equilan) according to specification 53 of the American Society for Testing and Materials (ASTM).[44] Specimens were exposed to 1008 hours of artificial aging and then subjected to final SH hardness readings. The hardness test and the color analysis were performed on the same specimens but in 3 different periods as follows: at the baseline (B), after 30 days of chemical disinfection (T1), and after 1008 hours of artificial aging (T2). All obtained data were cumulative. A multifactorial design provided a more relevant clinical scenario since facial prostheses are subjected to factors that affect the properties of silicone material simultaneously when exposed to the environment.

The color alterations were calculated after 30 days of chemical disinfection (T1B) and after 1008 hours of artificial aging (T2B) with regard to baseline (B). In addition, to understand the interaction between the silicone elastomer and the tested pigments, 1 specimen of each pigmented group was analyzed through energy dispersive spectroscopy (EDS - JSM 610LA; JEOL), allowing for the mapping of chemical components on the surface of each specimen using x-rays.[45]

The factors evaluated were pigmentation (pigments/opacifier) at 4 levels, disinfecting solutions at 5 levels, and periods at 3 levels; they were submitted to 3-way analysis of variance (ANOVA) through a repeated model of factorial analysis. The means were then compared with the Tukey (HSD) test (α=.05), performed with software (SPSS v19.0; IBM Corp). The EDS graphics were visually compared among the pigmented groups.

Table 2. Results of 3-way ANOVA for Shore A hardness

Source	*df*	Sum of Squares	Mean Square	F	*P*
Pigmentation	3	459487	153162	27465	<.001*
Disinfectant	4	44847	11212	2011	.095
Pigmentation×disinfectant	12	183695	15308	2745	.002*
Between specimens	180	1003792	5577		
Period	2	273079	136539	72208	<.001*
Period×pigmentation	6	292892	48815	25816	<.001*
Period×disinfectant	8	71020	8877	4695	<.001*
Period×pigmentation×disinfectant	36	319449	8874	4693	<.001*
Within specimens	360	680735	1891		

*$P<.05$ shows statistically significant difference.

Table 3. Results of 3-way ANOVA for color stability

Source	*df*	Sum of Squares	Mean Square	F	*P*
Pigmentation	3	785066	261689	47785	<.001*
Disinfectant	4	463281	115820	21149	<.001*
Pigmentation×disinfectant	12	264568	22047	4026	<.001*
Between specimens	180	985753	5476		
Period	1	417048	417048	75281	<.001*
Period×pigmentation	3	533106	177702	32077	<.001*
Period×disinfectant	4	109598	27400	4946	<.01*
Period×pigmentation×disinfectant	24	291344	12139	2191	<.01*
Within specimens	180	997182	5540		

*$P<.05$ shows statistically significant difference.

RESULTS

The 3-way ANOVA revealed a significant difference in the interactions of all the factors (pigmentation × disinfectants × period; $P<.001$) after the baseline (B), after 30 days of chemical disinfection (T1), and after 1008 hours of artificial aging (T2) for both Shore A hardness and color stability (Tables 2, 3). Tables 4, 5 and Figures 1, 2 show the mean and standard deviations for Shore A hardness and color stability for the experimental silicone after each testing period.

Table 4 shows that, in the GI group, neither the disinfecting solutions nor the artificial aging significantly reduced the hardness of the silicone material ($P>.05$). In the GII group, the plant extract HC and the water with

Table 4. Mean results (standard deviation) of Shore A hardness for each group, disinfecting solution, and period

		Period		
Group	**Disinfectant**	**Baseline**	**T1**	**T2**
GI	Saline solution	33.3 (1.39)^{Aa}	32.5 (1.29)^{Aa}	35.3 (1.49)^{Aa}
	Hidrastis canadensis	33.8 (1.22)^{Aa}	34.7 (1.63)^{Aa}	35.5 (1.23)^{Aa}
	Cymbopogon nardus	33.4 (1.19)^{Aa}	33.6 (1.58)^{Aa}	33.9 (1.72)^{Aa}
	Chlorhexidine 4%	33.0 (1.12)^{Aa}	33.1 (1.95)^{Aa}	34.4 (1.73)^{Aa}
	Neutral soap	33.5 (1.60)^{Aa}	33.1 (1.88)^{Aa}	33.9 (1.67)^{Aa}
GII	Saline solution	34.6 (1.30)^{Aa}	31.7 (0.78)^{Aa}	34.7 (1.27)^{Aa}
	Hidrastis canadensis	35.4 (1.49)^{Aa}	31.2 (0.73)^{Ab}	34.4 (1.27)^{Aab}
	Cymbopogon nardus	34.5 (1.14)^{Aa}	32.0 (0.93)^{Aa}	33.3 (2.20)^{Aa}
	Chlorhexidine 4%	35.5 (1.66)^{Aa}	32.5 (0.52)^{Aa}	34.4 (1.81)^{Aa}
	Neutral soap	36.1 (1.43)^{Aa}	31.7 (1.10)^{Ab}	33.5 (2.16)^{Aab}
GIII	Saline solution	32.5 (1.61)^{Aa}	30.8 (2.38)^{ABa}	32.5 (0.85)^{Aa}
	Hidrastis canadensis	30.8 (2.14)^{Aab}	27.9 (2.23)^{Aa}	31.3 (1.65)^{Ab}
	Cymbopogon nardus	32.3 (1.18)^{Aa}	32.3 (1.72)^{Ba}	31.7 (1.21)^{Aa}
	Chlorhexidine 4%	32.4 (2.00)^{Aa}	30.3 (1.77)^{ABa}	33.4 (2.14)^{Aa}
	Neutral soap	31.7 (2.05)^{Aa}	31.0 (2.92)^{ABa}	33.3 (1.39)^{Aa}
GIV	Saline solution	34.9 (1.91)^{Aa}	33.2 (2.22)^{ABCa}	32.9 (2.10)^{Aa}
	Hidrastis canadensis	33.7 (2.52)^{Aa}	31.3 (3.22)^{BCa}	31.2 (2.26)^{Aa}
	Cymbopogon nardus	35.4 (1.24)^{Aa}	34.2 (1.84)^{ABa}	32.8 (1.86)^{Aa}
	Chlorhexidine 4%	33.5 (1.30)^{Aa}	35.2 (2.87)^{Aa}	32.4 (1.23)^{Aa}
	Neutral soap	34.4 (2.02)^{Aa}	30.8 (2.75)^{Cb}	32.3 (1.64)^{Aab}

Statistically significant differences between groups are indicated by different superscript uppercase letters (within column) and lowercase letters (within row).

Table 5. Mean results (standard deviation) of color stability (ΔE) for each group, disinfecting solution, and period

		Period	
Group	**Disinfectant**	**T_1B**	**T_2B**
GI	Saline solution	6.44 (1.91)^{Aa}	2.18 (1.07)^{Ab}
	Hidrastis canadensis	7.68 (1.53)^{Aa}	4.88 (0.76)^{Ab}
	Cymbopogon nardus	7.72 (1.21)^{Aa}	2.63 (1.40)^{Ab}
	Chlorhexidine 4%	7.65 (1.35)^{Aa}	5.80 (1.38)^{Aa}
	Neutral soap	6.92 (1.56)^{Aa}	3.90 (1.79)^{Ab}
GII	Saline solution	3.66 (1.99)^{Aa}	5.55 (2.93)^{Aa}
	Hidrastis canadensis	3.37 (1.80)^{Aa}	6.29 (1.71)^{Aa}
	Cymbopogon nardus	6.67 (0.43)^{Aa}	6.63 (3.29)^{Aa}
	Chlorhexidine 4%	3.36 (1.42)^{Aa}	6.34 (3.26)^{Aa}
	Neutral soap	3.67 (1.33)^{Aa}	4.98 (2.10)^{Aa}
GIII	Saline solution	7.27 (2.47)^{Aa}	4.72 (1.85)^{Aa}
	Hidrastis canadensis	12.52 (1.86)^{Ba}	9.38 (4.87)^{Ba}
	Cymbopogon nardus	12.60 (4.73)^{Ba}	6.06 (2.93)^{ABb}
	Chlorhexidine 4%	12.51 (3.23)^{Ba}	9.10 (3.29)^{Ba}
	Neutral soap	8.27 (1.11)^{Aa}	4.80 (2.33)^{Aa}
GIV	Saline solution	6.60 (1.57)^{Aa}	3.09 (2.38)^{Aa}
	Hidrastis canadensis	8.45 (3.77)^{Aa}	6.69 (3.58)^{Aa}
	Cymbopogon nardus	9.29 (1.80)^{Aa}	4.76 (2.07)^{Ab}
	Chlorhexidine 4%	8.48 (2.34)^{Aa}	6.39 (1.94)^{Aa}
	Neutral soap	6.27 (1.80)^{Aa}	3.90 (0.73)^{Aa}

Statistically significant differences between groups are indicated by different superscript uppercase letters (within column) and lowercase letters (within row).

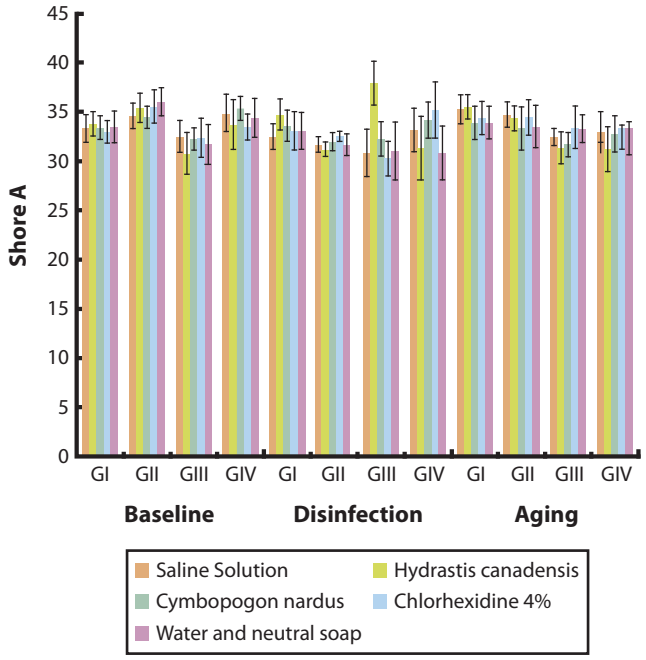

Figure 1. Shore A results for all tested groups according to different disinfecting solutions and periods.

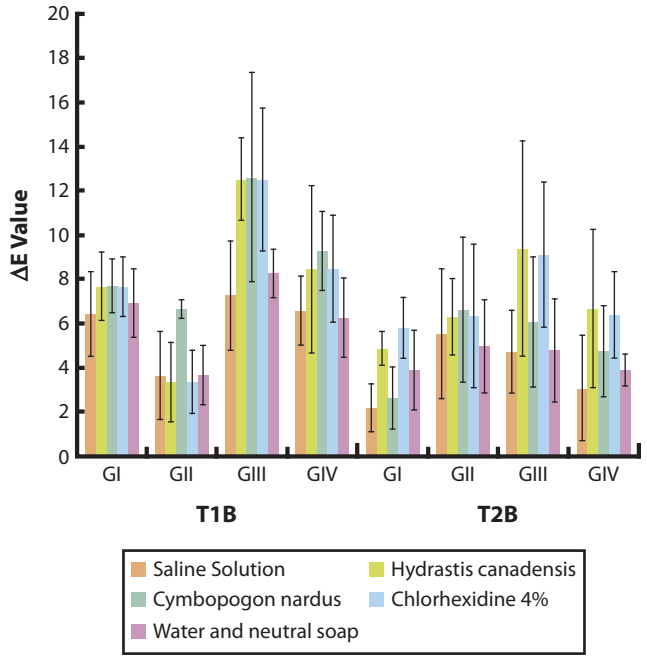

Figure 2. Color results (ΔE) for all tested groups according to different disinfecting solutions and different periods.

neutral soap significantly reduced the hardness in comparison with the baseline ($P<.05$). The factor period was not significant in this group. In the GIII group, the plant extract HC showed more influence on the hardness reduction, which was significantly different from CN ($P<.05$). Artificial aging did not affect the hardness of the analyzed subgroups, except for the subgroup disinfected with HC. In the GIV group, just

Table 6. Mean results (standard deviation) of Shore A hardness for each pigmentation, baseline, and after disinfection protocols, regardless of disinfecting solution

Groups	Baseline	T1
GI	33.4 (1.30)^{Aa}	33.4 (1.66)^{Aa}
GII	35.2 (1.40)^{Ba}	31.8 (0.81)^{Bb}
GIII	31.9 (1.79)^{Ca}	30.5 (2.20)^{Ca}
GIV	34.4 (1.79)^{Aba}	32.9 (2.58)^{ABb}

Statistically significant differences between groups are indicated by different superscript uppercase letters (within column) and lowercase letters (within row).

cleaning with water and neutral soap significantly reduced hardness. When the disinfecting solutions were compared, the HC had more influence on hardness reduction, which was statistically different from CN and CHX ($P<.05$). Artificial aging did not have a significant influence on any of the tested subgroups ($P>.05$). Table 6 shows the comparison among groups, which revealed that the opacifier significantly increased the hardness of the silicone (GII; 35.23 ±1.4) in comparison with the baseline (GI), while the medium-shade pigment promoted its reduction (GIII; 31.93 ±1.79) ($P<.05$). However, the black pigment (GIV) showed hardness similar to the colorless group (GI) and the colorless with the opacifier group (GII) ($P>.05$).

Regarding color stability, the specimens for all groups showed a numeric alteration in ΔE values depending on the disinfection and the artificial aging: ΔE>0 (Table 5). In the pigmented groups (GIII and GIV), artificial aging significantly reduced the ΔE values ($P<.05$) for subgroups disinfected with CN. The GII group showed the lowest color alteration after the disinfecting procedure ($P<.05$). Artificial aging did not promote color alteration for the GII ($P>.05$), regardless of the disinfecting solution. The GIII group showed the highest values of ΔE ($P>.05$) in comparison with the other groups (Table 7), although they were statistically similar to those of the GII group after aging (T2). A significant difference was found between the ΔE values of the specimens disinfected with HC, CN, and CHX and specimens subjected to saline solution and neutral soap (Table 8).

Because a significant difference was found in the hardness of the specimens pigmented with black and medium-shade pigments, representative EDS images have been inserted. Figure 3 shows the mapping of the surface of the colorless pigment, revealing that the bulk properties consisted mainly of silicon (Si) elements because the specimens were based on a polymer of dimethylsiloxane. The surface of the specimen with medium-shade pigment (GIII) (Fig. 4) shows its bulk properties consisted of Si, oxygen (O), and iron (Fe). Figure 5 lists the bulk properties of the specimen with black pigment (GIV) consisted mainly of oxygen (O), carbon (C), cobalt (Co), and silicon (Si).

Table 7. Mean results (standard deviation) of color stability (ΔE) for each group and period, regardless of disinfecting solution

	Period	
Group	T_1B	T_2B
GI	7.28 (1.51)^{Aa}	3.88 (1.28)^{Ab}
GII	4.15 (1.40)^{Ba}	5.96 (2.66)^{BCa}
GIII	10.63 (2.68)^{Ca}	6.81 (3.05)^{Cb}
GIV	7.82 (2.26)^{Aa}	4.97 (2.14)^{ABb}

Statistically significant differences between groups are indicated by different superscript uppercase letters (within column) and lowercase letters (within row).

Table 8. Mean results (standard deviation) of color stability (ΔE) for each period and disinfecting solution, regardless of group

	Period	
Group	T_1B	T_2B
Saline solution	5.99 (1.98)^{Aa}	3.88 (2.06)^{Ab}
Hidrastis canadensis	8.00 (2.24)^{Ba}	6.81 (2.73)^{Ba}
Cymbopogon nardus	9.07 (2.04)^{Ba}	5.02 (2.42)^{Ab}
Chlorhexidine 4%	8.00 (2.08)^{Ba}	6.91 (2.46)^{Ba}
Neutral soap	6.28 (1.45)^{Aa}	4.39 (1.73)^{Ab}

Statistically significant differences between groups are indicated by different superscript uppercase letters (within column) and lowercase letters (within row).

DISCUSSION

The null hypothesis that the disinfection and artificial aging of the silicone elastomer MDX4-4210 would not affect its hardness and color stability was rejected because the silicone material's hardness and color were affected by artificial aging, the use of a dry opacifier and oil pigments, and disinfecting solutions.

Recently, the incorporation of oil pigments and dry opacifiers into the silicon matrix to lengthen the lifetime of maxillofacial silicone prostheses has been proposed, because this strategy improves their color stability and protects the silicone material from UVB rays, environmental factors, and aging.[13,18,19] However, other studies have revealed that the incorporation of such ingredients may affect the properties of silicone elastomers.[13,24,34] In the present study, the opacifier promoted the lowest color alteration in the experimental groups, regardless of the disinfecting solution. The opacifier inhibited the effects of artificial aging and promoted color stability, except in the subgroup disinfected with CN, which showed a significant reduction in the ΔE values. The subgroups disinfected with CN showed the highest ΔE values before artificial aging. Possibly, this solution promoted an extrinsic pigmentation. However, after artificial aging, this subgroup showed a reduction in ΔE values, in that the exposure to water, temperature, and UV lights removed this extrinsic pigmentation promoted by the disinfecting solution. The same result was found in the colorless group, in which all the subgroups showed reduced ΔE values after artificial aging. Clearly, artificial aging tends to promote color alteration in colorless silicone, reducing

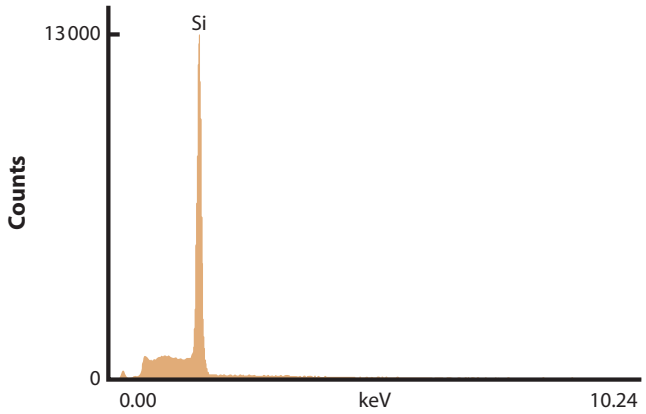

Figure 3. Representative energy dispersive spectroscopy image of colorless silicone material (MDX4-4210).

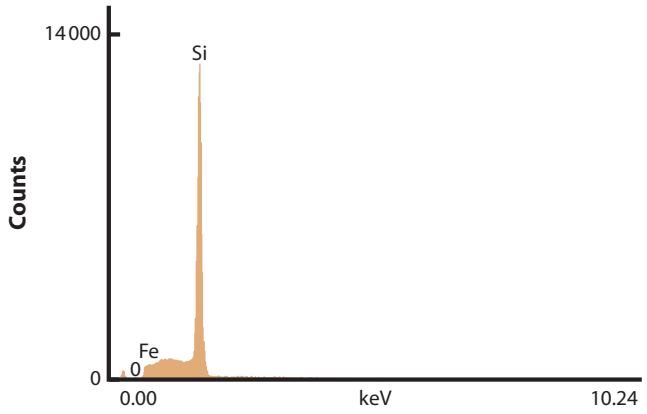

Figure 4. Representative energy dispersive spectroscopy image of pigmented silicone material (MDX4-4210) medium shade pigment.

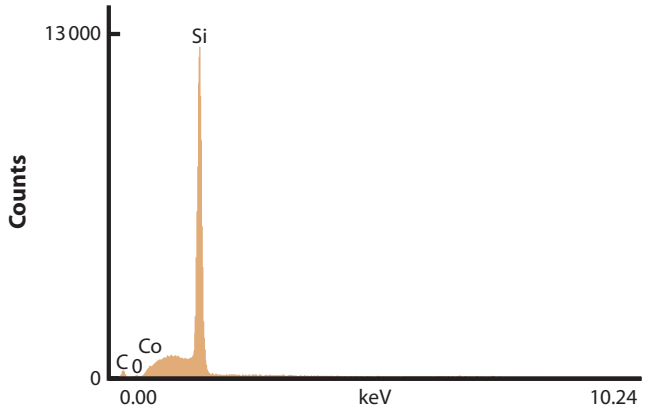

Figure 5. Representative energy dispersive spectroscopy image of pigmented silicone material (MDX4-4210) black shade pigment.

the ΔE values and potentially discoloring the silicone material. However, the opacifier helped preserve color over time, which is in agreement with other studies.[13,18,19]

The GI group was the only group not affected by the tested factors. This may have occurred because of the structural chain of the silicone rubber [poly(dimethylsiloxane), $PDMS^X$], which is composed of Si-O bonds surrounded by methyl groups (-O-Si-CH_3). This structure is different from that of natural rubber (hydrocarbons polymers, -C=C-CH_3), which has unsaturations; this structure provides silicone elastomer with resistance to some environmental conditions. Thus, disinfection and artificial aging did not affect the tested silicone elastomer (GI). However, alterations clearly occurred in the opacifier and pigment groups, and the opacifier (ZnO) significantly increased the hardness of the silicone material.[10,13,14] The incorporation of these particles should be performed carefully because silicone elastomers should be flexible enough to follow facial movements.[15,24] In addition, the type and concentration of pigment may influence the elastic and viscous portion of the properties of maxillofacial elastomeric materials; increasing the concentration of pigment decreases the energy absorption capacity.[15]

When groups were compared, the group with the medium-shade pigment (GIII) showed the lowest hardness at baseline but the highest color alteration (ΔE=10.63 ±2.68). The addition of this pigment may have affected the polymerization process of the silicone material. The manufacturer confirmed that this method of intrinsic pigmentation is a mixture of crushed cosmetic pigments and silicone oil fluid that is compatible with all silicone materials. The medium-shade pigment likely acted as a plasticizer, minimizing the networking of the polymeric chains of the silicone.[9] This hypothesis is corroborated by the manufacturer's instructions, which state that its resilience and physical properties may be affected if a silicone fluid is mixed with the silicone matrix. Thus, the highest mean ΔE for the GIII group might be explained by the lower interaction of the medium-shade pigment with the silicone matrix. This may have caused the greater susceptibly of this group to the alterations promoted by the cleaning and disinfection procedures.

This behavior, however, was not observed in the GI group, which was statistically similar to the GI and GII groups for hardness and statistically similar to the GI group for color stability (ΔE). In this context, EDS analysis was performed, and, according to this test, Fe and O were present in the medium-shade pigment. The different behaviors of the specimens in the GIII and GIV groups may be explained by the difference in the pigment composition (Figs. 4, 5). The cobalt (Co) likely worked as a filler particle and did not reduce hardness in the GIV group.

After artificial aging, a nonsignificant alteration was noted in the hardness of all tested groups when compared with the baseline. This result is advantageous, in that many studies show that artificial aging increases the hardness of the material, probably as the result of the

continuous polymerization that elastomer materials show over time.[20,24] Other studies have explained these changes in properties by alterations in the chemical structure of the polymer chains induced by the hot and humid environment. The alterations are mainly photo-oxidation of the polymers, with free radical formation (polymer oxy- and peroxyradicals) that would lead to chain scission. Other free radicals might react with each other, leading to crosslinking.[12] All those events occur simultaneously with the creation of microcracks, hardening, and the loss of color and brightness.[18] However, because aging chambers reproduce more extreme environmental conditions than occur during a patient's daily routine, such phenomena are less evident in the clinical performance of silicone prostheses.[24]

The results of the present study suggest that chemical disinfecting solutions should be the first choice for cleaning maxillofacial silicone prostheses because continuous digital friction may promote the detachment of pigments on their surface.[18,24] Cleaning the silicone material with water and neutral soap significantly reduced the hardness of the GII and GIV groups. In addition, other authors have reported that changes in elastomers after disinfection with the antimicrobial solutions used in this study are probably caused by the decomposition of the cleaning solutions into carbon monoxide, carbon dioxide, and sulfur dioxide, which could lead to either a hardening or a softening of materials.[8,21-23] This may explain why HC extract significantly reduced the hardness of the GII, GIII, and GIV groups. This extract probably also affected the resistance to compression of the pigments and opacifiers, leading to the particles being more susceptible to fracture and dissolution and producing lower resistance to penetration loading for the groups with pigments and opacifiers.[24] For color stability (ΔE), the disinfecting solutions (CHX, HC, and CN) showed similar behavior, regardless of the group, but higher ΔE values in comparison with saline solution (SS) and water and neutral soap (WN).

In general, maxillofacial silicone prostheses are considered effective for 6 months to 1 year[5] because of color instability,[10,11] the deterioration of their margins and texture, and the increase in their hardness.[4,5] Dentists and patients must minimize the factors that may affect the properties of silicone elastomers to improve their lifetime. Even though the MDX4-4210 hardness was affected as a result of aging, opacifier and pigments, and disinfecting solutions, the mean hardness results of all tested groups was considered acceptable for maxillofacial prostheses after 6 months to 1 year use (25 to 35 Shore A units).[35] However, for color stability, almost all the experimental groups showed ΔE values greater than 3.3, making them clinically unacceptable, regardless of the use of disinfecting solutions.[40-43] In summary, the statistically significant differences for hardness with regard to the experimental disinfecting solutions (HC and CN) did not seem to affect clinical performance in the silicone material over time, especially for silicone combined with compounds (pigments/opacifier).

The present study had some limitations. Only 1 silicone material was tested. In addition, the method used for artificial aging of the specimens was different from the mechanism to which maxillofacial silicone elastomers are naturally subjected.[17] Moreover, the present study manually incorporated the pigments. Further studies are necessary to improve the incorporation of such pigments into the silicone matrix so that more homogenous mixtures are obtained and the chemical interaction of both materials is improved.

CONCLUSIONS

The hardness of MDX4-4210 after the experimental procedure was considered clinically acceptable for facial prostheses. All groups showed clinically unacceptable color alterations, regardless of the disinfecting solution.

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