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Original Article

Effect of Plant-extract Disinfectant Solutions on the Specific Properties of Reinforced Maxillofacial Silicone Elastomers with Nanofiller and Intrinsic Pigment

Faiza Mohammed Hussain Abdul-Ameer

Department of Prosthodontics, College of Dentistry, University of Baghdad, Baghdad, Iraq

Abstract

Objective: This study aimed to evaluate the effects of disinfectant solutions, namely, the alcoholic extract of *Salvadora persica* L. (A1 = 10% and A2 = 15%) and chlorhexidine digluconate (A3 = 2%), on the tear strength and hardness of room temperature vulcanizing (RTV) VST50F and heat temperature vulcanizing (HTV) Cosmesil M511 silicone elastomers before and after reinforcement with nanofillers (TiO_2) and intrinsic pigment. **Materials and Methods:** A total of 320 specimens were prepared, with 160 specimens each for RTV and HTV silicone. Forty specimens were evaluated before disinfection and divided into two equal groups, namely, control (without additive) and experimental (with additive) groups, for tear strength and hardness tests. The 120 specimens were divided into three equal groups, with two equal subdivisions for tear strength and hardness tests, and were evaluated after disinfection. ANOVA and Tukey's honest significant difference tests were conducted for group comparisons (significance level set at $P < 0.05$). **Results:** The tear strength of all groups decreased after disinfection, with the highest values in the experimental group. Most comparisons showed significant differences. A1 exhibited no significant effect on the tear strength and hardness of the HTV control and the hardness of the RTV experimental specimen. The hardness of the HTV control was not significantly affected by A3. A1 with A3 did not significantly affect the tear strength and hardness of the RTV control and the tear strength of the RTV experimental specimen. The results of comparisons between A1 and A2, and A1 and A3 in the HTV tear strength of the experimental group and the A2 and A3 of the control and experimental groups were not significant. **Conclusions:** *S. persica* L. can be used as a natural disinfectant agent. The reinforcement of maxillofacial silicone prosthesis can extend its survival duration.

Keywords: Cosmesil M511 silicone, disinfectant agent, mechanical property, *Salvadora Persica* L., VST50F silicone

Introduction

Different materials are used in the construction of maxillofacial prostheses, but silicone is the most widely used material.[1] The most clinically important property of silicone is the tear resistance, particularly at the fluffy borders, which surround the maxillofacial prostheses. This feature integrates the boundary of prostheses with the facial texture. The specific adhesive is medically used to paste the margins of prostheses with surrounding tissue, and these margins are most prone to rupture when the patient tries to remove the facial prosthesis during cleaning or at night time.[2] The flexibility of the silicone used for maxillofacial prostheses is determined by its hardness, and using materials that are similar to the facial tissue softness surrounding the affected areas is preferred.[3]

Pigmentation is paramount in the manufacture of maxillofacial prostheses to improve the chances of success and effectiveness.[4] The addition of intrinsic pigment or nanofiller to the silicone has improved most of its mechanical properties, prolonging the service and use of maxillofacial prostheses.[5,6]

Several inevitable circumstances, such as prostheses disinfection, may increase the deterioration of the silicone properties. Digital friction can cause the secession of the compositions added into the matrix of the silicone for facial prosthesis, even if it is partially accomplished.[7,8] Immersion

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Address for correspondence: Dr. Faiza Mohammed Hussain Abdul-Ameer, Department of Prosthodontics, College of Dentistry, University of Baghdad, Bab-Almoadham. P.O. Box: 1417, Baghdad, Iraq.
E-mail: dr.fmha@codental.uobaghdad.edu.iq

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is a chemical disinfection method that is a substitute for cleaning the silicone maxillofacial prostheses.[7] Even though several types of solutions at different percentages are used as disinfectants, and the treatment techniques are obtainable, the properties of silicone are affected by all of them.[7,9] The ideal solution for disinfection remains debatable.[8,9]

Plants are the natural provenance of antibacterial compounds. Medicines extracted from plants have a section of care system in traditional health, and the antimicrobial properties of compounds extracted from plants are perfectly authenticated. Herbal medicines are less harmful, efficacious, and also have minimal side effects. They can be handled easily and offer low mammalian toxicity.[10] Guiotti *et al*. stated that the appropriate disinfection agents for maxillofacial silicone prostheses are phytotherapy solutions.[11]

Salvadora persica L. of the Salvadoraceae family is an evergreen shrub with whitebark, smooth green leaves, and 4–6 m short trunk. According to medicines used in the Ayurvedic system, *S. persica* L. is highly effective for dental grievance. This plant is one of the most widely applied oral health plants in the Muslim community.[12] Experimental and descriptive researches have extensively confirmed that the *S. persica* plant and its extracts provide advantageous effects on the oral tissues and assist in maintaining good oral hygiene.[13]

Al-Sabawi *et al.* reported the significant antimicrobial effect of the alcoholic extract of *S. persica* L. (1%, 5%, 10%, 15%, and 20% concentrations), with superior effect at 15%, against aerobic and anaerobic bacteria recovered from necrotic pulps teeth.[14]

This study was performed using the two following types of disinfectants: The 10% and 15% alcoholic extract of *S. persica* L. (Miswak) solutions and 2% chlorhexidine digluconate (as control disinfectant agent). Their effects on tear strength and shore A hardness for room temperature vulcanizing (RTV) VST50F and heat temperature vulcanizing (HTV) Cosmesil M511 silicone elastomers before and after the addition of nanofiller (TiO_2) and intrinsic pigment were evaluated.

Materials and Methods

TiO_2 nanofiller powder (Anatase, 10–30 nm, 99%, SkySpring Nanomaterials Inc., TX, USA) and one type of intrinsic cream color pigment, that is, FI-SK07–silicone intrinsic functional pigment (Factor II Inc., AZ, USA), were added into (RTV) VST50F and (HTV) Cosmesil M511 silicone elastomers (Factor II Inc., AZ, USA).

A total of 320 specimens were prepared, which included 160 specimens for VST50F (RTV) and 160 specimens for Cosmesil M511 (HTV). Each group of specimens was further split into two subgroups. The first group (40 specimens) was evaluated before disinfection and further split into two similar subgroups for tear strength and hardness tests as follows: 10 specimen controls before disinfection, that is, silicone elastomer without additions; and 10 specimens for the experimental groups before disinfection, that is, silicone elastomer with a mixture of TiO_2 nanofiller and intrinsic pigment. The second group (120 specimens) was evaluated after disinfection and further divided into three equal subgroups according to the type of disinfectant. Each subgroup was further divided into two other equal subdivisions for each test, that is, control and experimental groups, after disinfection.

The most suitable percentages of the mixture of TiO_2 nanofiller and intrinsic pigments that improved tear strength with low effect on hardness (as derived from a pilot study) were 0.25 wt% TiO_2 nanofiller + 0.25 wt% intrinsic pigment for VST50F and 0.2 wt% TiO_2 nanofiller + 0.25 wt% intrinsic pigment for Cosmesil M511.

A mold was made from acrylic (Glass-look acrylic, France) for VST50F and from metal (Cast iron sheets, Iraq) for Cosmesil M511. AutoCAD-2013 (Autodesk Inc., San Rafael, CA, USA) was used to design the dimensional specimens, and a computer numerical control machine was utilized to process the matrices of both molds that will be used for pouring the materials.[15]

The two groups of specimens were fabricated for each elastomer. The control group was made in accordance to the manufacturer's instruction by mixing a ratio of 1:10 by weight of a crosslinker (Part B) to a base (part A). The mixture was then mixed under vacuum by a mixer (Multivac 3 vacuum, Degussa, Germany) for 5 min at 360 rpm and 10 bar.[16,17] By contrast, the experimental group was made using a mixing ratio similar to that of the control group in addition to the mixture of TiO_2 nanofiller and intrinsic pigment mixed with the base before mixing the catalyst for 2 min in the absence of vacuum. The mixture was then mixed again for 5 min with a vacuum.[6,17]

The material was mixed and poured at a relative humidity (RH) of 50% ± 10% and controlled temperature of 23°C ± 2°C.[18] Based on the manufacturer's recommendation, VST50F required 2–4 h of setting time, whereas Cosmesil M511 necessitated an oven (hot and dry) and required approximately 1 h of setting time. In an air-conditioned room, a light-proof box (custom-made) was used to store the specimens. The storage temperature was 10°C–30°C and RH ≤80%.[19] Before testing and disinfection, the specimens were stored for 24 h at 23°C ± 1°C and 50% ±10% RH[20] and then at 23°C ± 2°C (standard laboratory condition) for at least 3 h following flash removal.[21] A sharp #10 surgical blade and a scalpel were utilized to remove the flash.[22]

Specimen fabrication and tear strength test were performed on the basis of ASTM (D624).[18] Tear initiation strength was measured using a type C specimen. A computer-controlled universal testing machine (WDW-20, Laryee Technology Co. Ltd., Beijing, China) was used to organize and conduct the test.[18] The tear strength values were measured using the following equation:

Tear strength = F/D,

Where F is the maximum force required to break the specimen (unit: Kilonewtons), and D is the average thickness of the specimen (unit: Meter).[18]

The Shore A hardness test was performed on the basis of ASTM (D2240) by using 25 mm × 25 mm × 6 mm square specimens, and a digital durometer tester (Type: A Shore hardness/HT6510/portable with a 1.25 mm-diameter blunt indenter) was used.[21] Five different reading points were selected on the specimen. The points were 6 mm apart and 6 mm from the periphery. The specimen hardness is the average of the measured values.[23]

Two types of disinfectant agents were selected. The plant extract disinfectant solutions were two concentrations of a diluted solution from the alcoholic extract of *S. persica* L. in aqueous powder form. This solution was selected as the natural disinfectant solution and compared with a conventional disinfectant solution (chlorhexidine digluconate, 2%) (GLUCO-CHeX 2%), which is the most suitable disinfectant agent for the maxillofacial silicone.[24]

The root sticks of *S. persica* L. (1600 g) were cut into small pieces by using a sharp knife and powdered using a commercially available food grinder. Approximately 120 ml of ethanol (60%) was then added to 40 g of *S. persica* L. powder in a well-capped and sterile flask. The mixture was left at room temperature for 3 days with continuous stirring in an electrical stirrer device (HY-HS11 S/N XM0802012 KOREA) to hasten the extraction. No. 1 filter paper was used for filtration. The extract was incubated at 37°C until dry, and the aqueous extract powder was stocked in the refrigerator and in the well-capped and sterile flask until the extract was used.[14]

Two *S. persica* L. concentrations, namely, 10% and 15%, were selected because these concentrations showed good antibacterial effect.[14] To prepare these solutions, 10 g and 15 g of the alcoholic extract of *S. persica* L. were weighted and placed in a 100 ml volumetric flask, and 100 ml of nonionized distilled water was added as solvent. Both solutions were shaken to dissolve the powder and then stocked in screw-capped and sterile flasks in the refrigerator until the solutions were used.

Tear strength and hardness were measured before and after each disinfection. The applied disinfection procedures are depicted in Table 1. Specimens were immersed in the disinfectant solution for 30 h, which is nearly equal to 1 year of use because 30 h is equal to 360 days of cleaning for 5 min daily.[25]

The data were evaluated using SPSS version 24 (IBM Corp., NY, USA), and one-way ANOVA and Tukey honesty significant difference tests were conducted for group comparison before and after disinfection with significance level set at $P < 0.05$.

Table 1: Disinfection procedures applied in this study

Disinfection solution	Procedure duration (h)	Simulated years of service	Coding
10% *S. persica* L.	30	1	A1
15% *S. persica* L.	30	1	A2
2% chlorhexidine digluconate	30	1	A3

S. persica – Salvadora persica

Results

The maximum values for the tear strength before disinfection was observed in the RTV experimental and control specimens, whereas the lowest values were observed in the HTV experimental and control specimens. All groups showed reduced values after disinfection [Table 2]. The tear strength in each type of specimen for each material showed significant differences ($P < 0.05$) [Table 2]. Multiple comparisons test showed significant differences ($P < 0.05$), but the decrease in the tear strength of the HTV control was not significant after disinfection with A1 ($P > 0.05$). The effects of A2 and A3 on the HTV control were not significant. A1 and A2, A1 and A3, and A2 and A3 solutions displayed the same effects on the tear strength of HTV experimental specimens. For the RTV silicone, the only nonsignificant difference was between A1 and A3 on the control and experimental specimens [Table 3].

The maximum values for hardness before disinfection were observed in HTV and RTV experimental specimens. After disinfection, the values in some groups were reduced, whereas those in others increased [Table 4]. The effect of disinfection on the hardness of each type of specimen for each material was significant [Table 4]. Multiple comparisons tests showed significant differences ($P < 0.05$). However, the hardness of the HTV control was not significantly different after disinfection with A1 and A3. No differences were found between A1 and A2 regarding the effects on HTV control and experimental specimens. The hardness of RTV experimental specimens was not significantly affected by disinfection with A1. A1 with A3 showed the same effect on the hardness of the RTV control [Table 5].

Discussion

After disinfection, the changes reported in the mechanical and physical properties of the silicone polymer were mostly caused by changes in the structure. These changes were related to the distribution of the molecular masses because of either further cross-linking or chain scission.[22,26]

Before and after disinfection, the tear strength values of the experimental group for both materials were higher than those of the control group. This phenomenon was due to the incorporation of nanofillers and intrinsic pigments into the silicone matrix, thereby prolonging the lifespan of the maxillofacial silicone.[6,7,16,27] For Cosmesil M511, the tear strength of the control and experimental specimens after disinfection decreased significantly except for the control group was not significantly reduced after A1 disinfection. This result may be due to the reduced A1 concentration. For VST50F, a significant reduction in tear strength was observed after disinfection. The reduction in tear strength following disinfection may be due to the degree of polymerization, crosslinking, or chain scission that resulted in degradation. Exposure to moisture has also propagated crosslinking. Acceleration in the polymerization of the silicone elastomer occurs after immersion in disinfecting solutions.[28] The tear

Table 2: Descriptive statistics and the effect of disinfection on the tear strength depending on the type of the specimen of each material using one-way ANOVA

Materials	Group	Disinfection	Descriptive statistics			Comparison	
			Mean±SD	Minimum	Maximum	*F*-test	*P*
HTV	Control	B	11.741±0.344	11.111	12.182	20.054	0.000*
		A1	11.157±0.709	10.476	12.38		
		A2	9.882±0.664	9.048	11.055		
		A3	10.186±0.643	9.5	11.429		
	Experimental	B	13.680±0.573	13.065	14.572	17.111	0.000*
		A1	12.017±0.614	10.909	12.857		
		A2	11.868±0.925	10.952	13		
		A3	11.540±0.761	10	12.38		
RTV	Control	B	24.620±0.391	23.737	25	70.372	0.000*
		A1	23.172±0.826	21.938	24.623		
		A2	20.545±0.805	19.597	21.827		
		A3	23.816±0.534	23.232	24.623		
	Experimental	B	27.259±0.501	26.262	28.061	40.328	0.000*
		A1	25.365±0.720	24.623	26.262		
		A2	23.600±0.976	22.5	25.252		
		A3	26.289±0.828	25.125	27.638		

*Significant differences (*P*<0.05). A1 – 10% *S. persica* L., A2 – 15% *S. persica* L., A3 – 2% chlorhexidine digluconate, B – Before disinfection, HTV – Cosmesil M511, RTV – VST50F. SD – Standard deviation, HTV – Heat temperature vulcanizing, RTV – Room temperature vulcanizing, *S. persica* – *Salvadora persica*

Table 3: Multiple comparisons with Turkey's honestly significant difference after ANOVA

Disinfectant	HTV				RTV			
	Control		Experimental		Control		Experimental	
	MD	*P*	MD	*P*	MD	*P*	MD	*P*
B								
A1	0.584	0.157**	1.663	0.000*	1.448	0.000*	1.895	0.000*
A2	1.859	0.000*	1.812	0.000*	4.074	0.000*	3.659	0.000*
A3	1.555	0.000*	2.141	0.000*	0.804	0.049*	0.970	0.039*
A1								
A2	1.275	0.000*	0.149	0.968**	2.626	0.000*	1.765	0.000*
A3	0.971	0.005*	0.478	0.471**	−0.644	0.153**	−0.925	0.053**
A2								
A3	−0.304	0.681**	0.329	0.747**	−3.270	0.000*	−2.689	0.000*

*Significant differences (*P*<0.05), **No significant differences (*P*>0.05). A1 – 10% *S. persica* L., A2 – 15% *S. persica* L., A3 – 2% chlorhexidine digluconate, B – Before disinfection, HTV – Cosmesil M511, RTV – VST50F. MD – Mean difference, HTV – Heat temperature vulcanizing, RTV – Room temperature vulcanizing, *S. persica* – *Salvadora persica*

strength of silicone was mostly influenced by the amount and arrangement of crosslinks. The arrangements with high crosslinking flexibility show the best tear strength, whereas those with a dense crosslinking strain with the network is brittle.[23]

Non-significant results in tear strength were reported between A1 and A2 and A1 and A3 on the HTV experimental group, between A2 and A3 on the HTV control and experimental groups, and A1 and A3 on RTV control and experimental groups. The similarity in the effects between two *S. persica* L. concentrations and A3 can be due to the saturation effect of chlorhexidine, which is a chemically inert agent.[29] *S. persica* L. has a low concentration and safe natural ingredients, such as trimethylamine, salvadorian, silicon dioxide, vitamin C, fluorides, chloride, sulfur, resins, sterol, flavonoids, acids, polysaccharide, phenol lignin derivatives, furans, essential oils, butanediamide, and N-benzyl-2-phenylacetamide.[30-33] Thus, the two concentrations of *S. persica* L. showed effects similar to that of chlorhexidine on silicone materials. The difference in the effects of the two concentrations of *S. persica* L. on both types of silicone materials was due to the various methods and degrees of curing. These methods resulted in the different degrees of polymerization and crosslinking. Incorporating nanofillers with intrinsic pigments did not protect the experimental specimens but reduced the degradation and deterioration of the material compounds. Tear strength reduction was possibly due to the crosslinking propagation, which occurred when silicone was exposed to moisture.

Table 4: Descriptive statistics and the effect of disinfection on the hardness depending on the type of the specimen of each material using one-way ANOVA

Materials	Group	Disinfection	Descriptive statistics			Comparison	
			Mean±SD	Minimum	Maximum	*F*-test	*P*
HTV	Control	B	25±0.464	24.1	25.9	6.957	0.001*
		A1	25.4±0.371	24.6	26		
		A2	25.7±0.583	24.9	26.4		
		A3	24.83±0.440	24.2	25.8		
	Experimental	B	28.55±0.587	27.6	29.4	44.126	0.000*
		A1	27.33±0.362	26.9	27.8		
		A2	27.19±0.390	26.7	27.8		
		A3	26.22±0.447	25.5	26.7		
RTV	Control	B	26.95±0.217	26.5	27.2	82.266	0.000*
		A1	28.45±0.615	27.2	29.3		
		A2	24.9±0.521	24.3	25.5		
		A3	28.1±0.741	26.8	29.1		
	Experimental	B	28.3±0.424	27.6	28.9	15.582	0.000*
		A1	28.56±0.613	27.4	29.5		
		A2	27.39±1.050	26.2	28.9		
		A3	29.55±0.606	28.8	30.5		

*Significant differences ($P<0.05$). A1 – 10% *S. persica* L., A2 – 15% *S. persica* L., A3 – 2% chlorhexidine digluconate, B – Before disinfection, HTV – Cosmesil M511, RTV – VST50F. SD – Standard deviation, HTV – Heat temperature vulcanizing, RTV – Room temperature vulcanizing, *S. persica* – *Salvadora persica*

Table 5: Multiple comparisons with Tukey honestly significant difference after ANOVA

Disinfectant	HTV				RTV			
	Control		Experimental		Control		Experimental	
	MD	*P*	MD	*P*	MD	*P*	MD	*P*
B								
A1	−0.4	0.246**	1.22	0.000*	−1.5	0.000*	−0.26	0.846**
A2	−0.7	0.011*	1.36	0.000*	2.05	0.000*	0.91	0.034*
A3	0.17	0.851**	2.33	0.000*	−1.15	0.000*	−1.25	0.002*
A1								
A2	−0.3	0.493**	0.14	0.901**	3.55	0.000*	1.17	0.004*
A3	0.57	0.048*	1.11	0.000*	0.35	0.506**	−0.99	0.018*
A2								
A3	0.87	0.001*	0.97	0.000*	−3.2	0.000*	−2.16	0.000*

*Significant differences ($P<0.05$), **No significant differences ($P>0.05$). A1 – 10% *S. persica* L., A2 – 15% *S. persica* L., A3 – 2% chlorhexidine digluconate, B – Before disinfection, HTV – Cosmesil M511, RTV – VST50F. HTV – Heat temperature vulcanizing, RTV – Room temperature vulcanizing, MD – Mean difference, *S. persica* – *Salvadora persica*

The polymerization of silicone is rapid because of immersion in the disinfecting solutions. The growth during cross-linking and increase in density occurred from the time of mixing of the ingredients of silicone to the time after the prostheses were employed. Even though cross-linking propagation improved tear strength, this process also decreased with every increase in cross-linking. The latter resulted from the fashioning of the hurdles that prohibited the slipping of molecules on each other. This phenomenon caused the production of a material that was inelastic and brittle and tears at less distortion.[26] The amount of crosslinking was adopted in accordance to the concentration and on the nature of the thermal initiator, the additives, the fillers, temperature required for curing, and time requirement for polymerization.[28,34]

For Cosmesil M511, most results displayed a significant difference in hardness. The hardness of all experimental specimens decreased significantly after disinfection, which may be due to the additives incorporated into the silicone matrix, thereby promoting water absorption.[25]

The increase in the hardness of the HTV control specimen after disinfection with A1 and its decrease after A3 disinfection were not significant. This result may be due to the saturation effect of A3, which is a chemically inert agent,[28] whereas A1 has a low concentration and safe natural ingredients. No difference was reported between the effect of A1 with A2 after disinfection on control and experimental groups, which may be due to the negligible variations between the two concentrations of *S. persica* L.

All results for VST50F showed a significant difference in hardness except for that after A1 disinfection in the experimental group. Thus, the additive protected the hardness of the material for this type of silicone. A similar effect was reported between A1 and A3 on the hardness of the RTV control group, which explained the similarity between the effects of the two disinfection solutions. The similarity in the effects between A1 and A3 may be due to the low concentration of *S. persica* L., and all the ingredients in the natural product showed a low and safe effect. By contrast, chlorhexidine acts via saturation and is considered as chemically inert.[29]

The difference between HTV and RTV silicone materials is due to the crosslinking amount adopted on the concentration, thermal initiator nature, additives, fillers, temperature required for curing, and polymerization time.[28,34]

The values of the hardness related to the maxillofacial elastomers should remain within a wide suitable range. This range was nearly between 10 and 45, depending on the region of the face required to be replaced given the distinct stiffness and hardness of the different facial.[3,8] From this scale, all changes in the average hardness values were clinically acceptable.

The significant increase in the hardness between several groups may be related to the continuous polymerization of the silicone that occurred through aging. The polymer density increased after polymerization cross-linking, resulting in cross-links with minimal spaces. This process has caused the deformation to decrease distance, that has led to a rigid polymer.[25,35] The decrease in the hardness of silicone displayed a high relationship between TiO_2 and intrinsic pigment with the matrix of the polymer. Goiato *et al*. stated that, during disinfection, if the additives particles were removed, a polymer with high porosity is obtained, and hardness is reduced.[25,29] The change in the hardness of polymer may be related to the change in the surface characteristics because of the removed contents from the polymer matrix into the water or into the solutions of the disinfection.[7,29,36] This phenomenon elucidated why some groups in the present study exhibited reduced hardness.

Conclusions

S. persica L. at 10% and 15% can be used as a natural disinfectant. The unreinforced HTV specimen was safely disinfected with 10% *S. persica* L. solution. Adding intrinsic pigments and nanofillers into the silicone matrix can extend the service time of maxillofacial silicone prostheses.

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Conflicts of interest

There are no conflicts of interest.

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