Effect of Disinfection on Some Properties of Heat-Vulcanized Maxillofacial Silicone Elastomer Reinforced by Nano Silicone Dioxide

Madiha Fouad, B.D.S. (a)  
Mohammed Moudhaffer, B.D.S., M.Sc. (b)

ABSTRACT

Background: The daily cleaning routine of the silicone maxillofacial prostheses by the patient may cause some alteration in the materials properties. The purpose of the present study was to investigate the effect of different disinfection procedures on some properties of silicon dioxide reinforced Cosmesil M511 HTV maxillofacial silicone.

Materials and Methods: One hundred and sixty (160) specimens were prepared by mixing 5% SiO nano particles and 0.5% intrinsic cream color into the silicone polymer according to manufacturer’s instructions. Specimens were divided into 4 groups according to the disinfection procedure tested (tear strength, surface hardness, surface roughness and color) with 40 specimens each. Each group was further subdivided according to the disinfection procedure conducted (control, microwave exposure, neutral soap and 4% chlorhexidine gluconate). Measurements for tear strength were done using universal testing machine. Surface hardness test was carried out with a Shore A Durometer. Surface roughness was analyzed with a portable digital Profilometer. Color change was established with a Spectrophotometer. After the initial testing, all specimens were submitted to disinfection procedure 3 times a week for 60 days. Measurements were repeated and data were statistically analyzed using one-way ANOVA followed by Fisher’s LSD or Games-Howell test.

Results: Spectrophotometer results showed non-significant decrease in the light absorbance of all experimental groups after disinfection, indicating a strong integration between the nano filler and the polymeric chains, which was not broken during the disinfection procedure. Highly significant increase in Shore A hardness was recorded, while the decrease in surface roughness was highly significant in all experimental groups. Tear strength reduced significantly after disinfection in all experimental groups.

Conclusion: Disinfection seemed to cause different amount of alteration in all of the tested properties of silicone. High color stability is expected in this type of maxillofacial silicone after disinfection. Although microwave exposure had increased the hardness of the material, it is considered a satisfactory disinfection procedure since it caused the least effect on the tear strength and surface roughness of the material. Therefore, microwave exposure is recommended for the disinfection of maxillofacial silicone prostheses.

Key words: Disinfection, maxillofacial prostheses, reinforced silicone. (J Bagh Coll Dentistry 2016; 28(4):16-21)

INTRODUCTION

Despite the advances in plastic and reconstructive surgery, there are cases with extensive loss of tissues that cannot be surgically corrected because of lack of sufficient donor tissue, age and general condition of the patient. Maxillofacial prostheses were introduced as a natural need of human to repair or hide their facial defect (1).

Since the introduction of silicone elastomer by Barnhart in 1960, it has been used as the material of choice in maxillofacial prostheses due to its inertness, strength, durability, biocompatibility and ease of manipulation and coloring. A successful maxillofacial prosthesis should be tough and strong, but at the same time it should remain soft and pliable in order to cope with facial movements (2).

However, deterioration of the properties of the prosthesis is a major problem that is mainly caused by environmental factors, UV light exposure, skin secretions, microbial ingrowth, use of adhesives and daily handling and cleaning of the prostheses by patients (3-8). For these reasons, facial prostheses require remake and replacement every 12-18 months, which is costly and time-consuming for both, patients and prosthodontists (9, 10).

Prosthesis hygiene is an important factor for maintaining the health of the soft tissue underneath the prosthesis and for keeping the prosthesis itself in a good condition. Since silicone prostheses are in direct contact with facial tissues and fluids for extended time, microorganisms can colonize and form a biofilm leading to skin infections and degrading the prostheses material as well (11).

Patients usually disinfect their prosthesis for 3 to 5 minutes daily. Neutral soap, chlorhexidine gluconate and using microwave exposure are some of the disinfectants used with silicone prostheses. Nevertheless, the daily use of disinfectants, using aggressive chemical solutions and mechanical cleansing reduce the service-life

M.Sc. student. Department of Prosthodontics. College of Dentistry, University of Baghdad.

Assistant Professor. Department of Prosthodontics. College of Dentistry, University of Baghdad.
of the prosthesis and raises the need to its replacement (9,12). Therefore, the disinfecting solution used must be selected with caution in order to avoid the extraction and deterioration of the material compounds during disinfection procedure (9,13).

The purpose of this study was to evaluate the possible alteration in some physical and mechanical properties of silicone dioxide reinforced M511 Cosmesil HTV maxillofacial silicone after application of three different disinfection procedures. The properties tested are tear strength, shore A hardness, surface roughness and color stability. These properties were tested under the influence of neutral soap, 4% chlorhexidine Gluconate and microwave exposure disinfection procedures.

MATERIALS AND METHODS

One-hundred and sixty (160) samples were prepared according to manufacturer’s instructions. The silicone used was Cosmesil M511 (Factor II Inc., USA) reinforced with Silicone dioxide nano fillers (US Research Nanomaterial, USA). Compounding of the nano SiO$_2$ to Part A (base) of the silicone was done before mixing with part B (crosslinker). The mixing ratio was 1:10 base to crosslinker with the addition of 5% nano SiO$_2$ concentration (14).

Cream color liquid pigment was added to the reinforced silicone at the mixing stage. The pigments were weighed in a precision scale to constitute 0.5% of the silicone weight. After mixing by a vacuum mixer, the material was injected into custom made metal molds, which were made according to the dimensions approved by ISO specifications (15,16) (Fig. 1). Molds were sandwiched by two Vaseline coated glass slabs and closed tightly. Silicone was then cured in a dry heat oven at 100 C° for 1 hour.

Figure 1: Custom made metal molds.

After polymerization, specimens were removed from the molds carefully and excess flush was trimmed with a scalpel. Scanning Electron Microscope (SEM) had been done for some samples in order to insure the homogeneity of SiO$_2$nano particles dispersion within the silicone polymeric matrix. Initial testing was then performed for the following properties:

- **a-Tear Strength:** Tear test samples were fabricated and tested according to ISO 34-1:2010 specifications (15). Trouser shaped samples with right angle were fabricated with 2 ± 0.2mm thickness. Computerized Universal testing Machine (Instrone) was used; samples were stretched at a rate of 500 mm/ min until rapture (17). Tear strength (T) was then calculated according to the following formula: $T=F/D$ where (F) is the maximum force exerted to break the specimen and (D) is the thickness of the specimen.

- **b-Shore A Hardness Test:** Samples were fabricated according to ISO 7619-1:2010 specifications (16), the dimensions of the test samples were 25mm x 25mm x 6mm (18). Samples were tested using a Digital Shore A Durometer (HT-6510A – China). Five measurements were carried out for each specimen and the average for these measurements was calculated (18,19).

- **c-Surface Roughness Test:** samples were fabricated according to ISO 7619-1:2010 specifications (16), test samples have the same dimensions of the samples used for testing surface hardness (7). A portable digital roughness tester (Profilometer) was used (TR 220, Beijing TIME High Technology Ltd., China). 3 readings were done for each specimen, which was then transformed into mean values (19).

- **d- Spectrophotometer Color Change:** Disc samples with diameter of 20mm and thickness of 2mm were fabricated according to Han et al. (20). Color absorption was evaluated using a Spectrophotometer UV (Model UV-1800, Shimadzu, Kyoto, Japan).

Thereafter, specimens were divided into 3 subgroups of 40 samples and stored in a light proof container. Samples were divided according to the mode of disinfection performed into:

- **Microwave exposure:** Samples were subjected to microwave radiation for 3 minutes at 650 W (Samsung – Model MS23F301EAK– 230 V- 50 Hz- 1150 W – Malaysia). Samples were immersed in a glass container with 200 mL of tap water which was replenished after each cycle (6,9,12).

- **Soap:** Samples were immersed in the solution (Johnson and Johnson GmbH, Italy) for 75 minutes a day, and then rinsed with water (9,12).

- **4% Chlorhexidine Gluconate:** Samples were immersed in the solution for 10 minutes a day and then rinse with water (5,18,21,23).

All disinfection procedures were carried out 3 times a week for 60 days (18,19,22,23). After disinfection, the specimens were dried with paper.
towel to insure that no absorption of solutions occurred, specimens were then stored again. At the end of the disinfection period, specimens were submitted to a new testing. Statistical analysis of the collected data was then performed with SPSS 19.0 software with a significance level of 0.05. One-Way ANOVA was used for comparing variables among groups, followed by Fisher’s LSD or Games-Howell test.

RESULTS

SEM images had shown regular and uniform distribution of the SiO$_2$ nano particles within the polymeric matrix as shown in (fig. 2).

Figure 2: SEM

Tear strength reduced significantly after disinfection in all experimental groups (table 1). Microwave exposure recorded the highest tear strength (19 N/mm), whereas soap disinfection group recorded the lowest (17 N/mm).

Shore A hardness increased high-significantly (table 2). Microwave exposure had recorded the most noticeable increase in hardness (38.55), whereas samples disinfected with chlorhexidine were the least changed (37.61).

The decrement in surface roughness was highly significant after disinfection (table 3). Microwave exposure was the group of least decrement in surface roughness (0.392 µm); whereas chlorhexidine gluconate disinfection was the group of highest decrement (0.227 µm) compared to the control group.

Spectrophotometer results had shown non-significant decrease in the light absorbance of all experimental groups after disinfection (table 4). Samples disinfected with 4% chlorhexidine gluconate were the most color stable with the least change in light absorption (1.94%), whereas samples disinfected with microwave exposure were the least color stable with the highest reduction in light absorption (1.91%).

### Table 1: Descriptive statistics, One-way ANOVA and LSD of Tear Strength

<table>
<thead>
<tr>
<th></th>
<th>Control A Mean</th>
<th>Soap B Mean</th>
<th>CHX C Mean</th>
<th>Microwave D Mean</th>
<th>ANOVA F-test</th>
<th>Sig.</th>
<th>Groups</th>
<th>P-value</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>10</td>
<td>10</td>
<td>10</td>
<td>10</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>21</td>
<td>17</td>
<td>18</td>
<td>19</td>
<td>3.501</td>
<td>0.025</td>
<td>(S)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SD</td>
<td>2.25</td>
<td>2.14</td>
<td>3.56</td>
<td>3.85</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SE</td>
<td>0.71</td>
<td>0.67</td>
<td>1.12</td>
<td>1.22</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Min.</td>
<td>18</td>
<td>15</td>
<td>12</td>
<td>13</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Max.</td>
<td>25</td>
<td>21</td>
<td>24</td>
<td>24</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Table 2: Descriptive statistics, One-way ANOVA and LSD of Surface Hardness

<table>
<thead>
<tr>
<th></th>
<th>Control A Mean</th>
<th>Soap B Mean</th>
<th>CHX C Mean</th>
<th>Microwave D Mean</th>
<th>ANOVA F-test</th>
<th>Sig.</th>
<th>Groups</th>
<th>P-value</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>34.835</td>
<td>37.710</td>
<td>37.610</td>
<td>38.550</td>
<td>42.575</td>
<td>0.000</td>
<td>(HS)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>0.634</td>
<td>0.844</td>
<td>1.028</td>
<td>0.534</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SD</td>
<td>0.201</td>
<td>0.267</td>
<td>0.325</td>
<td>0.169</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SE</td>
<td>0.353</td>
<td>0.404</td>
<td>0.456</td>
<td>0.356</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Min.</td>
<td>33.6</td>
<td>36.4</td>
<td>36.4</td>
<td>37.6</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Max.</td>
<td>35.7</td>
<td>39.1</td>
<td>39.1</td>
<td>39.2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Table 3: Descriptive statistics, One-way ANOVA and Games-Howell test of Surface Roughness

<table>
<thead>
<tr>
<th></th>
<th>Control A Mean</th>
<th>Soap B Mean</th>
<th>CHX C Mean</th>
<th>Microwave D Mean</th>
<th>ANOVA F-test</th>
<th>Sig.</th>
<th>Groups</th>
<th>P-value</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>0.680</td>
<td>0.261</td>
<td>0.227</td>
<td>0.392</td>
<td>102.659</td>
<td>0.000</td>
<td>(HS)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>0.105</td>
<td>0.039</td>
<td>0.026</td>
<td>0.057</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SD</td>
<td>0.033</td>
<td>0.012</td>
<td>0.008</td>
<td>0.018</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SE</td>
<td>0.443</td>
<td>0.208</td>
<td>0.19</td>
<td>0.312</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Min.</td>
<td>0.797</td>
<td>0.320</td>
<td>0.271</td>
<td>0.482</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Max.</td>
<td>0.797</td>
<td>0.320</td>
<td>0.271</td>
<td>0.482</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
DISCUSSION
Degradation of the physical properties and discoloration of maxillofacial silicone are the main causes that necessitate replacement of the prosthesis every 6 months (24). Maxillofacial silicone elastomers must have some properties which include: high tear resistance, similar hardness to the skin of the defective site and color stability (25). The changes in the physical and mechanical properties of silicone polymer after disinfection is mainly caused by structural changes in the distribution of the molecular masses due to either chain scission or further cross-linking (26,27). In order to have prosthesis with thin and fine margins that blind with the surrounding tissues, high tear strength is required. In the present study, significant reduction in the values of tear strength resulted after the disinfection period in all the experimental groups. This reduction could be attributed to the propagation of cross-linking that occurs as the material is exposed to moisture. Immersion in disinfecting solutions accelerates the polymerization of silicone (28). Tear strength is mainly affected by the arrangement and amount of cross-links. More flexible cross-linking arrangements yields in better tear strength, whereas high cross-linking densities tighten and brittle the network (25,29).

This increase in cross-linking density continues from the mixing of the component to after the structural application. Although tear strength increase upon cross-linking, it is also reduced with too high level of cross-linking due to the formation of obstacles that prevent the molecules from sliding past each other, resulting in inelastic brittle material that ruptures at lower deformation (3,26,29,30).

The results of tear strength in this test was in accordance with Hatamleh et al (26) and Gautriaud et al (29) who claimed reduction in tear strength values after disinfection. Highly-significant increase in Shore A hardness was resulted irrespective of the disinfection procedure. This increase in the materials' hardness was attributed to the ongoing silicone polymerization which occurs during aging process. Post-polymerization cross-linking increases the density of the polymer, leading to minimal space between the cross-links to deform to lesser distance, therefore increasing the rigidity of the material (18,19,31,32). This increase in the materials' hardness also indicates a strong association of the SiO\textsubscript{2}-nano-filler with the polymeric matrix. If these particles were removed during the disinfection procedure, increase in the porosity of the polymer and therefore reduction in the hardness would be expected as was indicated by Goiato et al (18).

Microwave exposure disinfection caused the most significant increase in the materials hardness. Thermal cycles which occur during microwave exposure, work against the water uptake that leads to softening of the material. In addition to that, temperature raise during microwave cycles could lead to further polymerization reaction (12,17). Elastomeric structure become denser when exposed to high energy radiation due to the intensified cross-linking, which is directly proportional to the dose and duration of the radiation (26). On the contrary, Chlorhexidine gluconate caused the least effect, which could be attributed to the fact that chlorhexidine is chemically inert and acts by saturation (18). Considering neutral soap, disinfected specimens showed mild alteration in materials hardness. Neutral soap was considered as control disinfectant in many studies since it is chemically inert (21, 26, 33). To be clinically applicable, the hardness value of maxillofacial silicone prosthesis should be close to the hardness of the missing facial part. This value ranges from 10-45 according to Eleni et al, 2013. Therefore, all the changes in hardness values in the present study could be considered as clinically acceptable.

The results of Shore A hardness in this study were in accordance with Eleni et al (3,9), Goiato et al (19); Hatamleh et al (26), Gautriaud et al (29) who recorded increase in the elastomeric hardness after disinfection. On the contrary, Eleni et al (12) had recorded decrease in the hardness of the material after disinfection; this could be attributed to the long period of immersion and different disinfecting solution.

### Table 4: Descriptive statistics and One-way ANOVA of Color Absorbance

<table>
<thead>
<tr>
<th></th>
<th>Control A</th>
<th>Soap B</th>
<th>CHX C</th>
<th>Microwave D</th>
<th>ANOVA F-test</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>10</td>
<td>10</td>
<td>10</td>
<td>10</td>
<td>1.316</td>
<td>0.284 (NS)</td>
</tr>
<tr>
<td>Mean</td>
<td>2.090</td>
<td>1.929</td>
<td>1.940</td>
<td>1.917</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SD</td>
<td>0.097</td>
<td>0.249</td>
<td>0.293</td>
<td>0.208</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SE</td>
<td>0.031</td>
<td>0.079</td>
<td>0.093</td>
<td>0.066</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Min</td>
<td>1.930</td>
<td>1.631</td>
<td>1.426</td>
<td>1.623</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Max</td>
<td>2.180</td>
<td>2.244</td>
<td>2.234</td>
<td>2.151</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Restorative Dentistry

19
Surface roughness was tested in the present study since it is a good indicator for the bacterial colonization and adhesion. In addition to that, mechanical properties are also affected by the roughness of the surface since irregularities may lead to nucleation sites for cracks. Significant reduction in the surface roughness had resulted irrespective of the disinfection procedures. This decrement is mostly attributed to the continuous polymerization process which leads to enhancement and complement of the polymeric chain structure, therefore, smoother silicone surface will results with time. These results were in line with Goiato et al. but against the results of Al-Dharrab et al. which could be due to different disinfecting solution and longer period of immersion.

Color change and optical properties are the most frequent reason that makes patients seek remake for their maxillofacial prostheses. The type of silicone used and the duration of exposure to the disinfectant significantly affect the color stability of silicone prostheses. Regarding color absorbance in the present study, it was the most stable property after the disinfection procedure. Non-significant reduction in the absorbance of the material indicates high association of the nano-filler with the polymeric matrix, which was not removed during the disinfection procedure. Unlike fillers with large particles that could be washed away upon the disinfection procedure leading to color instability, the extremely small particles of the SiO₂ linked strongly with the polymeric matrix forming an integration that was not broken upon disinfection. These particles act as a physical barrier that prevents the silicone chromatic deterioration.

The small, yet non-significant decrease in the color absorption might be a consequence of chemical or mechanical activation (wiping the specimens before storage) that could probably washed away some of the pigment particles that accumulated on the surface of the elastomer during storage. Due to its biocompatibility, chlorhexidine gluconate caused the least effect on the color property; whereas the change in color absorption after microwave radiation was more than other disinfection procedures which might be due to thermal cycling that leads to structural alteration of silicone. Nevertheless, the difference between the disinfection groups was non-significant.

These results agreed with Kiat-Amnuay; Haddad et al; Griniari et al; Hatamleh and Watts and disagreed with Goiato et al. which could be due to different material and disinfecting procedure.

REFERENCES


