ORIGINAL ARTICLE

Evaluation of some mechanical properties of a new silicone elastomer for maxillofacial prostheses after addition of intrinsic pigments

Hussein A. Abdullah [a], Faiza M. Abdul-Ameer [b],*

[a] *Department of Prosthodontics, College of Dentistry, University of Baghdad, Thi-Qar, Iraq*
[b] *Department of Prosthodontics, College of Dentistry, University of Baghdad, Baghdad, Iraq*

Abstract *Objective:* The approximate life span of a silicone maxillofacial prosthesis is as short as 1.5–2 years of clinical service, then a new prosthesis should be fabricated. The most common reason for re-making the prosthesis is silicone mechanical properties degradation. The aim of this study was to assess some mechanical properties of VST-30 silicone for maxillofacial prostheses after addition of intrinsic pigments.

Methods: Two types of intrinsic pigments (rayon flocking and burnt sienna); each of them was incorporated into silicone. One hundred and twenty samples were prepared and split into 4 groups according to the conducted tests (tear strength, hardness, surface roughness, and tensile strength and elongation percentage) with 30 samples for each test. Each group was equally split into three subgroups. Group (A) was without pigment (control group), group (B) was with rayon flocking and group (C) was with burnt sienna.

Results: Samples with rayon flocking showed a highly significant decrease in hardness and there was a significant increase in tear strength, while there were non-significant differences in surface roughness, tensile strength and elongation percentage. Samples with burnt sienna showed a highly significant increase in tear strength and a highly significant decrease in hardness, but surface roughness, tensile strength and elongation percentage showed non-significant differences. However, there were non-significant differences between experimental groups in all tests.

* Corresponding author.
  E-mail address: dr.fmha@codental.uobaghdad.edu.iq (F.M. Abdul-Ameer).
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Conclusions: The addition of each of rayon flocking and burnt sienna changed the mechanical properties of the VST-30 silicone, while no superior pigment-silicone combination was revealed in all the conducted tests.

1. Introduction

"Every human has the divine right to look human.". This is a quote given by a psychiatrist Dr. William J. Mayo concerning the patient with facial deformities. Keeping in mind the importance of this philosophy, a maxillofacial prosthodontist should work to ensure the return back of the affected individual to society (Rajni et al., 2006).

Increasing numbers of maxillofacial deformity cases were reported in Iraq that are related to non-fatal injuries caused by explosive devices, which now comprise 30% of all battle-field injuries (Lew et al., 2010; Owens et al., 2008). Plastic surgery is the first choice of treatment, but when surgery is inadvisable, rehabilitation with maxillofacial prostheses provides a means of improving patient aesthetics and self-esteem and facilitating their return to society (Guiotti et al., 2010).

Results of the prosthetic treatment are influenced by the properties of the prosthetic material. Mechanical properties and color degradation are the most common reason for maxillofacial prostheses re-making (Begum et al., 2011). Concentration of fillers, additives and pigments used and their types determine the required physical and mechanical properties of the silicone prosthesis, thus it should be tailored to fulfill the requirements of a strong yet elastic material having mechanical properties that fulfill the clinical requirements (Chi, 2014; Eleni et al., 2009).

Pigments used for prostheses coloration are classified as intrinsic and extrinsic pigments. In comparison with extrinsic pigment, intrinsic pigment which forms the requisite color and translucency is less susceptible for handling and ecological status, while it is more probable to influence the mixture characteristics (Han et al., 2010).

However, the effects of commonly used pigments by maxillofacial prosthodontists on the mechanical properties of popular materials used for maxillofacial prostheses have not been investigated (Montgomery and Kiat-Amnuay, 2010).

2. Materials and methods

Two types of intrinsic pigments, rayon flocking and burnt sienna (FI (functional intrinsic)) (Factor II Inc., Lakeside, USA) were separately incorporated into a room temperature vulcanized VST-30 silicone (Factor II Inc. Lakeside, USA). About 120 samples were prepared and split into 4 groups according to the conducted tests with 30 samples for each test. Each group was further more split into three subgroups: (A, B and C) with 10 samples for every subdivision. Group (A) represents control group without pigment, group (B) with rayon flocking and group (C) with burnt sienna (FI).

2.1. Pilot study

A pilot study was carried out to determine the optimum concentration of each pigment to be used in the main study by testing its effect on tear strength and hardness. For rayon flocking, the optimum concentration was 0.1 wt.% concentration, while it was 0.2 wt.% for burnt sienna (FI).

2.2. Mold making

Samples dimensions were designed utilizing AutoCAD 2013 (Autodesk Inc., San Rafael, CA, USA) then processed using computer numerical control machine to form the matrix part of the mold into which the material was poured (Chi, 2014).

2.3. Mixing of the silicone base with the pigments

TheVST-30 silicone mixing was in a proportion of 10:1 for the base and catalyst as recommended by manufacturer's instructions.

Each pigment was hand-mixed with the base for 5 min ± 5 s by the same operator with a clean stiff flat-ended metal spatula followed by 5 min ± 5 s mixing by a mechanical mixer in a glass beaker (Guiotti et al., 2015; Han et al., 2013; Nguyen et al., 2013).

2.4. Deaeration of the mixture

The mixture of experimental groups was deaerated in a vacuum chamber and allowed to reach its maximum capacity and fall to the bottom of the mixing beaker. Afterward, the vacuum was held for another 5 ± 1 min to eliminate all the air bubbles (Zayed et al., 2014).

The vacuum pressure was 28 inches Hg as recommended by the manufacturer. Deaeration at this stage would decrease the time necessary to have a pore-free mixture after addition of the catalyst (according to the pilot study).

2.5. Refrigeration

The glass beaker containing the material was placed in a zip-locked plastic bag and placed in a refrigerator. Improvement of handling properties of the material was achieved by refrigeration of the base prior to use as suggested by the manufacturer.

2.6. Adding the catalyst

Mixing of the base and catalyst was at 50 ± 10% RH (relative humidity) and 23 ± 2 °C (controlled temperature). A flat-ended metal spatula was used for mixing of the base and catalyst as recommended by the manufacturer. The base and catalyst were hand-mixed by stirring with the spatula for 1 min by the same operator and in one direction (Guiotti et al., 2015; Hulterström, 2012; Willett and Beatty, 2015).

2.7. Pouring of the mixture into the deaeration and pouring syringe

After mixing of the base for the control group or the pigmented base for the experimental groups with the catalyst, the mixture was loaded into a custom-made syringe for deaeration and pouring.

In order to remove all the air bubbles entrapped during mixing with the catalyst, a vacuum pump was attached to the deaeration and pouring syringe for (3 ± 1) minutes as recommended by the manufacturer's instructions(Fig. 1).

2.8. Pouring the mixed material into the mold

The matrix and the bottom parts of the mold were previously securely attached and placed on the vibrator with the mold spaces coated with petroleum jelly (Hatamleh and Watts, 2010; Zayed et al., 2014).

The material was injected from the deaeration and pouring syringe into the mold and a glass slab, which was previously coated with petroleum jelly, was laid onto the matrix filled with the material.

Lying of the glass slab was started from one side by resting the bottom edge of the slab and holding the top edge, while the glass slab was carefully and slowly lowered onto matrix to force excess material and air out ahead of it (Fig. 2). Finally, the cover of mold was placed on the glass slab, a mass of 1 kg was applied on the center and the cover was tightened.

Fig. 1 Deaeration of silicone in the syringe after mixing with the catalyst.

2.9. Demolding and storage of samples

The material sets in about 30 min according to manufacturer's product description, then the samples were removed carefully from the mold (Pinheiro et al., 2014). Samples that had visible defects (to the same operator) were discarded before testing (Al-Harbi et al., 2015).

The samples were stored in a custom-made lightproof box in an air-conditioned room. During storage, the temperature was 10–30 °C and RH did not excess 80% (Brown, 2006).

2.10. Conditioning of samples

Samples were conditioned for 24 h prior to testing and an ultrasonic humidifier was used to increase humidity if RH was below 50% (ASTMD624, 2012). Then, samples were conditioned at a standard laboratory temperature of 23 ± 2 °C for a minimum of 3 h after removal of flash (ASTM International, 2010). The flash was removed with a scalpel and sharp surgical blade # 10 (Zayed et al., 2014).

2.11. Mechanical testing procedures

2.11.1. Tear strength test

Samples preparation and testing were done according to ASTM, D624 (Standard and ISO, 2010) (American Society for Testing and Materials). Type C sample was used to measure tear initiation strength. The following equation was used to determine the tear strength:

Tear strength $= F/D$

where

F: The maximum force required for sample breaking in kilonewtons.
D: The median thickness of each sample in meter (ASTMD624, 2012).

2.11.2. Hardness test

The test was performed according to ASTM D2240 on $25 \times 25 \times 6$ mm^3 samples and type A shore hardness digital tester was used (Standard, 2010).

The mean value of five readings from five different points apart from each other by 6 mm while keeping 6 mm away from
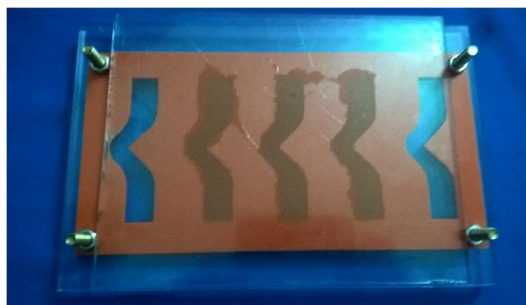

Fig. 2 The glass slab placed on the mold after injection of the material.

the border was considered as the hardness of the sample (Hatamleh and Watts, 2010).

2.11.3. Surface roughness test

In the surface roughness average (Ra) test, the sample dimensions were (10 mm × 10 mm × 2 mm) (Al-Askari et al., 2014; Khalaf et al., 2014). Profilometer tester was used and for each sample, three measurements were taken, then the mean value of them was calculated and considered as the surface roughness of the sample (Goiato et al., 2009).

2.11.4. Tensile strength testing

The test was managed depending on ISO 37 (International Organization for Standardization) and dumbbell-shaped samples (type 2) were prepared (Standard and ISO, 2010). The ultimate tensile was calculated from the maximum stretching force at break divided by the sample original cross-sectional area using the equation below:

$$\text{Tensile strength(MPa)} = F/A$$

where

F: The force recorded at break in N.
A: The original cross-sectional area of the sample in mm^2 (Standard and ISO, 2010).

2.11.5. Elongation percentage

In accordance with ISO 37, elongation before break was executed at the time of tensile strength measuring. The break elongation was measured from the original length of tensile sample and the length of the sample at break using the equation:

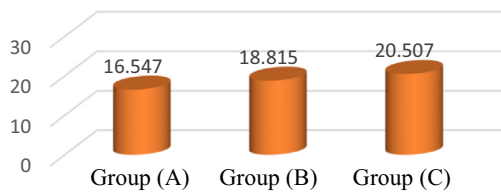$$\text{Elongation percentage at break} = (Lb - L°) * 100/L°$$

Fig. 3 Bar chart display of tear strength mean values of all groups in kN/m.

where

L°: The original length in mm.
Lb: Extension at break in mm (Standard and ISO, 2010).

2.12. Statistical analyses

The statistical package for the social sciences software (version 23) was used for analyzing the data of this study. The following statistics were performed:

(a) Descriptive statistics: Graphical display by bar charts.
(b) Inferential statistics: One-way ANOVA (One-way analysis of variance) and LSD (least significant difference) as a post hoc were used with the following significance levels:
P > 0.05 NS Non-significant
$0.05 \geq P > 0.01$ S Significant
$P \leq 0.01$ HS Highly significant

3. Results

3.1. Tear strength test

The highest mean value of tear strength test appeared in group (C), then followed by group (B), while group (A) mean value was the lowest among the groups (Fig. 3). One-way ANOVA for tear strength results showed a highly significant difference (Table 1).

To compare the mean values of each two groups of all the three groups, Post-hoc LSD test was performed. There was a significant difference between (A and B) groups and a highly significant difference between (A and C) groups while there was a non-significant difference between experimental groups (Table 2).

3.2. Hardness test

The highest mean value appeared in group (A), then followed by group (C), while the lowest mean value among the groups was in group (B) (Fig. 4). One-way ANOVA for shore A hardness results showed highly significant difference among groups (Table 3).

Table 1 One-way ANOVA for tear strength test.

	Sum of squares	df	Mean square	F	Sig.
Between groups	78.961	2	39.480	9.318	0.001 HS
Within groups	114.401	27	4.237		
Total	193.362	29			

Table 2 LSD test between all studies groups of tear strength test.

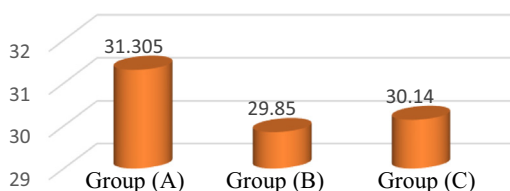| Study groups		Mean difference	SE	Sig.
Group (A)	Group (B)	−2.268	0.921	0.020 S
Group (B)	Group (C)	−1.692	0.921	0.077 NS
Group (C)	Group (A)	3.960	0.921	0.000 HS

Fig. 4 Bar chart display of shore A hardness test mean values of all groups.

Table 3 One-way ANOVA for shore A hardness test results.

	Sum of squares	df	Mean square	F	Sig.
Between groups	11.861	2	5.931	11.856	0.000 HS
Within groups	13.506	27	0.500		
Total	25.367	29			

Table 4 LSD test between all studies groups of hardness test.

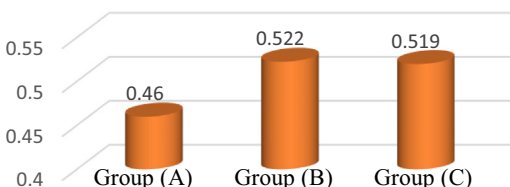| Study groups		Mean difference	SE	Sig.
Group (A)	Group (B)	1.455	0.316	0.000 HS
Group (B)	Group (C)	−0.290	0.316	0.367 NS
Group (C)	Group (A)	−1.165	0.316	0.001 HS

Fig. 5 Bar chart display of surface roughness test mean values of all study groups in μm.

Post-hoc LSD test was performed to compare mean values of each two groups for all the three groups. Comparison between the control group and each of the experimental groups showed highly significant differences. The difference between the experimental groups was non-significant (Table 4).

3.3. Surface roughness test

The highest mean value appeared in group (B), and then followed by group (C), while group (A) mean value was the lowest among the groups (Fig. 5). One-way ANOVA for roughness test results showed non-significant difference among groups (Table 5).

3.4. Tensile strength test

The highest mean value of tensile strength test appeared in group (B), and then followed by group (A), while group (C)

Table 5 One-way ANOVA for roughness test results.

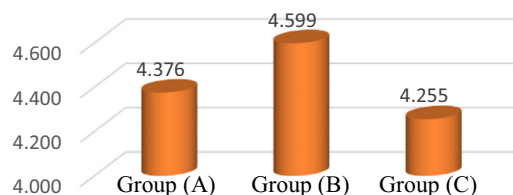|	Sum of squares	df	Mean square	F	Sig.
Between groups	0.025	2	0.012	3.223	0.056 NS
Within groups	0.104	27	0.004		
Total	0.129	29			

Fig. 6 Bar chart display of tensile strength mean values of all study groups in MPa.

mean value was the lowest among the groups (Fig. 6). One-way ANOVA for tensile strength test results showed a non-significant difference among groups (Table 6).

3.5. Elongation percentage test

In group (A), the highest mean value of elongation percentage test was found, then followed by group (B), while group (C) mean value was the lowest among the groups (Fig. 7). One-way ANOVA for the results of elongation percentage test revealed a non-significant difference among groups (Table 7).

4. Discussion

The mechanical value of silicones is only reported by manufacturers without pigments, fillers or additives and this is not a real representation of silicones clinical performance when used for extra-oral prosthesis. For this reason, maxillofacial prosthodontists and anaplastologists should deal cautiously with the manufacturers' values when using a material for making a facial prosthesis (Nguyen et al., 2013).

The results of tear strength test indicated that the tear strength was increased significantly when rayon flocking was added and highly significantly when burnt sienna (FI) was added.

The significant increase in tear strength when rayon flocking was incorporated may be attributed to the rayon flocking being fibers and these fibers bridged the tear and hindered or obstructed the propagating tear (Kumar and Thomas, 1995; Murty and De, 1984; Sreeja, 2012).

The highly significant increase in tear strength when burnt sienna (FI) was added may be due to liquid colorant's action as a plasticizer which could enhance the tear strength as one of the main functions of plasticizer is improvement of tear resistance (Guiotti et al., 2015; Haug et al., 1999; Wypych, 2004).

The result of hardness test revealed a significantly high decrease in the mean value of hardness when each of rayon

Table 6 One-way ANOVA for tensile strength test results.

	Sum of squares	df	Mean square	F	Sig.
Between groups	9.885	2	4.943	1.148	0.332 NS
Within groups	116.216	27	4.304		
Total	126.101	29			
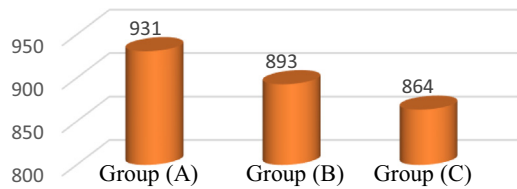
Fig. 7 Bar chart display of elongation percentage (%) test mean values of all groups.

flocking and burnt sienna (FI) was added in comparison with the control group.

The highly significant decrease in hardness results may be because the intrinsic pigment incorporation affected the process of silicone polymerization, resulting in decreased hardness (Guiotti et al., 2015).

The results of surface roughness test indicated that both types of pigments increased the roughness mean value as compared with the control group.

Rayon flocking has short whiskers protruding from its surface (Leny and Narayanankutty, 2009). It is assumed that the rayon flocking fibers were randomly arranged during sample preparation. These different orientations across the surface along with these protruding whiskers that were distributed on the surface of the silicone might cause the increase in mean value after addition of rayon flocking.

Burnt sienna (FI), which is a liquid pigment, uses a vehicle for the pigment that facilitates handling of the pigment in liquid form. When the vehicle was absorbed or evaporated the material hardens (Haug et al., 1999). Eventually, the distributed pigment particles on the silicone surface may increase surface roughness (Yu et al., 1980).

To the knowledge of the researcher, to date, no researchers have attempted to assess the effect of rayon flocking on surface roughness of maxillofacial silicones (both types RTV and HTV) and that was the uniqueness of this study.

The results of tensile strength test indicated that rayon flocking addition to silicone increased the tensile strength mean value, while the addition of burnt sienna (FI) reduced the mean value of tensile property in comparison with the control group.

The increase in tensile strength mean value after rayon flocking incorporation may be due to stress transmit from the weaker resin matrix to the much stronger fibers and the effective restraining of the matrix by fibers, which led to hindering of the growing crack (Leny and Narayanankutty, 2009; Rosato and Rosato, 2004; Sreeja, 2012).

According to the manufacturer's product description, burnt sienna (FI) is a combination of crushed cosmetic pigments in cross-linking fluid of silicone making a liquid but viscous pigment. The reduction in tensile strength mean value after addition of burnt sienna (FI) may be explained by the increased degree of cross-linking, which was caused by the silicone cross-linking fluid, that interferes with the redistribution of strain energy resulting in greater localized stress then early fracture(Polyzois et al., 1992).

The results of elongation percentage showed that both types of pigments decreased the elongation percentage mean value in comparison with the control group.

The reduction in elongation percentage mean value after addition of rayon flocking may be due to that the fibers prevent the flow and orientation of molecular chains making the matrix more restrained leading to initiation of failure at multiple points and hence causing considerably lower elongation percentage values(Leny and Narayanankutty, 2009; Sreeja and Kutty, 2002; Sreeja, 2012).

The decrease in mean value after adding burnt sienna (FI), most likely due to the gradually increased crystallization facilitated by the increased chain mobility and the interactions in the presence of plasticizer as stated previously in tear strength that liquid pigment may act as a plasticizer (Wypych, 2004).

5. Conclusions

As a conclusion, a change in the mechanical properties resulted when intrinsic pigments were incorporated into the RTV silicone VST-30, while both intrinsic pigments exhibited different results. No superior pigment-silicone combination was revealed in all the conducted tests.

Table 7 One-way ANOVA for elongation percentage test results.

	Sum of squares	df	Mean square	F	Sig.
Between groups	22708.267	2	11354.133	0.946	0.401 NS
Within groups	323977.600	27	11999.170		
Total	346685.867	29			

Conflict of interest

The author of this article declares no conflict of interest.

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