

Effect of Intrinsic Pigmentation on the Tear Strength and Water Sorption of Two Commercially Available Silicone Elastomers

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Abstract The purpose of this study was to evaluate the water sorption and tear strength of two commercially available silicone elastomers. Silicone test specimens with the dimension of 150 mm × 150 mm × 3 mm were prepared for cosmesil M511 silicone (Cosmedica Ltd, Cardiff, UK) and biomed silicone (MP Sai Enterprises, Mumbai, India). Sixty test specimens were divided equally into two groups—I and II. Group I and II were further subdivided into A, B, and C with 10 specimens each. Subgroup A represented the control group (without colorant), test specimens in subgroup B (incorporated with intrinsic pigments) were evaluated for tear strength, and subgroup C specimens, incorporated with intrinsic pigments were evaluated for water sorption. Students's *t* test was performed. Among the control group, cosmesil M511 silicone showed more tear strength with the mean of 11.42 ± 0.73 compared to biomed silicone which showed 6.64 ± 0.70 . The tear strength values increased for both silicones after intrinsic pigmentation. Cosmesil M511 silicone showed more water sorption compared to biomed silicone. Medical grade cosmesil M511 silicone had better tear strength values compared to biomed silicone.

Keywords Silicone · Tear strength · Water sorption

Introduction

Extraoral maxillofacial prostheses can be a valuable treatment option for patients' with orofacial defects. Many

materials have been used in the fabrication of the maxillofacial prostheses. Among them silicone have become the material of choice, because of the material strength, durability and life like appearance [1]. The use of silicone elastomers for facial prostheses was first demonstrated in 1960 by Barnhart [2]. Since then various newer silicone elastomer formulations have come to the market. They have been tried and tested for different properties. In 1971, Roberts [3] published the physical properties of a heat-polymerized silicone material and two room temperature polymerized silicone elastomers. Later from 1974 there has been a significant increase in research on maxillofacial materials [4–6]. The ideal maxillofacial material should have original physical and mechanical properties, comparable to human tissue they are replacing, maintaining these properties during service, and being easy to process and insensitive to processing variables [6].

Testing of mechanical properties is an essential step toward the acceptance of the silicone elastomer. Tensile strength is an indication of the overall performance and durability of a prosthetic material, and along with the tear strength, it relates to the problem of prostheses tearing while in use, particularly at the fine edges of the prosthesis. It has been reported [7, 8] that although the material must possess reasonable tensile strength, tear strength is more important clinically in predicting the durability of the material. Conroy et al. [9] reported that the tear strength must be interpreted carefully because in clinical use the elongation at a break may have an overriding influence. A high elongation necessarily means that much energy has to be dissipated before stress builds up sufficiently in the region of stress concentration to initiate and then propagate tearing.

Water sorption of the prosthetic material is important since facial prostheses may absorb saliva or sweat from the

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surrounding facial tissue, and also after washing the prosthesis in water. Any absorbed water may affect the perception of color matching to the surrounding facial tissue [10]. Silicones are the most widely accepted materials for maxillofacial prostheses; the Institute of Maxillofacial Technology initiated a study to research and develop a new maxillofacial silicone elastomer in 1978. The Institute established a link with the university of Wales Institute of Science and Technology, and developed cosmesil, a room temperature vulcanizing silicone material [11, 12]. In 1982, cosmesil M511 silicone SM4 and Cosmesil M511 silicone HC2 were introduced [13, 14]. Later in 1993 Cosmesil M511 siliconeK10 was introduced to the market and profession. The latest cosmesil silicone elastomers available are the M511 and Z004. Studies relating to the properties of these materials are very less in the literature, especially the effect of pigments on the properties of M511 and Z004.

The purpose of the present study was to compare the tear strength and water sorption of cosmesil M511 silicone and Biomed silicone elastomer upon addition of intrinsic pigments. Biomed silicone is a newly developed medical grade silicone, manufactured in India. The hypothesis for the study is that both the silicones have same tear strength and water sorption values.

Materials and Methods

Wax pattern sheets with the dimension of 150 mm × 150 mm × 3 mm were invested with improved dental stone (Kalrock; Kalabhai Dental Pvt Ltd, Mumbai, India) according to the conventional dental flasking technique. Following the setting of stone, the flasks were removed. The stone mould surfaces were treated with tin-foil substitute and silicone elastomers were packed and processed using compression molding technique (Figs. 1, 2). Silicone elastomers used in the study are cosmesil M511 silicone (Cosmedica Ltd, Cardiff, UK) and Biomed silicone (MP Sai Enterprises, Mumbai, India) (Fig. 3).

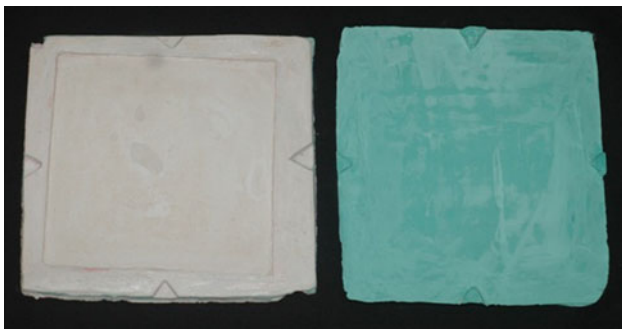


Fig. 1 Fabricated mold for silicone packing

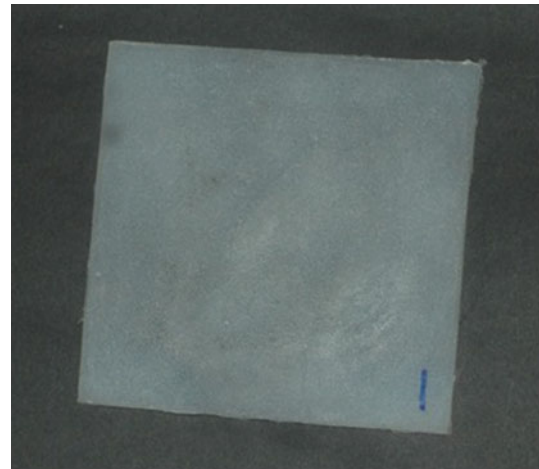


Fig. 2 Fabricated silicone sheet



Fig. 3 Silicones used for the study

The silicone sheets were retrieved from the moulds after a polymerizing period of 48 h at room temperature. They were examined for tear or nicks on the area to be tested. Cosmesil M511 silicone and biomed silicone sheets were subjected to test specimen preparation. Using an American standard test measurements (ASTM) D624 type C tear test measurements (ASTM) D624 type C tear test specimen cutting die, the specimens were cut from the silicone sheets (Fig. 4). The cut was done with a single impact stroke by machine to ensure smooth cut surfaces.

A total of 60 specimens were made. They were divided into groups I and II with 30 specimens each for cosmesil M511 silicone and biomed silicones respectively. Group I and II were further subdivided into A, B and C with 10 specimens

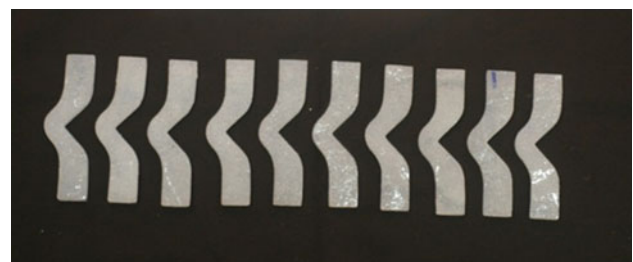


Fig. 4 Silicone test specimens cut from the silicone sheet

each. Subgroup A represented the control group (without colorant), test specimens in subgroup B incorporated with intrinsic pigments (Cosmedica Ltd, UK) were evaluated for tear strength, and subgroup C specimens, incorporated with intrinsic pigments were evaluated for water sorption after they were stored at 23 °C and 50 % humidity.

Tear strength (T) is defined as the maximum force (F) required breaking the specimen divided by the thickness of the specimen (D).

$$T = F/D$$

Tear tests were performed for the subgroup A (control) and subgroup B of both the groups I and II, using instron universal testing machine (Instron corporation Series IX automated material testing machine 8.25.00). The test specimen was placed in the grips of the machine (Fig. 5). Care was taken to adjust the test specimen, so that it strained uniformly along its length. Sufficient area of specimen was clamped in the grips to avoid slippage. The specimens were stretched at a rate of 500 mm/min breaking force was recorded on a chart and torn specimens were evaluated to determine if failure correlated with defects in specimen.

The test specimens of the subgroup C of both the groups I and II were subjected to water sorption test. The size and shape of the specimens were similar to the one used for tear strength test. The specimens were weighed on a digital weighing machine before immersing them in water and the initial reading was taken as W_1 (Fig. 6). Later these specimens were placed in water for a period of 3 months (Fig. 7). The specimens were removed from water, excess water was blotted and re-weighed as before (W_2) in gram. The difference in weight was calculated and was designated as W_3 in gram.

The data obtained for the tear strength and water sorption were subjected to statistical analysis.

Results

The statistical comparison of the mean and the standard deviation of group IA and IIA (control group) are shown in



Fig. 5 Test specimen held in testing machine



Fig. 6 Test specimen weighed before water sorption

Table 1. The cosmesil M511 silicone exhibited more tear strength (11.4287 ± 0.7332) compared to biomed silicone (6.6466 ± 0.7029). Student's *t* test was performed for group IB and IIB. There was significant increase in the tear strength values after addition of intrinsic pigments in both

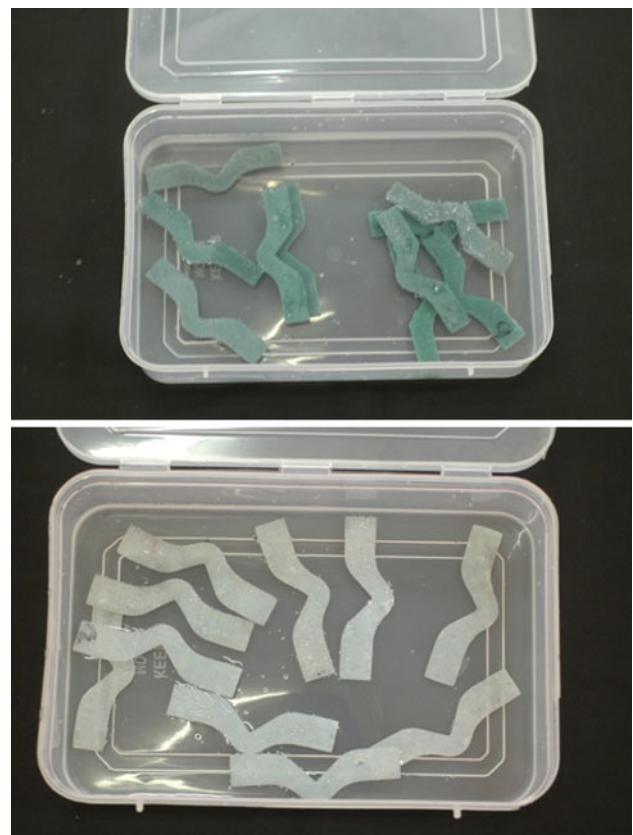


Fig. 7 Specimens kept in water

Table 1 Student's *t* test for the control group IA and IIA

Group	<i>N</i>	Mean	SD	Mean difference	SD difference	<i>t</i> value	<i>p</i> value
Group IA	10	11.4287	0.7332	4.7821	0.0303	14.8883	0.0000
Group IIA	10	6.6466	0.7029				

Table 2 Student's *t* test for the test group (tear strength) IB and IIB

Group	<i>N</i>	Mean	SD	Mean difference	SD difference	<i>t</i> value	<i>p</i> value
Group IB	10	12.328	0.8201	5.2797	0.0702	13.7932	0.0000
Group IIB	10	7.0484	0.8903				

types of silicone (Table 2). Statistical results for the water sorption study are presented in Table 3. Student's *t* test was performed for group IC and IIC. Cosmesil M511 silicone showed more water sorption with the mean of 0.0839 ± 0.0060 .

Discussion

The primary goal of maxillofacial prosthetics is to restore the patients' appearance to allow improvement in self-esteem and help the patient lead as normal a life as possible. The key to achieve this goal is the selection of suitable material. A variety of materials have been used for the making the facial prostheses, such as polymethyl methacrylate, polyurethane elastomers and silicone elastomers. A successful facial prosthesis depends on several factors; durability, biocompatibility, flexibility, weight, color, hygiene, thermal conductivity, ease of use, texture and availability. No facial material has all of these ideal properties although several materials are available that possess most of these properties with increased tear strength, tensile strength and significant durability [15, 16]. However silicone elastomers have been widely used because of their chemical inertness, strength, durability, ease of manipulation and biocompatibility [17, 18].

Various studies on the mechanical properties of different formulations of silicone elastomers have been reported in the literature [17–19]. The literature is scanty with respect to the studies on properties of cosmesil M511 silicone and biomed silicone elastomers. Among the properties tear strength of silicone elastomers is clinically important especially at the thin margins surrounding facial prostheses, which blend with the facial tissues. Margins are

usually glued with medical adhesives, and are highly susceptible to tear [20]. The increase in tear strength of a material will increase the esthetic quality of a facial prosthesis by permitting a thinner margin with a greater possibility of stretching and less possibility of tearing. Additions of intrinsic pigments to the silicone elastomers have shown change in the physical properties of silicones. Haug et al. [21] conducted a study of colorant effect on physical properties of silicones. They evaluated three of the more commonly used elastomers: silastic medical adhesive type A, silastic 4-4210 and silicone A-2186. The results showed that the addition of artists' oil pigments to medical adhesive type A increased tear strength by 21 % compared to other two elastomers. Yu et al. [22] checked the physical properties of a pigmented silicone material. They demonstrated that the incorporation of pigments can alter the physical and mechanical properties of the base elastomer.

In the present study, effect of intrinsic pigmentation on the tear strength and water sorption of two silicone elastomers was evaluated. Cosmesil M511 silicone exhibited higher tear strength values compared to the biomed silicone ($p < 0.05$). Further there was marked change in the tear strength values between the control group and the tear test group of both the silicones, suggesting that there was increase in tear strength after intrinsic pigmentation. The colorants action as a plasticizer may increase the tear strength. This statement is in accordance with the findings of the study conducted by Haug et al. [21]. The use of dry earth pigments affects the physical properties, since they act as a solid filler without bonding to the silicone. Silicone liquid suspension colorants may blend well with the silicone matrix, thereby increasing the hardness and tear strength. The addition of rayon fiber flocking may act as fibrous filler, which may increase the hardness and color stability of prosthesis.

Table 3 Student's *t* test for the statistical comparison of the mean and standard deviation of group IC and IIC (Water sorption)

Group	<i>N</i>	Mean	SD	Mean difference	SD difference	<i>t</i> value	<i>p</i> value
Group IC	10	0.0839	0.0060	0.0827	0.0056	43.6096	0.0000
Group IIC	10	0.0012	0.0004				

Aziz et al. [20] conducted a study to evaluate five commonly used maxillofacial silicone elastomers for physical properties. They concluded that cosmesil M511 silicone standard and prestige absorbed the large amount of water after 12 months in distilled water at 37 °C. Cosmesil M511 silicones had high compliance, A-2186 and nusil had negligible water sorption. In this study, cosmesil M511 silicone had least water sorption as compared to the biomed silicone. This may be attributed to the type of silicone used. Cosmesil M511 silicone is an addition type silicone and biomed is a condensation type. Their curing chemistries are different. The addition type elastomers cure without any byproducts forming, while the condensation type polymers form byproducts that later leaves the polymeric structure. This would probably lead to a more porous polymeric structure than in the addition type polymers [23]. Hence biomed silicone being condensation type silicone may be the reason for more water sorption. Another explanation for more water sorption may be due to the presence of hydrophilic non-surface treated silica fillers in the polymer matrix. The presence of –OH groups on the surface of the silica fillers helps to absorb water into the polymer matrix [10].

Further scope exists for the other researchers to study the other properties of biomed silicone and compare them with the previously introduced medical grade silicones.

The Clinical Implications of the Study Being

The knowledge of the physical properties of the material will help to know the longevity of the material when used for the fabrication of the maxillofacial prosthesis. By checking on the water sorption property of the material we come to know the impact the environment will be having on the material as well as to know whether the addition of the intrinsic pigments would enhance the tensile strength property of the material.

Limitations of the Present Study

Only two main properties namely tear strength and water sorptions have been studied as they have a major impact over the selection of material for the prosthesis. The other properties are not tested and that has been admitted by suggesting that there is scope for further study and research.

Conclusions

Within the limitations of the study the following conclusions were drawn:

1. Both the silicone elastomers exhibited different results, disproving the null hypothesis.

2. Cosmesil M511 silicone elastomer had better tear strength compared to the biomed silicone.
3. Cosmesil M511 silicone had less water sorption compared to biomed elastomer.
4. The use of cosmesil M511 silicone may be recommended for the clinical purpose.

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