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Effect of Addition of Intrinsic Pigments on the Tensile Strength, Percentage Elongation and Water Sorption of Two Maxillofacial Silicone Elastomers

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Abstract: *Silicone elastomers are used to fabricate maxillofacial prosthesis which intended to improve esthetics, restore and maintain the function and health of the tissue bed, and allow patients to return to society in the best possible condition and lead a normal life. The present study evaluated the effect of intrinsic pigments on the tensile strength, percentage elongation and water sorption of Multisel epithetics silicone and biomed silicone elastomer. A total of eighty specimens were fabricated , forty for each of the two silicone elastomers. For each elastomer, twenty specimens were made with incorporation of intrinsic pigments and twenty specimens without intrinsic pigments. The results showed that there was no significant decrease in the tensile strength values after addition of intrinsic pigments in multisil epithetic silicone with $p > 0.05$. But there was significant decrease in the tensile strength values after addition of intrinsic pigments in biomed silicone with $p < 0.001$. Also there was significant decrease in the percentage elongation values after addition of intrinsic pigments in both multisil epithetic silicone with $p > 0.05$ and biomed silicone with $p < 0.01$. Both the silicones exhibited significantly less water sorption after the incorporation of intrinsic pigments.*

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I. Introduction

Acquired and congenital defects of the face create an unfortunate condition for an individual to lead a comfortable life and these individuals require rehabilitation using maxillofacial prosthesis. The history of masking maxillofacial defects dates centuries back when the Egyptians and Chinese used wax and resins to reconstruct missing portion of the head and neck region.[1]

The prosthodontists are limited by the materials used in fabrication for facial prosthesis, movable tissue beds, graft and flap applications, unsuitability of anatomic undercuts, and patient acceptance toward the use of prosthesis. There is no ideal facial prosthetic material, although there have been improvements in the last few decades, and silicone rubbers have established the current state-of-the-art material.[2]

Silicones, also known as polydimethyl siloxane is the most successful maxillofacial prosthetic material till now and the new advances are being made to this material to overcome their weaknesses. These became more popular over other materials as they have a range of good physical properties (such as excellent tear and tensile strength) over a range of temperature, easier to manipulate, high degree of chemical inertness, low degree of toxicity, and high degree of thermal and oxidative stability. Further they can be stained intrinsically and/or extrinsically to give them more life-like natural appearance. When adequately cured, silicones elastomers resist absorbing organic materials that lead to bacterial growth and so with simple cleaning these materials are relatively safe and sanitary compared to other materials.[3] 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[4] and the resulting elongation gives an indication of the flexibility of the prosthesis. A prosthesis with a high elongation at break is desirable especially when peeling a nasal or eye prostheses from facial tissue.[5] The water absorption of the prosthetic material is important since facial prostheses may absorb saliva or sweat from surrounding facial tissue, and also after washing the prosthesis in water. Any absorbed water may affect the physical properties and also affect the perception of colour matching to the surrounding facial tissue.[6]Pigmentation and coloration play a key role in fabricating a maxillofacial prosthesis. The addition of pigments to the maxillofacial material may alter the properties of the prosthesis, possibly influencing the success of the prosthesis.[7]

II. Materials And Methods

A total of eighty specimens were made. They were divided into groups I and II with 40 specimens each for Multisel epithetics (Bredent group, Germany) silicone and M.P. Sai enterprises biomed silicone elastomer (Mumbai, India) respectively. Group I and II were further subdivided into subgroups A, B, C and D with ten specimens each. Subgroup A and B represented the control group (without colorant) and, test specimens in subgroup C and D were incorporated with intrinsic pigments (M.P. Sai Enterprise, Mumbai, India).

Experimental groups

- Group I: Multisel epithetics transparent silicone elastomer (Bredent group, Germany).
- Group I.A : Multisel epithetics (Bredent group, Germany) silicone elastomer without intrinsic pigment to be tested for tensile strength and percentage elongation.
- Group I.B : Multisel epithetics (Bredent group, Germany) silicone elastomer without intrinsic pigment to be tested for water absorption.
- Group I.C : Multisel epithetics (Bredent group, Germany) silicone elastomer with addition of intrinsic pigment to be tested for tensile strength and percentage elongation.
- Group I.D Multisel epithetics (Bredent group, Germany) silicone elastomer with addition of intrinsic pigment to be tested for water absorption.
- Group II : M.P. Sai enterprises biomed silicone elastomer (Mumbai, India)
- Group II.A : M.P. Sai enterprises biomed silicone (Mumbai, India) without intrinsic pigment to be tested for tensile strength and percentage elongation.
- Group II.B : M.P. Sai enterprises biomed silicone (Mumbai, India) without intrinsic pigment to be tested for water absorption.
- Group II.C : M.P. Sai enterprises biomed silicone (Mumbai, India) with addition of intrinsic pigment to be tested for tensile strength and percentage elongation.
- Group II.D : M.P. Sai enterprises biomed silicone (Mumbai, India) with addition of intrinsic pigment to be tested for water absorption.

Methodology

For fabrication of specimens, plastic moulds were fabricated according to the American standard test measurements ASTM 412 for testing of tensile strength, percentage elongation and water absorption (figure1,2). The silicone material was manipulated according to the manufacturer's instructions and was then poured into the moulds. The specimens of M.P. sai enterprises biomed silicone elastomer were retrieved from the moulds after a polymerizing period of 24 hr at room temperature. And the specimens of multisil epithetics silicone elastomer were polymerised at 60^0C. They were examined for the tears or nicks on the area to be tested.

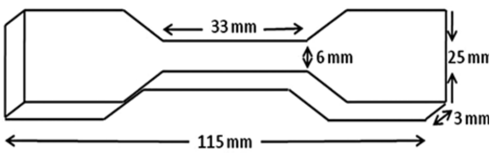

Figure 1. Dumbbell-shaped specimen according to ASTM D412 specification.

Tensile Strength and Percentage Elongation

Twenty specimens from each commercially available maxillofacial silicone elastomer material were made, ten with incorporation of intrinsic pigments and ten without intrinsic pigments and were subjected to tensile strength testing. The testing was carried out on universal testing machine (Instron corporation 3382), fitted with 100 KN load cell linked to an IBM compatible computer (figure 3). The speed maintained in the machine was 20 mm/min. After the specimens were broken, failed specimens were evaluated to determine if failure was correlated with defects in the specimens.

For the elongation test, the universal testing machine was equipped with extensometer and fitted with a 100 kg load cell and extensometer grips were set apart at a distance of 50 mm.

Tensile strength and percentage elongation were calculated automatically by the software using the equations below,

$$\text{Stress (N/mm}^2) = \frac{\text{Load}}{\text{Initial cross sectional area}}$$

$$\text{Percentage Strain (\%)} = \frac{\text{Extension}}{\text{Original Length}} \times 100$$

Water Absorption

For water absorption testing, twenty specimens were made for each commercially available maxillofacial silicone elastomer, ten with incorporation of intrinsic pigments and ten without intrinsic pigments. The size and shape of the specimens were similar to the one used for tensile strength test (according to ASTM D412 specification).

The specimens were weighed on a electronic weighing machine before immersing them in water and the initial reading was taken as W_1 in grams. Later these specimens were stored in water at 23^0 C for a period of 3 months. The specimens were removed from water, excess water was blotted with the help of blotting paper and re-weighed as before (W_2) in grams. The difference in weight was calculated and was designated as W_3 in grams.

The data obtained for the tensile strength, percentage elongation and water sorption was subjected to statistical analysis.

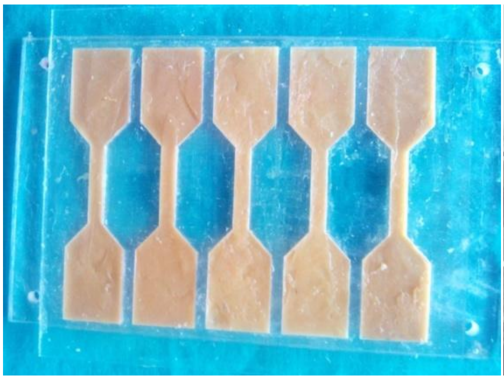

Figure 2. Dumb-bell specimens fabrication with addition of intrinsic pigments.

Figure 3. Specimen without intrinsic pigmentation stretched in the universal testing machine (Instron corporation 3382).

Statistical analysis

The readings obtained for various groups were tabulated. Descriptive statistics (means, standard deviations, and coefficients of variation) were determined for all the groups. Paired and unpaired Student's t test were performed for statistical comparison of the mean and standard deviation of the groups. Tukey's Post Hoc Analysis was done for intergroup comparison of tensile strength and percentage elongation. The statistical significance was fixed at $p \leq 0.05$. The results were analysed using software package SPSS Version 22 (USA).

III. Result

The results procured showed that there was no significant decrease in the tensile strength values after addition of intrinsic pigments in multisil epithetic silicone with $p > 0.05$. But there was significant decrease in the tensile strength values after addition of intrinsic pigments in biomed silicone with $p < 0.001$(Table1).

There was significant decrease in the percentage elongation values after addition of intrinsic pigments in both multisil epithetic silicone with $p > 0.05$ and biomed silicone with $p < 0.01$(Table 2).

There was significant decrease in the mean of weight difference values before and after addition of intrinsic pigments in both multisil epithetic silicone and biomed silicone with $p = 0.000$ (Table 3).

Table 1 : Post Hoc Table For Intragroup Comparison For Tensile Strength

Reference Group	Comparison Group	Mean Difference (Reference And Comparison Group)	Standard Error	95 % Confidence Interval		p Value
				Lower Bound	Upper Bound	
I.A	I.C	0.067	0.039	-0.039	0.173	0.342
II.A	II.C	0.205	0.039	0.098	0.311	0.000

Table 2: Post Hoc Table For Intragroup Comparison For Percentage Elongation.

Reference Group	Comparison Group	Mean Difference (Reference And Comparison Group)	Standard Error	95 % Confidence Interval		p value
				Lower Bound	Upper Bound	
I.A	I.C	21.972	13.515	-14.42	58.37	0.377
II.A	II.C	42.6	13.515	-28.90	116.89	0.007

Table 3: Paired Sample t Test To Assess Statistical Difference In Weight Of Water Sorption Before And After Adding Intrinsic Pigments Among Group I.B, I.D, II.B And II.D.

Pair	Pair Details	Mean Difference	Standard Deviation	95% Confidence Interval		t value	p value
				Lower Bound	Upper Bound		
Pair 1	Pre I.B- Post I.B	-0.106	0.040	-0.134	-0.077	-8.368	0.000
Pair 2	Pre II.B- Post II.B	-0.110	0.046	-0.143	-0.076	-7.416	0.000
Pair 3	Pre I.D- Post I.D	-0.086	0.049	-0.121	-0.050	-5.471	0.000
Pair 4	Pre II.D- Post II.D	-0.099	0.025	-0.117	-0.080	-12.238	0.000

IV. Discussion

Silicone and methyl chloride react to form dimethyldichlorosilane. When water is added to dimethyldichlorosilane, a fluid polymer, polydimethyl siloxane (PDMS), is formed that is white and translucent and of varying viscosity, which is determined by the length of the polymer.[8]

The PDMS chains and the silica fillers and the interactions between these two components affect the overall strength and service life of the silicone based maxillofacial prosthetic material.

Also prostheses made with silicones are considered effective for six months up to one year, having the need of substitution due to color instability, deterioration of the texture, and margins and decrease of resistance. This occurs in function of the effects of ultraviolet rays, deposition of microscopic residues on surface porosities, use of skin adhesives, by continuous patient handling and cleansing.[9,10,11,12]

In the present study effect of intrinsic pigmentation on the tensile strength, percentage elongation and water sorption of two silicone elastomers was evaluated. Multisil epithetics silicone exhibited higher tensile strength values compared to the biomed silicone ($p < 0.05$). But multisil silicone showed no significant changes in tensile strength values after incorporation of pigments, whereas biomed silicone showed significant decrease in tensile strength values. Further there was marked change in the percentage elongation values between the control group and the percentage elongation test group of both the silicones, suggesting that there was decrease in percentage elongation after incorporation of intrinsic pigments. This statement is in accordance with the findings of the study conducted by Haug et al in which kaolin and dry earth pigments affected the initial physical properties of the prosthesis. By acting as a solid filler without bonding to the silicone, and these particles decreased the tensile strength and increased the hardness of the silicone.[13]

In this study Multisil epithetics silicone exhibited less water sorption after three months compared to the biomed silicone ($p = 0.000$). Further there was a marked difference in weight (in grams) before and after incorporation of intrinsic pigments. This may be attributed to the type of silicone used. The condensation type polymers form by-products that later leaves the polymeric structure. This would probably lead to a more porous polymeric structure than in the addition type polymers.[14] 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.[6]

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

V. Conclusion

Within the limitations of the study the following conclusions were drawn: Both the silicone elastomers exhibited different results, disproving the null hypothesis. There was no significant decrease in the tensile strength values but there was significant decrease in percentage elongation values after addition of intrinsic pigments in multisil epithetic silicone. And there was significant decrease in the tensile strength values and percentage elongation values after addition of intrinsic pigments in biomed silicone. Both the silicone elastomers exhibited significantly less water sorption after the incorporation of intrinsic pigments.

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