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Evaluation and Comparison of Tensile Strength, Water Absorption, Hardness and Colour Stability of Three Commercially Available Maxillofacial Silicone Elastomers - An *In Vitro* Study

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Abstract

Aim: To evaluate and compare three maxillofacial silicone materials with respect to tensile strength, water absorption, hardness and colour stability.

Material and Methods: Three silicone materials were taken and divided into - Group A, Group B, Group C. Group A consisted of A-2186 silicone maxillofacial material, Group B consisted of MDX4-4210 silicone maxillofacial material and Group C consisted of MP Sai Biomed silicone maxillofacial material. Each of the groups was tested for four different properties - tensile strength, water absorption, hardness and colour stability. 30 Metal dies including control group were fabricated according to American Society for Testing and Materials (ASTM) specifications. The specimens (experimental group) were submitted to the reading process with a sphere spectrophotometer at intervals of 6, 12 and 24 hours. Colour difference (AE), which is directly proportional to colour stability of any material was calculated.

Results: ANOVA test was used followed by Bonferroni (post hoc) multiple comparison test. Statistical analysis showed significant difference between A-2186, MDX4-4210, MP SAI BIOMED with respect to tensile strength, water absorption, hardness and colour stability. Based on the data, none of the three maxillofacial silicones possessed all the ideal properties required by a maxillofacial elastomeric material.

Conclusion: A-2186 maxillofacial Silicone possess all round better properties with respect to colour stability and water absorption than the other two commercially available materials. With respect to hardness and tensile strength, MDX4-4210 was found to be the best material followed by A-2186 and MP SAI BIOMED silicone material. MP Sai Biomed maxillofacial Silicone material produced least ideal properties.

Keywords: Maxillofacial prosthesis; Silicones; Elastomers; Hardness; Strength

Introduction

The speciality of maxillofacial prosthetics is currently finding itself changing and evolving more than at any other specialty over the past few decades. Traditional prosthodontic principles are still used for the management of many patients which require special skill eg: treatment of patients with head and neck malignancy, post surgical therapy, surgical reconstruction and congenital, developmental defects [1].

Maxillofacial prosthetics dates back long into ancient civilization. Artificial eyes, ears, and noses were found on Egyptian mummies. In China waxes and resins were used to reconstruct missing or defective parts of the head and face [2]. Now a day's, patients with craniofacial defects cannot be corrected completely with surgery. They should be routinely referred to dentists for the construction of maxillofacial prostheses to restore their form and function. The dental profession possesses the

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knowledge, artistic skills, and materials and has been trained in the techniques for the repair of these defects. These skills, knowledge and techniques can be used for the rehabilitation of patients. This requires a cooperative effort from bioengineers and chemists as a team is needed to treat patients with maxillofacial prosthetics. Maxillofacial prosthetics is defined as the art and science of anatomic, functional or cosmetic reconstruction by means of artificial substitutes of those regions in the maxilla, mandible, and face that are missing or defective because of surgical intervention, trauma, pathology, or developmental or congenital malformation [3].

Maxillofacial prosthetics is that branch of Prosthodontics which deals with the restoration and/or replacement of the stomatognathic and craniofacial structures with the prosthesis that may or may not be removed on a regular or elective basis (Glossary of Prosthodontic Terms) [3]. The normal anatomy and appearance is restored by the maxillofacial prosthesis, it protects the tissues of a defect, and provides great psychological benefits to the patient [4]. Rehabilitation of patients with disabilities of the craniofacial region due to either congenital or acquired defects is a difficult task. These defects may be minor in nature (aesthetics) or major discrepancies (functional limitations). The Prosthodontic management of these patients should aim at restoring the functional and aesthetic features as well as also ensure complete psychological well being [5]. Since the sixteenth century, various surgical defects or trauma to the craniofacial region has been treated by maxillofacial prosthetic replacements which had been constructed from a variety of materials [6]. Maxillofacial materials are used primarily to replace missing facial parts which have been lost due to disease or trauma [7]. For facial rehabilitation, assessment of all the materials used in the maxillofacial prosthesis is of utmost importance. Materials for maxillofacial prostheses should have ideal characteristics of biocompatibility, high strength, highly durable, lightweight, and resistant to wear and tear, ease of use, fabrication, cleansing, natural appearance and texture [8].

Now a day's facial prosthesis are primarily made of medical grade silicones. Less concentration of silica to elemental silicon is the first step in manufacture of silicones. Silicone is combined with methyl chloride to form dimethyl dichlorosiloxane, which then can react with water to form a translucent watery, white polymer known as Poly Dimethyl Siloxane [9]. Viscosity of any material is determined by the length of the polymer chain. Fillers are added to increase the strength of the polymer and they are usually comprised of poly (dimethylsiloxane) (PDMS) elastomers.

Air bubbles are likely to be entrapped while silicone is mixed during manipulation (rubber, hardener and pigments). Such voids greatly affect the silicone prostheses, its elasticity, elongation, tear, resistance and aesthetics [9]. Environmental factors, such as weathering, normal aging and cleaning agents can cause severe degradation of the aesthetic and mechanical properties of the silicone elastomer [10]. Aesthetically the colour, texture, form and translucency of the elastomer should always duplicate the part to be replaced as well as be a perfect match with the adjacent skin for ideal aesthetics [11]. Material must be compatible with human tissue, nontoxic, non allergenic and easily cleaned (breathable, allow moisture release, nonporous, but permeable, odourless, resistant to microbial contamination, no toxic by-products (no toxic components to harm operator) [12]. Hence to fill this lacuna of which elastomeric material had the best properties, this study was done to compare and evaluate tensile strength, water absorption, hardness and colour stability of three commercially available maxillofacial silicone elastomers and to find out which material has the best physical property to be used effectively for clinical usage.

Materials and Methods

Our study was done to evaluate and compare the tensile strength, water absorption, hardness and colour stability of three commercially available Maxillofacial Silicone Elastomers. The study by Tariq A, Waters M and Jagger R (2003) was considered for sample size estimation [7]. Three maxillofacial silicone materials were used in this study- A-2186 Medical Grade Elastomer Silastic, MDX4-4210 Medical Grade Elastomer, MP Sai Biomed Elastomer. Stainless steel dies as per American Society for Testing and Materials (ASTM) specifications for testing tensile strength, water absorption, hardness and colour stability were made (Figure 1 and 2).

30 specimens were tested for each of the three groups in regards with each of the four properties including control group as well as experimental group. For tensile strength, specimens were tested using Universal testing machine that had software which automatically calculated the tensile strength. Hardness for each specimen was based on needle penetration on the material surface with manual pressure using Shore A tester (Durometer). For water absorption, specimens were weighed with an electronic balance machine then immersed in distilled water. After immersion for 48 hours, the specimens were reweighed and then kept in a dessicator and then were again weighed. Percentage weight difference was calculated. For colour stability, the specimens (control group) made were stored in three different dark boxes, without the interference of direct or indirect light (Figure 3). The specimens (experimental group) were submitted to the reading process with a sphere spectrophotometer at intervals of 6, 12 and 24 hours. Colour difference (AE), which is directly proportional to colour stability of any material was calculated.

Statistical analysis

Descriptive statistics such as mean and SD was used. Comparison between three different materials was done by one-way ANOVA test followed by Bonferroni (post hoc) multiple comparison test. Comparison between experimental and control group with respect to colour stability was done by t-test. A *p*-value less than 0.05 were considered as significant.

Results

MDX4-4210 had the highest mean of 6.0080, A-2186 had second highest mean of 3.7093 and BIOMED had the least mean of 2.7400 with respect to tensile strength and hardness (Table 1 and 2). A-2186 had the highest mean of 0.422333 which underwent less water absorption compared to MDX4-4210 which had the mean of 0.466333 and BIOMED which had underwent highest water absorption of 0.607667 (Table 3). Colour stability among all the three materials was similar and no statistically significant difference was seen. Upon application of t-test for comparison of specimens of the control and experimental group after 24 hrs time interval, A-2186 had the highest mean of 0.172 (experimental group) and mean of 4.3010 (control group) followed by MDX4-4210 had the second highest value of 0.1597 (experimental group) and mean of 3.1780 (control group) and BIOMED had the least mean value of 0.0105 (experimental group) and 1.9443 (control group) (Table 4). Also as the ΔE value for A-2186 was the greatest followed by MDX4-4210 and BIOMED silicone material, indicating that A-2186 is the best among the three tested materials in this study (Table 5).

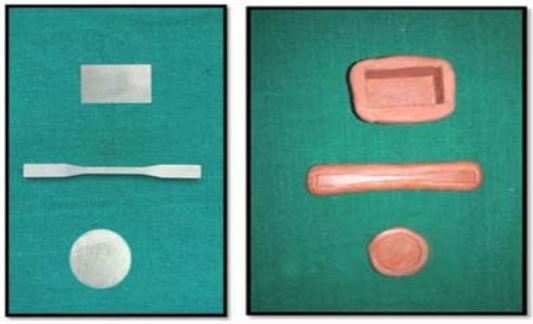

Figure 1: Metal master dies and Putty impression of master dies.

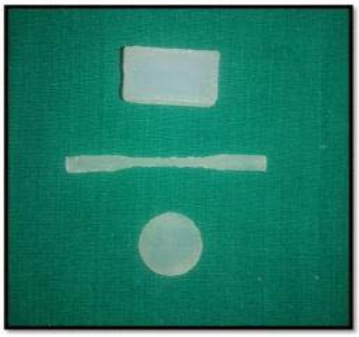

Figure 2: Specimens made.

Figure 3: Specimen held to be tested for colour stability.

Discussion

Materials for maxillofacial prostheses should always possess the following characteristics: biocompatibility; high strength; highly durable, lightweight; resistance to wear and tear, ease of manipulation, fabrication, easy to clean and should have natural appearance [8]. Materials which are used externally for making maxillofacial prosthesis should show good tensile strength and yet be soft enough to respond adequately with facial movement [8,13]. Ideally maxillofacial prosthesis materials should possess values in the range of 2.5-6.5 N/m^2 with respect to tensile strength [14].

In this study, hardness was tested with Shore A durometer using the methodology as mentioned above. The colour stability has been thoroughly investigated as a part of the primary physical property studies of maxillofacial elastomers [10]. An ideal elastomer-colourant combination should not only have satisfactory aesthetics, but should also provide above average physical properties. The addition of the colourant should enhance the physical properties of the elastomer, but it should be made sure that the ideal colorant added should not degrade any of its properties [15].

Table 1: Tensile strength.

Descriptive Statistics	N	Mean	Std. Deviation
A-2186	30	3.7093	0.20686
MDX44210	30	6.008	0.46609
BIOMED	30	2.74	0.6622
Total	90	4.1524	1.45838

Table 2: Hardness of materials.

Descriptive Statistics Materials	N	Mean	Std. Deviation
A-2186	30	31.8903	0.77780
MDX4-4210	30	46.2820	2.25850
MP SAI BIOMED	30	27.4173	1.49128
Total	90	35.1966	8.25166

Table 3: Water absorption.

Descriptive Statistics Materials	N	Mean	Std. Deviation
A-2186	30	0.422333	0.0950384
MDX 4210	30	0.466333	0.0760437
BIOMED	30	0.607667	0.0846772
Total	90	0.498778	0.1161250

Wear and tear along with environmental factors causes a high degradation of polymers, colour changes of the silicone elastomer itself. The weathering of polymers can cause changes in physical and chemical characteristics, which can result in an actual alteration of their tensile strength and hardness. The primary cause of deterioration is a photo-oxidative attack for most polymeric materials which can be described as the combined action of oxygen and sunlight, on their chemical structure [10]. The physical properties of tensile strength and hardness were tested as potential indicators of overall strength and flexibility, durability, and marginal integrity in clinical service. The desirable properties of any material which is going to be used as a maxillofacial prosthesis should include high tensile strength, hardness and low water absorption [7].

The complete success of any maxillofacial prosthesis depends on the physical and mechanical properties of the material used in its fabrication [16]. The main goal of maxillofacial prosthetics is to restore the patient's natural appearance and also to allow improvement in self confidence which will help the patient lead a normal life. The key to achieve this goal is to select of suitable material which fulfils all the requirement of the prosthesis required [17]. For facial rehabilitation assessment of materials used in maxillofacial prosthesis is absolutely necessary [5]. The highest combination of these properties in the present study was produced with A-2186 maxillofacial Silicone, Silastic 4-4210 maxillofacial Silicone and MP Sai Biomed maxillofacial Silicone material. For widespread use in India, silicones available commercially are very expensive in cost. Majority of the maxillofacial defects stricken patients belong to lower middle class group, making it difficult to afford and maintain the prosthesis. To avoid these monetary problems, an indigenous silicone MP Sai Biomed can be used by the clinicians, which are more cost effective as compared to commercially available conventionally used silicones.

Silicones are probably the most widely used materials in dentistry and for facial restoration nowadays. They are a combination of organic and inorganic compounds [6]. The elastomers chosen for this study were considered to be a representative selection of the currently marketed silicone rubber maxillofacial prosthetic materials.

Table 4: T-test for equality of means.

Materials	t	df	Sig. (2tailed)	Mean difference	Std. error difference	95% Confidence interval of the difference	
						Lower	Upper
A-2186	-204.939	58	0	-4.12900	0.02015	-4.16933	-4.08867
MDX-44210	-491.750	58	0	-3.01833	0.00614	-3.03062	-3.00605
Biomed	-37.069	58	0	-1.93383	0.05217	-2.03826	-1.82941

Table 5: Comparison of all materials with properties.

Materials	Properties		
	Hardness	Tensile Strength	Water Absorption
A - 2186	31.8903	3.7093	0.4223
MDX 44210	46.282	6.008	0.4663
BIOMED	27.4173	2.74	0.6077

Tariq Aziz et al., [7] observed that relatively low viscosity and very high mechanical properties were seen for Factor II (A-2186). They stated that Factor II (A-2186) produced superior tensile strength, tear strength and elongation at break in comparison to the other elastomeric materials [7]. In their study they had tested tensile strength by determining tensile stress strain properties. Similar methodology was used in this study.

Factor II (A-2186) had good all round mechanical properties and highest tear strength than the other materials. Polyzois et al., [8] stated that hardness reflects the tactile response of lifelike feel [14]. The hardness of the maxillofacial material is also a measure of flexibility and is important since it is desirable to have a material with similar hardness to the missing facial tissue, this provides support for the surrounding tissues and makes it look more aesthetic [7]. Factor II showed better hardness according to this study in comparison to MP SAI biomed siliocone material. Han et al., [14] tested UV-shielding nano-oxides (TiO_2, ZnO, CeO_2) as opacifiers for silicone A-2186 maxillofacial prostheses. After artificial aging the best colour stability was reached with mixed pigments and 1% nano-CeO_2, and 2% and 2.5% nano-TiO_2 used as opacifiers. When yellow silicone pigments are mixed with all three nano-oxides, colour stability of A-2186 silicone elastomer was significantly affected [10]. In this study, no pigments were mixed with the material. All the three materials were compared for colour stability according to the CIELAB (Commission Internationale de l'eclairage) color system. Registration of the color according to the Lab color system showed color changes. According to this study, A-2186 has good colour stability amongst all the three materials tested.

Water absorption is an important property for a maxillofacial material. All the silicone materials are significantly less wetted than the acrylic resin denture base material. Polyzois et al., [8] stated that potential of producing friction and micro trauma to the surrounding tissues may be reduced by improving wettability and by achieving sufficient lubrication around all the margins of the prosthesis [18]. Aziz et al., [19] stated that A-2186 had negligible water absorption. They tested water absorption using dessicator and electronic weight balance. Using the similar methodology, water absorption was tested for this study. According to the results of this study, water absorption was least for A-2186. The water absorption studies on the commercial materials allow us to find out which of these materials contain surface treated filler [20]. The Silastic 4-4210 maxillofacial silicone material is termed as a medical grade silicone as it has been experimentally implanted to test its acceptance in tissues. The filler used in the compound is a very pure, which is finely divided silica (particle size of about 30mp). Without this filler the silicone rubber would have insufficient strength [2]. MDX4-4210 elastomeric material is the most commonly used among most of the clinicians [3]. Moore reported that it exhibited excellent qualities of colour stability and edge strength around the margin. It is not heavily filled, making it translucent. Platinum acts as a catalyst; the cross-linking agent is hydromethylsiloxane. It has high tensile strength (compared to other RTV silicones). It shows increased elongation and resistance to tear. According to this study, this material has good tensile strength.

Colouring in RTV silicones (MDX 4-4210) is accomplished by adding various dry earth pigments. It is non toxic and biologically compatible [5]. Craig stated that all the Silicone materials, PVC and polyurethane exhibited good colour stability especially Silastic 4-4210 [3]. According to this study, when compared with A-2186 silicone maxillofacial material, MDX4-4210 had less colour stability than A-2186. Barhate AR et al., stated that with MDX4-4210, a increased elongation and hardness is measured within the range of human skin, colour stable, simple processing and compatible with adhesives [4]. The tensile strength of the silicone elastomer has the overall strength of the material and the elongation seen shows an indication of the flexibility of the prosthesis. A prosthesis which has high elongation property at breaking point is desirable especially when peeling a nasal or eye prostheses from facial tissue. MDX4-4210 showed best tensile strength as compared with other two materials. MP Sai Biomed maxillofacial Silicone material is a condensation type material. It is RTV one component silicone material. Aziz et al., [19] stated that MP Sai Biomed maxillofacial Silicone material had highest amount of water sorption [21]. According to this study, this material showed the greatest water sorption amongst all the three materials tested. The rate of water absorption of any material is continuous and it increases with time [20]. The condensation type polymers form a byproduct that later is excluded from the polymeric structure. This would probably lead to a more porous polymeric structure than in the addition type polymers. Hence biomed silicone being condensation type silicone may be the reason for more water sorption [20].

In this study, hardness and tensile strength were possessed best by the Silastic 4-4210 maxillofacial Silicone material whereas MP Sai Biomed maxillofacial Silicone material possessed least hardness and tensile strength of three materials tested. A-2186 maxillofacial Silicone showed least water absorption and MP Sai Biomed maxillofacial Silicone material showed more water absorption than the three materials tested. Reddy et al., stated that physical properties of A-2186 are better than MDX4-4210 [3]. According to this study, A-2186 maxillofacial Silicone possess all round better properties with respect to colour stability and water absorption than the other two commercially available materials that were used in this study. With respect to hardness and tensile strength, MDX4-4210 was found to be the best material followed by A-2186 and MP Sai Biomed silicone material. MP Sai Biomed maxillofacial Silicone material produced least ideal properties required than both the other materials tested.

The differences observed in the physical and mechanical properties of the commercial materials are due to different components used in their formulations [7,14]. When reviewing the advantages and disadvantages of each of these materials, it is obvious that no single material is ideal for every patient [3]. It was seen that none of the above mentioned commercially available maxillofacial elastomeric materials tested possessed all the ideal properties required to be a universal successful maxillofacial prosthetic material. Therefore further need for an improved silicone elastomeric material which specifically fulfils the requirements for this unique medical use should be made.

Conclusion

According to this study, A-2186 maxillofacial Silicone possess all round better properties with respect to colour stability and water absorption than MDX4-4210 and MP Sai Biomed maxillofacial silicone materials that were used in this study.

With respect to hardness and tensile strength, MDX4-4210 was found to be the best material followed by A-2186 and MP Sai Biomed silicone material.

MP Sai Biomed maxillofacial Silicone material produced least ideal properties required than both the other materials tested.

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