EFFECT of SILICA FILLER ON THE MECHANICAL PROPERTIES OF SILICONE MAXILLOFACIAL PROSTHESIS

By

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INTRODUCTION

After the second world war, maxillofacial prosthetic treatment started to become popular¹. Barnhart first introduced silicone elastomeric material in 1960². Many papers were published on this subject. Some authors focused on the materials, instruments and appliances that were available and used to fabrication of maxillofacial prosthesis³. Other authors focused on evaluating the effectiveness of the maxillofacial prosthesis in restoring psychological defects of the patient⁴. The primary goal of maxillofacial prosthesis is to restore the patients' appearance to allow improvement in self-esteem and help the patient to live as normal life as possible. Maxillofacial prosthetic materials are expected to be desirable, and attain ideal physical, esthetic and biological properties in order to gain patient acceptance and can be fabricated easily in the dental lab. The ideal properties of a maxillofacial prosthesis are to be⁵:

- 1. Physically and mechanically similar to the replaced tissue.
- 2. Compatible with human tissue.
- 3. Capable of adhering to human tissue.
- 4. Coloring or staining can be done both intrinsically and extrinsically.
- 5. Polymerizing process of the maxillofacial material should be simple, sensitivity to polymerizing processing should be nonexistent or negligible and materials required for fabrication and processing techniques should be used in a common basis in the dental settings.
- 6. The material should be capable of serving the patient at least one year while maintaining those properties.

Different materials have been used in the past including ivory, wax, metal, wood and recent polymers. Polysiloxane rubber materials were introduced into maxillofacial technology in the 60's and nowadays silicone elastomers or poly-dimethylsiloxanes are materials of choice⁶.

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Silicone maxillofacial prosthesis can be categorized to (1) room temperature-vulcanizing silicone (RTV) and (2) high temperature-vulcanizing silicone (HTV). Andres et al⁷ indicated that polydimethylsiloxane silicone elastomer that is vulcanized at room temperature is the most common silicone elastomer that has been used to fabricate maxillofacial prosthesis, because these materials are less time consuming, can be processed easily, are flexible and durable. However, a number of problems with the current materials are known notably low tear and tensile strength. The tear strength needs to be adequate, so that very thin margins of the prosthesis can be produced to blend in with surrounding tissue. It is also important that the material is not excessive hard, and ideally the material should be as skin like as possible. In addition, the basic strength and flexibility of the materials needs to be adequate so the material can be removed, washed and handled without any damage. Thus, improved materials with enhanced properties are needed. Many studies have been conducted to improved existing material or to develop new maxillofacial prosthetic materials⁸⁻¹⁰.

REVIEW OF LIERATURE

Silastic[®] MDX4-4210 (Dow Corning Corp, Midland, Mich.) is a medical grade RTV silicone elastomer. It is a two component platinum-cured poly(dimethylsiloxane), curable at room temperature and can be accelerated with high temperature. It is currently the most popular maxillofacial prosthetic elastomer among clinicians^{5, 11} because of their acceptable properties, such as dimensional stability, improved tear strength and translucency.

VST-50 (Factor II Inc., Lakeside AZ) is also an RTV silicone elastomer. VST-50 was introduced to use for maxillofacial prosthesis as an alternative material due to the high cost of MDX4-4210¹². However, limited clinical success was seen due to the lower mechanical properties of VST-50.

To enhance the mechanical properties of the materials, the most predictable method is incorporation of a hydrophobic surfaced treated silica filler with a small particle size and therefore a high surface area. Under deformation, the surface-treated fillers help increase the strength of the elastomer by allowing the polymer chains to uncoil and slide past the neighboring chains⁸. In addition, the hydrophobic silica also prevents the incorporation of water^{13, 14}.

Karayazgan¹⁵ has shown in published report that tulle can be incorporated in silicone maxillofacial prosthesis to increase tear strength of the prosthesis at the edges. Tulle is commonly used in operas and theaters to make artificial mustaches and beards. The application of the tulle into a silicone maxillofacial prosthesis margins result in having margins more resistant to tearing during fabrication by the professional and application by the patient.

Gunay et al¹⁶ performed further investigation on the incorporation of tulle in silicone maxillofacial prosthesis by conducting a study comparing the physical properties of silicone maxillofacial prosthesis reinforced by tulle to the non-reinforced silicone elastomer. The result of the study showed that tensile and tear strengths were significantly higher with silicone

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maxillofacial prosthesis reinforced with tulle than non-reinforced silicone maxillofacial prosthesis.

Andreopoulos et al. in 1994¹⁷ examined the effect of using silica and fibrillar fillers on the mechanical properties of polydimethyl siloxane rubber (C-50, Bater AG, Leverkusen, Germany) maxillofacial material. Fiber fillers used in the study were:

- 1. Short aramid fibers.
- 2. Glass fibers.
- 3. High modulus polyethylene fibers

The study showed that there was no improvement in tensile strength and modulus when fiber fillers were used. However, when particular silica was used, improvements of tensile and tear were shown. The author concluded that ultra high modulus fibers should not be used as reinforcement and silica fillers should be used instead.

Andreopoulos et al. later in 1998¹⁸ studied silicone maxillofacial materials reinforced with silica powder up to 50-percent concentration. Tensile strength improved with increasing silica fillers up to 35 percent, then showed small decline, and tear strength was increased with increasing silica filler content.

Aziz et al.⁸ studied the effect of three parameters on the development of new improved maxillofacial material C50. Parameters used were:

1. Silica fillers: R104, R106, R202, R972, R974, and R812 S

and Silica filler concentrations; 0 wt%, 5 wt%, 10 wt%, 15 wt%, 20 wt%, and 25 wt%.

2. Cross-linker concentration, 0.12 g, 0.20 g, 0.28 g, 0.36 g, 0.54 g, and 0.72 g (per 10 g of base polymer).

3. Ratio of high and low molecular weight polymers.

Tear strength of maxillofacial material reinforced with AEROSIL[®] R 812S was significantly higher than all the other silica fillers. Increasing AEROSIL[®] R 812S silica filler concentration from 15 wt% to 20 wt% was associated with significant increase in tear strength. There was a significant increase in tear strength as the cross-linker was increased to 0.28 percent. Tensile and tear strength were increased at low concentrations (20 wt%) of low molecular weight polymer DMS-S21 added to the high molecular weight polymer C50. Hardness of the new developed maxillofacial material is relatively higher than the commercially-available materials and this feature was considered as a problematic feature⁸.

In summary, AEROSIL[®] R 812S has been found to be an effective filler leading to higher tear strength than those with other silica fillers (AEROSIL R104,R106,R202, R972, R974). But the use of R812S in reinforcing VST-50 still need to be confirmed ⁸.

MATERIALS AND METHODS

Materials

Materials	Description	Manufacturer	Composition
VST-50	Addition-cured RTV	Factor II Inc.,	Poly(dimethylsiloxane)
Base & catalyst	silicone	Lakeside, AZ,	% Silica: unknown
Lot no.		USA	
F13U129R01			
Silastic [®] MDX4-	Addition-cured	Dow Corning	Poly(dimethylsiloxane)
4210	medical	Corp,	dimethylvinyl-
Base & catalyst	grade RTV silicone	Midland, Mich.,	terminated with 15-
Lot no. 0007695786		USA	40%
			trimethylated silica
Silica filler	Hydrophobic surface-	EVONIK Corp,	Silicon dioxide
AEROSIL [®] R 812S	treated fumed silica	Parsippany, NJ,	Surface treated with
Lot no. 3152111135	filler	USA	hexamethyldisilazane

Preparation of a modified silicone elastomer

Two formulations (A and B) of modified silicone elastomers containing of 2 and 4 phr (part per hundred part of rubber) of the hydrophobic surface-treated silica filler, AEROSIL[®] R 812S, were prepared.

The base part of VST-50 was mixed with AEROSIL[®] R 812S for 30 minutes and the modified base was mixed with catalyst in a manufacturer recommended ratio of 10:1 by weight for 10 minutes by using the mixer at 150 rpm. A constant vacuum of 28 inches of mercury was

applied for 10 minutes to remove air bubbles. The mixture was poured onto a machined plastic mold to produce a silicone sheet 3.0 ± 0.2 mm thick. A 3mm thickness plastic slab was placed on top and a load of 2 kg was applied to extrude any excess material. Curing time was 24 hours at room temperature.

Preparation of Silastic[®] MDX4-4210 and VST-50 silicone elastomer

The base part of each material was mixed with its catalyst in a manufacturer recommended ratio of 10:1 by weight for 10 minutes by using the mixer at 150 rpm. The molding process was the same as that of the modified material. The curing time of VST-50 was 24 hours while Silastic[®] MDX4-4210 was 72 hours at room temperature.

Methods

Tensile property testing

ISO 37¹⁹: Rubber, vulcanized or thermoplastic – Determination of tensile stress-strain properties describes a method for the determination of the tensile stress-strain properties of vulcanized and thermoplastic rubbers.

Dumbbell-shaped specimens were cut from the strips of cured material to the dimensions of the type 2 standard test piece. Ten specimens per formulation were tested. The test specimen were inserted into the Universal testing machine (MTS Sintech ReNew 1123, Eden Prairie, MN) and the extensometers were clamped at the fixed gauge length (20 mm). The specimen was stretched at a constant rate (a crosshead speed of 500 ± 50 mm/min.) The changes in length and force were monitored continuously throughout the test.

The ultimate tensile strength is defined as the force required to break the dumbbell-shaped specimen, divided by the cross-sectional area (width x thickness of the narrow portion) of the unstretched specimen. The thickness measurement were made at the center of the reduced section of the specimen using a vernier caliper with digital readout (Mitutoyo Corp., Tokyo, Japan).

The percentage elongation at break was calculated from the original length ($Lo = 20 \pm 0.5$ mm) and the length at break (*Lb*), using the equation: % Elongation = 100(Lb - Lo) / Lo

Tear resistance

According to ASTM D624²⁰: Standard test method for tear strength of conventional vulcanized rubber and thermoplastic elastomers: Type C, an un-nicked test piece with a 90° angle, was selected for testing tear resistance because this test is a combination of tear initiation and propagation. The angle test piece has a uniform thickness of 3.0 ± 0.2 mm. Ten specimens per formulation were tested. The tear test was performed on the Universal testing machine (MTS Sintech ReNew 1123). The constant rate of jaw separation is 500 ± 50 mm/min until the specimen was broken. A continuous recording of the force was made throughout the tearing process. Tear strength is defined as the maximum force required to break the specimen, divided by the original thickness of the specimen.

Shore A hardness test

According to ASTM D 2240²¹: Standard test method for rubber property – Durometer hardness, Type A durometer is generally used for soft vulcanized rubber, thermoplastic elastomers. The specimen was at least 6.0 mm in thickness. The hardness test was conducted using a digital Shore A hardness tester (Landmark model HT-6510A, Landmark Industrial Inc.,

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USA). The tester was held in a vertical position with the point of indenter at least 12 mm from any edge of the specimen. Sufficient pressure was applied to obtain firm contact and readings were made 1 second after firm contact was achieved. Ten specimens per formulation were tested and ten readings will be taken at ten different positions (6 mm apart) for each specimen. RESULTS

The data was collected from all quantitative studies of the modified silicones were compared to MDX4-4210 silicone elastomer using one-way analysis of variance (ANOVA) statistical with concentration as main variable for tensile, tear, elongation at fracture and shore A hardness. A significance level of 0.05 was used for all tests.

The mean values of tensile strength of MDX4-4210, VST-50, VST-50 (2phr colloid silica) and VST-50 (4phr colloid silica) are: 3.67 MPa, 5.35 MPa, 6.53 MPa and 7.43 MPa, respectively. The standard deviation of the above mentioned values are: 0.60, 0.76, 0.92, 0.84 respectively. Results are shown in Table I and Figure 24.

There was a significant difference (p<0.001) in the mean tensile strengths between the control group MDX4-4210 and VST-50, VST-50 (2phr colloid silica) and VST-50 (4phr colloid silica). There was also a significant difference between VST-50 and VST-50 (4phr colloid silica) ; however, there was not a statistically significant difference between VST-50, VST-50 (2phr colloid silica) and VST-50 (2phr colloid silica), VST-50 (4phr colloid silica).

The mean values of tear strength of MDX4-4210, VST-50, VST-50 (2phr colloid silica) and VST-50 (4phr colloid silica) are: 5.48 N/mm, 8.01 N/mm, 9.15 N/mm and 34.82 N/mm, respectively. The standard deviation of the above mentioned values are: 0.38, 0.55, 0.94, 1.68 respectively. Results are shown in Table II and Figure 25.

There was a significant difference (p<0.001) in the mean tear strengths between the control group MDX4-4210 and VST-50, VST-50 (2phr colloid silica) and VST-50 (4phr colloid silica). There was also a significant difference between VST-50 and VST-50 (4phr colloid silica), VST50 (2phr colloid silica) and VST-50 (4phr colloid silica); however, there was not a statistically significant difference between VST-50, VST-50 (2phr colloid silica).

The mean values of elongation at fracture of MDX4-4210, VST-50, VST-50 (2phr colloid silica) and VST-50 (4phr colloid silica) are: 803.9%, 899.7%, 897.3% and 1114.6%, respectively. The standard deviation of the above mentioned values are: 115.46, 138.37, 90.45, 93.38 respectively. Results are shown in Table III and Figure 26.

There was a significant difference (p<0.001) in the mean elongation at fracture between the VST-50 (4phr colloid silica) and control group MDX4-4210 and VST-50, VST-50 (2phr colloid silica); however, there was not a statistically significant difference between MDX4-4210 and VST-50, MDX4-4210 and VST-50 (2phr colloid silica), VST-50 and VST-50 (2phr colloid silica).

The mean values of shore A hardness of MDX4-4210, VST-50, VST-50 (2phr colloid silica) and VST-50 (4phr colloid silica) are: 31.5, 34.7, 38.6 and 40.4, respectively. The standard deviation of the above mentioned values are: 0.64, 0.82, 0.48, 0.51 respectively. Results are shown in Table IV and Figure 27.

There was a significant difference (p<0.001) in the mean shore A hardness between all groups.

TABLES AND FIGURES

TABLE I

Tensile Strength of Control Group (MDX4-4210, VST-50), 2phr and 4phr reinforced colloid silica (Unit:MPa)

Specimen #	MDX4-4210	VST-50	VST-50 (2phr)	VST-50 (4phr)
1	4.080	4.499	5.607	7.420
2	4.118	5.913	6.494	7.784
3	3.013	6.289	6.367	6.778
4	4.414	5.959	7.078	8.907
5	4.352	4.925	6.899	7.477
6	3.646	4.393	6.336	6.085
7	3.711	6.185	5.630	7.731
8	2.847	5.243	5.217	6.334
9	3.716	4.360	7.378	8.040
10	2.787	5.704	8.268	7.720
Average	3.668	5.347	6.527	7.428
SD	0.60	0.76	0.92	0.84

TABLE II

Tear Strength of	Control Group	(MDX4-4210,	VST-50),	2phr and	4phr reinforced	colloid silica
		(Unit:	N/mm)			

Specimen #	MDX4-4210	VST-50	VST-50 (2phr)	VST-50 (4phr)
1	5.712	7.589	9.037	31.560
2	5.247	8.589	7.862	33.754
3	5.196	8.038	9.273	34.501
4	5.234	8.641	7.787	34.568
5	5.481	8.039	7.979	34.573
6	5.440	8.095	9.735	35.686
7	5.542	6.984	10.133	36.627
8	5.879	8.316	10.194	37.834
9	4.884	7.335	9.802	34.401
10	6.224	8.425	9.685	34.704
Average	5.48	8.01	9.15	34.82
SD	0.38	0.55	0.94	1.64

TABLE III

Specimen #	MDX4-4210	VST-50	VST-50 (2phr)	VST-50 (4phr)
1	998.2	661.3	743.2	1104.9
2	886.3	986.3	939.7	1154.1
3	758.9	1063.8	894.3	1028.2
4	848.6	1023.4	989.9	1244.8
5	891.6	828.2	950.9	1181.1
6	789.2	727.4	888.1	960.6
7	716.8	949.2	796.1	1199.3
8	725.0	984.2	799.9	990.5
9	840.6	784.1	960.4	1153.1
10	584.0	989.1	1010.6	1129.4
Average	803.92	899.7	897.3	1114.6
SD	115.46	138.37	90.45	93.38

Percentage elongation of Control Group (MDX4-4210, VST-50), 2phr and 4phr reinforced colloid silica (Unit:%)

Unit: %

TABLE IV

Specimen #	MDX4-4210	VST-50	VST-50 (2phr)	VST-50 (4phr)
1	31.8	34.7	38.8	40.0
2	30.9	34.1	38.5	40.6
3	32.2	34.1	38.2	39.7
4	31.9	33.1	38.7	40.6
5	30.5	34.7	38.0	40.8
6	31.0	34.5	39.2	40.1
7	32.3	35.8	39.3	39.7
8	32.1	35.0	37.9	41.0
9	30.9	35.7	38.5	40.5
10	31.6	35.3	39.0	41.1
Average	31.5	34.7	38.6	40.4
SD	0.64	0.82	0.48	0.51

Shore A hardness of Control Group (MDX4-4210, VST-50), 2phr and 4phr reinforced colloid silica



FIGURE 1. EXPERIMENTAL DESIGN-Tensile Test



FIGURE 2. EXPERIMENTAL DESIGN-Tear Test



FIGURE 3. EXPERIMENTAL DESIGN-Shore A hardness test

FIGURE 4. VST-50 SILICONE ELASTOMER

FIGURE 5 . MDX4-4210 SILICONE ELASTOMER

FIGURE 6. 3MM THICKNESS HARD PLASTIC MOLD
FIGURE 7. SAMPLE PREPARATION BY PLASTIC MOLD AND PLASTIC SLAB

FIGURE 8. VAC-U-MIXER

FIGURE 9. VACUUM POWER MIXER

FIGURE 10. MIXING SAMPLE BY VACUUM POWER MIXER AND VAC-U-MIXER

FIGURE 11. VST-50 SAMPLE

Figure 12. Shape of dumb-shell test pieces. The standard thickness of the narrow portion is 3.0mm +/- 0.2mm and test length is 20 +/- 0.5mm

Figure 13. Die for dumb-shell test pieces : A) overall length 75mm, B) width of ends 12.5 +/-0.1mm, C) length of narrow portion 25 +/- 0.1mm, D) width of narrow portion 4 +/-0.1mm, E) transition radius 4 +/- 0.1mm, F) transition radius inside 8 +/- 0.5mm

Figure 14. Dumb-bell-shape cutting jig

Figure 15. ASTM D624 : specifications for trouser shaped specimen

Figure 16. Trouser-shape cutting jig

Figure 17. VST-50 samples (prepared specimens)

Figure 18. VST-50 (2phr) samples (prepared specimens)

Figure 19. VST-50 (4phr) samples (prepared specimens)

Figure 20. Tensile strength test

Figure 21. Tear resistance Test

Figure 22. Shore A hardness test machine

Figure 23. Shore A hardness test

Figure 24. Result: Tensile Strength (MPa)

Figure 25. Result: Tear Strength (N/mm)

Figure 26. Result: Percentage of elongation (%)

Figure 27. Result: Shore A hardness

DISCUSSION

The need for improved maxillofacial prosthetic materials was described by Lewis and Castleberry⁶, who define the ideal properties of these materials. Due to the low strength of currently used silicone materials. The purpose of this study was to develop an improved silicone elastomer and focus on the tensile, tear strength and hardness.

Silastic[®] MDX4-4210 is a widely used maxillofacial prosthetic silicone elastomer, its acceptable mechanical properties and the advantage of both HTV and RTV addition-cured silicone. However, its tear strength is still low, and the cost of material is expensive.

VST-50 is a new economical RTV silicone elastomer. This material is a translucent two component, low viscosity platinum-cured silicone elastomer. Due to the same polymerization reaction, addition type, as Silastic[®] MDX4-4210, no by-products occur and thus it has great dimensional stability. It was proposed that the mechanical properties of VST-50 are acceptable, and it has greater tear strength than Silastic[®] MDX4-4210.

VST-50 also has a faster processing time (24 hours) at room temperature than Silastic[®] MDX4-4210 (72 hours). In addition to the enhanced properties, its cost is less than Silastic[®] MDX4-4210 about two times.

In this study, hydrophobic surface-treated fumed silica filler was used to reinforce the silicone elastomer to provide enhanced mechanical properties. The fumed silica with a high surface area is used to maximize the polymer/filler interactions. AEROSIL[®] R 812S used in this study is a hydrophobic surface-treated fumed silica with 7 nm particle size and a BET surface area of $220 \pm 25 \text{ m}^2/\text{g.}^{22}$ The hexamethyldisilazane surface-treated groups on these silica particles repel water molecules and thus prevent water absorption into the cured material.

The surface of the silica filler particles is modified with trimethyl-silyl groups, so the resulting polymer matrix can withstand greater deformation without rupture or tearing. The

surface modification allows the poly(dimethylsiloxane) chains to slip over the silica particles. Effectively, a more flexible network is produced, and a higher number of hydrogen bridge linkages act in the direction of the force, therefore, increasing the mechanical strength²².

The four mechanical properties evaluated were tensile strength, percentage elongation, tear strength, and Shore A hardness. These properties are useful for predicting how the material will perform in service. The ideal maxillofacial prostheses should be durable and possess sufficient flexibility for use on movable facial tissues and strong enough to prevent any edge tearing. The tensile strength, percentage elongation at break, and tear strength define the resistance of prostheses to rupture during use and maintenance and its compliance to facial movement. Desirable ranges of all these properties were proposed by Lewis and Castleberry as follows: tensile strength 1,000 to 2,000 psi (6.89 to 13.79 MPa); percentage elongation 400 to 800%; tear strength 30 to 100 ppi (5.25 to 17.51 N/mm); and hardness 25 to 35 Shore A units.

The results showed that Silastic[®] MDX4-4210 had lower tensile strength (3.67 ± 0.60 MPa) than the proposed range but other mechanical properties were in the range. The results of the tensile strength and percentage elongation of Silastic[®] MDX4-4210 are in agreement with the findings of Bell et al,²³ and the tear strength and Shore A hardness are in agreement with the results of Su and Zhao.²⁴ It was shown that VST-50 and the modified materials had greater tensile strength, percentage elongation, and tear strength than Silastic[®] MDX4-4210. The modified VST-50 with filler loading of 4 phr was found to have the greatest tensile strength (7.43 ± 0.84 MPa) which fell well within the proposed range; however VST-50 and the modified materials had greater percentage elongation (897.3 to 1114.2%) and tear strength (8.01 to 34.82 N/mm) than the proposed range. Shore A hardness is a simple test that can show the softness or hardness of the silicone elastomers. The results showed that Shore A hardness of modified VST-

50 with filler loading of 4 phr and Silastic[®] MDX4-4210 was significantly different and fell higher the upper end of the proposed range.

The tear strength and the viscosity of the silicone elastomer increased when the silica filler concentration was increased. This reinforcing effect was due to the interaction between the silanol groups on the silica surface and the siloxane chains of the polymer. The modified material with filler loading of 6 phr was not considered to test in this study because of its high viscosity and difficulty to molding and processing. A problem seen by increasing the tear strength was that the hardness of the modified material was relatively high in comparison to VST-50. This is a consequence of the higher silica filler loading and high cross-link density, which is needed to improve the tear strength.

The superior tear resistance of the modified silicone to Silastic[®] MDX4-4210 may be explained by the degree of cross-linking in each material.⁷ High degree of cross-linking of Silastic[®] MDX4-4210 leads to reduced segmental mobility of polymeric chains, resulting in large stress concentrations and tear. The superior tensile strength and percentage elongation of the modified silicone to Silastic[®] MDX4-4210 can also be explained in the same way. At high degrees of cross-linking, the material will break before the extension is sufficient for crystallization to occur, which prevents early breaking. The strength and degree of the filler/polymer bonding will also have an influence on tear and tensile properties. Stronger bonding increases the values of these properties.

From the overall results, tensile strength, percentage elongation, and shore A hardness of the modified silicone elastomers increased respectively with the increased amount of fumed silica. The modified silicone elastomer with filler loading of 4 phr was found to have greater tensile strength, percentage elongation, tear strength and shore A hardness than Silastic[®] MDX4-

4210. Also, such silicone elastomer evidently possessed acceptable mechanical properties while maintaining ease of mixing and handling. In addition, using this modified VST-50 can reduce the cost of maxillofacial prosthetic treatment. Future work is being undertaken to further study other properties of this modified material before a clinical trial is considered.

SUMMARY AND CONCLUSIONS

1. The modification of VST-50 silicone material elastomer with a hydrophobic surfacetreated fumed silica filler, AEROSIL[®] R 812S of 2phr and 4phr, was found to have greater tensile strength when compared with VST-50 and Silastic[®] MDX4-4210.

2. The modification of VST-50 silicone material elastomer with a hydrophobic surfacetreated fumed silica filler, AEROSIL[®] R 812S of 4phr, was found to have greater tear strength when compared with VST-50 and Silastic[®] MDX4-4210.

3. The modification of VST-50 silicone material elastomer with a hydrophobic surfacetreated fumed silica filler, AEROSIL[®] R 812S of 4phr, was found to have greater percentage elongation when compared with VST-50 and Silastic[®] MDX4-4210.

4. The modification of VST-50 silicone material elastomer with a hydrophobic surfacetreated fumed silica filler, AEROSIL[®] R 812S of 2phr and 4phr, was found to have greater tensile strength when compared with VST-50 and Silastic[®] MDX4-4210.

In conclusion, the modified VST-50 with 4phr silica revealed improved mechanical properties to use as a maxillofacial prosthetic silicone elastomer. Future work is being undertaken to further study other properties of this modified material before a clinical trial is considered.

REFERENCES

- 1. Sela M, Lowental U. Therapeutic effects of maxillofacial prostheses. Oral Surg Oral Med Oral Pathol 1980;50(1):13-16.
- 2. Barnhart GW. A new material and technic in the art or somoto-prothesis. J Dent Res 1960;39:836-44.
- 3. Bulbulian AH. Maxillofacial prosthetics: evolution and practical application in patient rehabilitation. J Prosthet Dent 1965;15(3):554-69.
- 4. Sykes BE,Curtis TA, Canter R. Psychosocial aspects of maxillofacial rehabilitation. A long-range evaluation. J Prosthet Dent 1972;28(5):540-45.
- 5. Andres CJ,Haug S, Brown DT, Bernal G. Effects of environmental factors on maxillofacial elastomers: Part II Report of survey. J Prosthet Dent 1992;68(3):519-22.
- 6. Lewis DH,Castleberry DJ. An assessment of recent advances in external maxillofacial materials. J Prosthet Dent 1980;43(4):426-32.
- Andres CJ, Haug S, Munoz CA, Bernal G. Effects of environmental factors on maxillofacial elastomers (Part I). Literature review. J Prosthet Dent 1992;68(2):327-30.
- 8. Aziz T,Waters M, Jagger R. Development of a new poly(dimethylsiloxane) maxillofacial material. J Biomed Mater Res Part B : Appl Biomater 2003;65B:252-61.
- 9. Farah JW,Robinson JC, Koran A, Craig RG, Hood JAA. Properties of a modified crosslinked silicone for maxillofacial prosthesis. J Oral Rehabil 1987;14:599-605.
- 10. Moore DJ,Glazer ZR, Tabacco MJ, Linebaugh MG. Evaluation of polymeric materials for maxillofacial prosthetics. J Prosthet Dent 1977;38(3):319-24.
- 11. Beumer J,Curtis TA, Marunick MT. Maxillofacial Rehabilitation: Prosthodontic and surgical considerations. St Louis: Ishiyaku Euro America, Inc.; 1996.
- 12. Gunay Y, Erkan M, Gurbuzer B, Karayazgan B. Facilitation of facial prosthesis placement with tattoo markers: A clinical report. J Prosthet Dent 2007;97(5):256-60.
- 13. Waters MGJ, Jagger R. Mechanical properties of an experimental denture soft lining material. J Dent 1999;27(3):197-202.
- 14. Waters MGJ, Jagger R, Winter RW. Effect of suface modified fillers on the water absorption od a (RTV) silicone denture soft lining material. J Dent 1996;24(4):297-300.
- 15. Karayazgan B. Improved edge sterngth in a facial prothesis by incorporation of tulle: a clinical report. J Prosthet Dent 2003;90(6):526-29.
- 16. Gunay Y KC, Atay A, Karayazgan B, Gurbuz CC. Effect of tulle on the mechanical properties of a maxillofacial silicone elastomer. Dent Mater J 2008;27(6):775-79.
- 17. Andreopoulos AG, Evangelatou M. Evaluation of various reinforcements for maxillofacial silicone elastomers. J Biomater Appl 1994;8(4):344-60.
- 18. Andreopoulos AG, Evangelatou M, Tarantilli PA. Properties of maxillofacial silicone elastomers reinforced with silica powder. J Biomater Appl 1998;13(1):66-73.
- 19. ISO 37 : Rubber, vulcanized or thermoplastic Determination of tensile stress-strain properties; 2005.
- 20. ASTM D624: Standard test method for tear strength of conventional vulcanized rubber and thermoplastic elastomers. Philadelphia; 2000.
- 21. ASTM D2240 : Standard test method for rubber property Durometer hardness Philadelphia; 2005.

- 22. Aziz T, Waters M, Jagger R. Analysis of the porperties of silicone rubber maxillofacial prosthetic materials. J Dent 2003;31(1):67-74.
- 23. Bell WT, Chalian V, Moore BK. Polydimethyl siloxane materials in maxillofacial prosthetics: Evaluation and comparison of physical properties. J Prosthet Dent 1985;54(3):404-10.
- 24. Su F, Zhao Y. The test of the mechanical properties of SY-28, SY-20 and MDX-4-4210 Silicone elastomers. J US-China Med Sci 2006;3(2):36-40.

ABSTRACT

EFFECT of SILICA FILLER ON THE MECHANICAL PROPERTIES OF SILICONE MAXILLOFACIAL PROSTHESIS

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Background: VST-50 (a room temperature-vulcanizing silicone (RTV) by Factor II Inc.) has long been proposed as a potential alternative material for MDX4-4210, another RTV by Dow Corning Corp. and the current material of choice for maxillofacial prosthesis. Though VST-50 has similar chemistry and flexibility as MDX4-4210, its mechanical properties is still too low for it to be used in the clinic. An improvement in the mechanical property of VST-50 is a critical step to bring the material to clinical application. Objective: To investigate the effect of AEROSIL[®] R 812S (colloid silica) addition on the mechanical properties of VST-50 and compared to that of MDX4-4210. Methods: The VST-50 was mixed with AEROSIL[®] R 812S at 2 or 4 parts per hundred parts of rubber. That material was mixed with the catalyst under vacuum. The mixture was poured onto a machined plastic mold to produce a silicone sheet $3.0 \pm$ 0.2 mm thick. All samples were prepared by manufacturer recommended method. Testing samples were prepared and tested following ISO 37 for tensile strength, ASTM D624 for tear strength and ASTM D2240 for shore A hardness test. One way ANOVA was used to compare the groups (Alpha=0.05). Result: Significant differences (P<0.001) were found between MDX44210 and modified VST-50 groups. The mean value of tensile strength, tear strength and hardness of VST-50 (4phr colloid silica) were 7.43(MPa), 34.82(N/mm) and 40.4 respectively, compared to MDX4-4210 were 3.67(MPa), 5.48(N/mm) and 31.5, respectively. Conclusion: Modified VST-50 with 4phr silica revealed improved mechanical properties to use as a maxillofacial prosthetic silicone elastomer.

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