NANO CERAMIC FIBER REINFORCED SILICONE MAXILLOFACIAL PROSTHESIS

by

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INTRODUCTION

Maxillofacial prosthetic treatment started to become popular in the literature after the Second World War.[1] Silicone elastomeric materials were first introduced by Barnhart in 1960.[2] Some authors focused on evaluating the effectiveness of the maxillofacial prosthesis in restoring psychosocial defects of the patient.[3] Other authors focused on the materials, instruments and appliances that were available and used for fabrication of maxillofacial prostheses.[4] The main purpose of maxillofacial materials is to restore the function and form of defective and missing parts of the face, maxilla and mandible so that the psychological defects that result can be restored as well.[5] In addition, the patient's self esteem is raised since they can communicate in public knowing that the defect is unnoticed by the public.[6] Maxillofacial prosthetic materials are expected to be desirable, and attain ideal physical, aesthetic, and biological properties in order to gain patient acceptance and can be fabricated easily in the dental setting. The ideal properties of a maxillofacial prosthesis are to be:

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.[7]

Different materials have been used in the past including ivory, wax, metal, wood, and recently polymers. Many types of elastomers have been used since 1970, e.g. polysiloxane elastomers, polyurethane elastomers, and acrylic resins.[8] Silicone materials almost always refer to polydimethylsiloxane because it is widely used as the material of choice for fabricating maxillofacial prosthesis.[7] Silicone maxillofacial prosthesis can be categorized to either (1) Vulcanized at room temperatures, or (2) Vulcanized by heat. Beumer et al.[9] categorized maxillofacial materials according to their applications. In a paper by Andres et al.,[8] they 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. The expected half-life of maxillofacial prosthesis average is approximately six months and degradation of physical and color properties of silicone maxillofacial prosthesis are the most common reasons for refabrication.[10] Silicone elastomeric materials possess some undesirable properties; most important are low tensile and tear strength, and insufficient elasticity. In the past, silica powders have been used to enhance the properties of these elastomers. Physical and mechanical properties of the material should be similar to the surrounding tissues, material must be compatible with surrounding tissues, material can be adhered to the surrounding tissues, can be colored intrinsically and extrinsically, easily processed, and these properties must be maintained at least for one year. The tear strength should be sufficient so that the thinned margins of the prosthesis can be produced to blend in with

the surrounding tissues , and hardness of the material should be similar to the surrounding tissues.[11] Therefore improving properties of the material is needed.

Surface-treated silica fillers with an increased surface area and a small particle size are an important factor to enhance the physical and mechanical properties of silicone elastomers, which made using silica fillers essential for enhancing tensile and tear strength, elongation at fracture and Shore A hardness. Lately, researchers have found even stronger enhancement through the use of nano silica powder, which has an even larger surface area than micrometer-size silica powder.[12] Nano fibers have even larger surface area. However, whether nano ceramic fiber will further enhance the mechanical property or not has not been investigated so far.

REVIEW OF LITERATURE

Many attempts have been made throughout the literature to evaluate the physical and mechanical properties of different silicone maxillofacial materials. Results of these studies have shown a wide range of variation among tensile and tear strength, percentage elongation and Shore A hardness tests, in addition to the variation between different studies examining the same silicone maxillofacial material such as silicone MDX 4-4210.[11, 13-20]

Enhancing the physical and mechanical properties of silicone elastomers by using fillers has been mentioned in the literature. Karayazgan et al.[21] has shown in a 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. Flesh toned nylon tulle was sewn with artificial hair, and this tulle was adhered to the skin by using prosthetic adhesive. The application of the tulle into the 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 al.[22] 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 results of the study showed that tensile and tear strengths were significantly higher with silicone maxillofacial prosthesis reinforced with tulle, than non reinforced silicone maxillofacial prosthesis.

Hatamleh et al.[23] examined the effect of fiber reinforcement on the bonding of silicone liners prosthesis and dental acrylic. They examined the differences of shear bond strength between smooth, rough, and stick net fiber-reinforced acrylic and silicone liner material Molloplast-B. The experiment was conducted by fabricating the acrylic specimen first then the silicone maxillofacial material was bonded to it. There was significant improvement in shear bond strength between smooth surface acrylic and fiber reinforced acrylic groups. The author observation was that the mode of failure among all silicone liners acrylic interface was mainly cohesive in the silicone material, while smooth surface and fiber reinforced acrylic groups were both adhesive and cohesive failures. They felt further investigations may be needed to improve the cohesive force within the silicone liners.

Andreopoulos et al. in 1994[24] examined the effect of using silica and fibrillar fillers on the mechanical properties of poly(dimethyl siloxane) rubber (C-50, Bayer 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. On the other hand, when particulate silica was used, improvements of tensile and tear strength were shown. The author concluded that ultra high modulus fibers should not be used as reinforcement and silica fillers should be used instead.[24]

Andreopoulos et al. later in 1998[25] 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.[26] 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 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 of Silica filler R812 was significantly higher than all the other silica fillers. Increasing the R812 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 feature.

Han et al.[12] studied the effect of increasing nanosized oxide concentration on tensile and tear strength and percent elongation of maxillofacial material (A-2186). Ti, Zn, or Ce Nanosized oxides were added in, 0.5-percent, 1.0-percent, 1.5-percent, 2.0-percent, 2.5-percent, or 3.0-percent by weight concentrations. Results showed that 2.0

percent and 2.5 groups of all nanosized oxides demonstrated significantly higher tear and tensile strengths and percent elongation.

Much research has been done and many investigations appear in the literature referencing different types of fillers used during the fabrication of different kinds of materials.

Petsalas et al.[27] examined the effect of using aramid fiber-reinforced polyethylene. Light weight, thermal resistance, and high modulus made aramid fibers one of the promising reinforcement materials in the engineering field. The main problem was making an adequate adhesive bond between polyethylene matrix and aramid fiber; therefore fiber pretreatment was done to aramid fibers so that the reinforced polyethylene material could withstand elevated temperatures such as hot water pipelines. They showed that there was an increase in tensile strength with increasing the fiber volume and also showed that there was a clear difference between the resultant forces between surface-treated aramid fibers and the non surface-treated fibers. The surface-treated aramid fibers showed a remarkable increase in strength.

Andreopoulos et al. in 1989[28] examined different surface treatments for aramid fibers, such as Kevlar 49 aramid fiber with a diameter of 12 μm, so improved adhesion to polymeric matrices could be achieved by either chemical modification performed by grafting, or surface roughness of the aramid fibers. The chemicals used for surface roughness were: acetic acid anhydrate, methacryloyl chloride, sulfuric acid, and acrylamide. Preparation of tensile specimens was performed and determination of the effect of the chemical treatments on tensile strength was done. Results showed that methacryloyl chloride was the most favorable coupling agent with the least loss of tensile

strength resulted from chemical treatment. Results have also shown that using the appropriate chemical treatment with the amount of chemical attack was very important in the resultant tensile strength. Increasing the amount of filler used may have a negative effect on the tensile strength of material used.

Liu et al.[29] studied the effect of using up to 5-percent wt nano SiO2 and TiO2 fillers on the mechanical properties of linear low-density polyethylene mixed with low-density polyethylene, with a fixed ratio of 80 wt linear low-density polyethylene and 20 wt low-density polyethylene, for the fabrication of agricultural micro irrigation water pipes to withstand the detrimental harsh environmental effects, such as ultra violet irradiation, temperature differences, and the effect of sand dust. Nano SiO2 and TiO2 fillers are amorphous white particles 20 to 60 nm in size. Liu et al.[29] demonstrated that mechanical properties of low-density polyethylene can be improved by blending it with the proper mix of low-density polyethylene, nano particles of SiO2 and TiO2 as fillers. The study also has shown that using 91-percent resin matrix, 6-percent EVA dispersion factor, and 3-percent mixed nano Sio2 and TiO2 fillers can provide mechanical properties, processability, and environmental adaptability that are very balanced.

Abdelmouleha et al.[30] studied the effects of short natural fibers and coupling agents on the mechanical properties, absorbance behavior and thermal properties of low density polyethylene and natural rubber. Five different types of cellulose fillers with different average lengths:

1. Commercial microcrystalline fibers with 50 μm average length.
2. Technocol 2500 fibers with average length of 2.5 mm.
3. Alfa fibers with 500 μm average length.

4. Bleached soft wood pine fibers with 3.5 mm average length.
5. Avicel fibers with 70 μm of average length.

They also studied the effect of three different kinds of silane-coupling agents on the physical properties of polymer matrixes:

1. γ-Methacryloxypropytrimethoxysilane.
2. Hexadecylthtrimethoxysilane.
3. γ-Mercaptoproyltrimethoxysilane.

Their results demonstrated that the mechanical properties of the composites significantly increased with increasing filler content, length, and with using γ-Methacryloxy-propytrimethoxysilane and γ-Mercaptoproyltrimethoxysilane silane-coupling agents.

Frogley et al.[31] studied the effect of single-wall carbon nano tubes or vapor grown carbon nano fibers on RTV silicone elastomers after dissolving the silicone elastomer in toluene (1mg /ml) so the viscosity can be reduced and also after dispersing the fillers in toluene to help dispersion of the fillers. Nanofibrils have 200 nm diameter and few hundreds of microns of length. RTV silicone elastomer was compared to the reinforced RTV silicone with 0.3 wt%, 0.6 wt% and 1.0 wt% single-wall carbon nano tubes, and compared also to 1.0 wt%, 2.0 wt%, and 4.0 wt% fibrils. They found that tensile stress tests of the reinforced RTV silicone elastomers were significantly higher than the non reinforced RTV silicone elastomer; however, the ultimate strain of the reinforced former is less than the non reinforced later elastomer. Forgley et al.[31] stated that dispersion and interface of the filler in the matrix are the two major detrimental factors in the usefulness of the fillers used for reinforcements.

Mirabedini et al.[32] studied the effect of TiO2 on the mechanical and adhesion properties of RTV silicone elastomer coatings that has been used commonly for marine applications. Tensile stress, modulus, hardness and abrasion resistance were compared between non reinforced RTV silicone elastomer and reinforced RTV silicone elastomer with 5.0 wt%, 10.0 wt%, 15.0 wt% and 20.0 wt% TiO2 fillers. In order for the composite silicone elastomer material to exhibit improved physical properties during marine applications the author mixed the following materials;

1. Silicone elastomer ELSTOSIL (RTV-4511).
2. TiO2 fillers.
3. Hardener (T-21).
4. Epoxy primer coating.
5. Amino silane compound (Silquset A-1170).
6. Dispersing agent (EFKA-3232).

Results showed that tensile stress, modulus, and abrasion resistance increased with increasing the filler content up to 15.9 wt%. Hardness was increased with increasing filler contents up to 25.0 wt%, but on the contrary, elongation to fracture was decreased with increasing filler content. Coating adhesion strength was increased with increasing the filler content up to 10.0 wt% and further reduction of adhesion and cohesion was attributed to difficulties of dispersion of higher fillers contents.

MATERIALS AND METHODS

The major deficiency for unfilled poly(dimethylsiloxanes) maxillofacial prosthesis is the very low tear strength. Surface-treated silica fillers with an increased surface area and a small particle size is an important factor on the physical and mechanical properties of silicone elastomers, which made using silica fillers essential for enhancing tensile strength. The reason behind increased strength is the strong physical and chemical bonds between the vulcanized polymer and filler. The required physical characteristics of the fabricated silicone elastomer, dependant on the type and amount of filler used, which has to be tailored to meet the requirement of strong yet elastic, with mechanical properties that meet the clinical requirements. The degree of cross linking between polymer chains is another factor affecting the physical and mechanical properties. Cross linking concentration has to be tailored to provide silicone elastomer with clinically sufficient tensile and tear strength, on the same time an elastic non brittle material. High cross linking can provide a very strong yet brittle material and a low cross linking can provide very elastic yet weak elastomeric material.[26]

Assessment of the effect on varying the nano ceramic fiber fillers on hardness, tensile strength, tear strength and elastic deformation on poly(dimethylsiloxanes) has been done in this study by laboratory experiments and comparison with VST-50HD silicone elastomer (Factor II Inc., Lakeside, AZ), commercially-available silicone elastomer materials. Durometer Method (Shore A hardness) test based on ISO 7619-1:2004 has been used in this study. Dumbbell-shaped specimens have been used to determine the tensile strength and percentage elongation according to ISO 37:2005.

Trouser-shaped test pieces have been used to determine the tear strength according to ISO 34-1:2004. Ten specimens with different nano ceramic fiber fillers with 2-percent, 4-percent, and 6-percent have been prepared, examined, experimented upon, and compared to the commercially-available silicone elastomer material, VST-50HD silicone elastomer (Factor II Inc.) (Figures 1 through 4)

The control group samples were prepared first by weighing the silicone elastomer (Figure 5), adding the appropriate amount of catalyst, then both were placed in a pressure pot (Figure 6), so the incorporated bubbles were eliminated. The procedure was repeated twice to eliminate further bubbles from erupting (Figure 7). The prepared sample was placed in the Vac-U-Mixer (WhipMix, Louisville, KY) then placed in the Vacuum power mixer (WhipMix). A very small amount of petroleum jelly was placed on the surface of the glass slabs and wiped with tissue paper very well so the set material could be removed after setting without sticking on the glass slabs. The prepared material was placed on a petroleum jelly-lubricated glass slab with dimensions 6" x 3" x 0.75" (Figure 8). A second glass slab was used with two pieces of glass 1 mm in thickness used as a spacer. The glass slabs were then placed in the pressure pot with a pressure of 20 Pascal for 24 hours. Samples with reinforced Nano alumina fibers (Argonide, Sanford, FL) were prepared by weighting the silicone elastomer, adding the Nano alumina fibers, placing the sample in the Vac-U-Mixer (WhipMix) (Figure 9), then moving the sample to the Vacuum power mixer (WhipMix) (Figure 10) for 30 seconds, the catalyst was added and was further mixed in the Vacuum power mixer. Specimens were prepared in the same manner as the control groups were prepared (Figures 11 through 14). Translucency

of the Nano alumina fibers/silicone mixture was visually inspected to ensure that the Nano alumina fibers were evenly distributed during mixing (Figure 15).

TENSILE PROPERTY TESTING

ISO 37:2005[33] standard test for rubber and vulcanized or thermoplastic rubber material was used to determine the tensile stress–strain properties. Strips of cured material were fabricated. Then ten dumb-bell-shaped type 2 (Figures 16 and 17) specimens per formulation were cut from the die (Figures 18 through 20) to the dimensions of the type 2 standard test piece. Dumb-bell-shaped specimens 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) (Figure 21). The specimens were stretched at a constant rate (a cross head speed of 500 ± 50 mm/min.).

The force required to break the dumb-bell-shaped specimen, divided by the cross-sectional area (width x thickness of the narrow portion) of the unstretched specimen, is defined as the ultimate tensile strength. Vernier caliper with digital readout (Mitutoyo Corp., Tokyo, Japan) was used to measure the thickness at the center of the reduced section of the specimen. The equation:

$$\% \text{ Elongation} = 100(Lb\text{-}Lo)/Lo$$

was used to calculate the percentage elongation at break from the original length (Lo = 20 ± 0.5 mm) and the length at break (Lb).

TEAR RESISTANCE

ASTM D624[34] standard test method for tear strength of conventional vulcanized rubber and thermoplastic elastomers was followed for testing tear resistance. Strips of cured material were fabricated, then ten trouser-shaped test specimens per formulation were cut from the die of type C, an non-nicked test piece with a 90^{o} angle was used (Figures 22 through 24). The angle test piece had a uniform thickness of 2.0 ± 0.2 mm. This test piece was selected because this test was a combination of tear initiation and propagation. The Universal testing machine (MTS Sintech) was used to perform the tear test (Figure 25). The constant rate of jaw separation was in the range of 500 ± 50 mm/min until the specimen was broken. Tear strength was defined as the maximum force required to break the specimen, divided by the original thickness of the specimen.

SHORE A HARDNESS TEST

ASTM D 2240[35] standard test method for rubber property-Durometer hardness, Type A. A durometer is generally used for soft vulcanized rubber and thermoplastic elastomers. The specimens were 6.0 mm in thickness (Figure 26). Digital Shore A hardness tester (Landmark model HT-6510A, Landmark Industrial Inc., Ramsey, NJ) (Figure 27) was used to measure hardness (Figure 28). Ten specimens per formulation were tested and ten readings taken at ten different positions (6 mm apart) for each specimen.

RESULTS

The data were collected from all quantitative studies of the modified silicones were compared to VST-50HD silicone elastomer (Factor II Inc.) using one-way analysis of variance (ANOVA) statistical analysis 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 for tensile strength of control group 2-percent, 4-percent, and 6-percent reinforced nano ceramic fiber fillers are: 5.48 MPa, 3.98 MPa, 3.43 MPa, and 3.78 MPa, respectively. The standard deviation of the above mentioned values of control group 2-percent, 4-percent, and 6-percent reinforced nano ceramic fiber fillers are: 0.71, 0.60, 0.12, 0.25 respectively. Results are shown in Table III and Figure 29.

There was a significant difference ($p < 0.001$) in the mean tensile strengths between the control group VST-50HD silicone elastomer maxillofacial material and 2-percent, 4-percent, and 6-percent reinforced nano ceramic fiber fillers; however, there was not a statistically significant difference ($p > 0.05$) between 2-percent, 4-percent, and 6-percent reinforced nano ceramic fiber fillers.

The mean values for tear strength of control group 2-percent, 4-percent, and 6-percent reinforced nano ceramic fiber fillers are: 5.01 MPa, 2.44 MPa, 2.34 MPa, and 2.56 MPa, respectively. The standard deviation of the above-mentioned values of control group 2-percent, 4-percent, and 6-percent reinforced nano ceramic fiber fillers are: 0.39, 0.18, 0.37, and 0.38, respectively. Results are shown in Table IV and Figure 30.

There was a significant difference ($p < 0.001$) in the mean tear strengths between the control group VST-50HD silicone elastomer maxillofacial material and 2-percent, 4-percent, and 6-percent reinforced nano ceramic fiber fillers; however, there was not a statistically significant difference ($p > 0.05$) between 2-percent, 4-percent, and 6-percent reinforced nano ceramic fiber fillers.

The mean values for elongation at fracture of control group, 2-percent, 4-percent, and 6-percent reinforced nano ceramic fiber fillers are: 793.51, 699.66, 775.15, and 783.07, respectively. The standard deviation of the above-mentioned values of control group, 2-percent, 4-percent, and 6-percent reinforced nano ceramic fiber fillers are: 57.27, 43.69, 32.96, and 38.13, respectively. Results are shown in Table V and Figure 31.

There was a significant difference ($p < 0.001$) in the mean elongation at fracture between the 2-percent reinforced nano ceramic fiber VST-50HD silicone elastomer maxillofacial material and control group, 4-percent, and 6-percent reinforced nano ceramic fiber fillers; however, there was not a statistically significant difference ($p > 0.05$) between control group, 4-percent, and 6-percent reinforced nano ceramic fiber fillers.

The mean values for Shore A hardness of control group, 2-percent, 4-percent, and 6-percent reinforced nano ceramic fiber fillers were: 38.76, 25.76, 26.31, and 29.79, respectively. The standard deviation of the above-mentioned values of control group, 2-percent, 4-percent, and 6-percent reinforced nano ceramic fiber fillers were: 1.83, 2.18, 1.59, and 3.69, respectively. Results are shown in Table VI and Figure 32.

There was a significant difference ($p < 0.001$) in the mean Shore A hardness between the control group VST-50HD silicone elastomer maxillofacial material and 2-percent, 4-percent, and 6-percent reinforced nano ceramic fiber fillers; however, there was not a significant difference ($p > 0.05$) between 2-percent, 4-percent, and 6-percent reinforced nano ceramic fiber fillers.

TABLES AND FIGURES

TABLE I

Variation in tensile and tear strength, percentage elongation and Shore A hardness between different maxillofacial materials and between individual ones

	Tensile Strength (MPa)	Tear Strength (N/mm)	Percentage Elongation	Shore A Hardness
MDX 4-4210 Lewis et al. 4/1980[20]	3.24 -7.04	21.07	410.0-514.0percent	15.00
Bell et al. 9/1985[13]	3.23	10.59	430.4-percent	31.60
Farah et al. 1987[17]	1.24		296.0percent	31.00
Haug et al. 10/1992[10]	2.47	5.56	356.0percent	28.93
Polyzois et al. 1995[18]	1.65	6.49	307.9percent	25.40
Haug et al. 4/1999[15]	4*	7*	240.0percent	27.00
Haug et al. 4/1999[16]	5*	7*	280.0percent	28.00

(continued)

TABLE I (continued)

Variation in tensile and tear strength, percentage elongation and Shore A hardness between different maxillofacial materials and between individual ones

Silicone A-2186				
Haug et al. 10/1992[10]	2.47	35.50	488.0percent	28.93
Haug et al. 4/1999[15]	10*	15*	310.0percent	27.00
Haug et al. 4/1999[16]	11*	14*	340.0percent	26.00
Aziz et al. 2003[11]	4.23	17.63	650.0percent	16.21
Bellamy et al. 2003[36]		5.58		18.25
Medical adhesive type A				
Farah et al. 1987[17]	2.20		296.0percent	35.00
Haug et al. 10/1992[10]	1.13	12.20	304.0percent	29.37
Haug et al. 4/1999[15]	4.5*	5*	240.0percent	34.00
Haug et al. 4/1999[16]	5*	4*	250.0percent	36.00

(continued)

TABLE I (continued)

Variation in tensile and tear strength, percentage elongation and Shore A hardness between different maxillofacial materials and between individual ones

Cosmesil Polyzois et al. 1999[18]	1.30	10.59	364.0percent	15.70
Aziz et al. 2003[11]	4.24	4.87	577.1percent	44.99
Cosmesil HC Aziz et al. 2003[11]	3.87	15.55	888.0percent	44.47

*Indicate that results has been taken from a graph

TABLE II

Material information as reported by manufacturer

Product Name & Manufacturer	**Elastomer Component**	**Curing Agent Component**
VST-50HD MEDICAL GRADE ELASTOMER BASE	Dimethylsiloxane Polymer Reinforcing Silica platinum Catalyst	Dimethylsiloxane Polymer Inhibitor Siloxane Crosslinker

TABLE III

Tensile strength of control group, 2-percent, 4-percent, and 6-percent reinforced nano ceramic fiber fillers

Specimen #	Control(MPa)	2-percent(MPa)	4-percent(MPa)	6-percent(MPa)
1	5.5	4.5	3.4	4.0
2	6.0	3.1	3.4	4.0
3	5.3	3.6	3.5	3.3
4	4.8	3.8	3.2	3.9
5	6.5	4.3	3.4	3.9
6	4.5	4.6	3.6	3.5
7	4.8	3.3	3.4	4.0
8	5.0	4.6	3.4	3.8
9	5.3	4.6	3.5	3.6
10	6.1		3.6	
11			3.3	
Average	5.48	3.98	3.43	3.78
SD	0.71	0.60	0.12	0.25

TABLE IV

Tear strength of control group, 2-percent, 4-percent, and 6-percent reinforced nano ceramic fiber fillers

Specimen #	Control(MPa)	2-percent(MPa)	4-percent(MPa)	6-percent(MPa)
1	4.563	2.376	2.385	2.439
2	4.983	2.673	2.887	2.659
3	5.683	2.468	1.976	2.335
4	5.468	2.260	2.490	2.888
5	5.025	2.328	2.166	3.145
6	4.899	2.479	1.998	2.727
7	4.899	2.697	2.169	2.506
8	4.580	2.260	2.432	2.880
9		2.597	2.796	1.854
10		2.597	1.898	2.175
11			2.873	
Average	5.01	2.44	2.34	2.56
SD	0.39	0.18	0.37	0.38

TABLE V

Percentage elongation of control group, 2-percent, 4-percent, and 6-percent reinforced nano ceramic fiber fillers

Specimen #	Control	2-percent	4-percent	6-percent
1	785.7	734.4	765.3	806.2
2	840.6	671.5	765.2	821.3
3	866.1	636.3	766.9	710.8
4	724.4	652.1	698.1	773.8
5	867.4	684.3	774.3	815.8
6	727.8	732.7	800.5	763.0
7	727.8	743.4	779.0	818.6
8	768.2	742.6	776.8	793.5
9	784.8		798.0	744.6
10	842.3		833.8	
11			768.7	
Average	793.51	699.66	775.15	783.07
SD	57.27	43.69	32.96	38.13

TABLE VI

Shore A hardness of control group, 2-percent, 4-percent, and 6-percent reinforced nano ceramic fiber fillers

Specimen #	Control	2-percent	4-percent	6-percent
1	39.4	27.7	26.0	30.5
2	40.1	29.7	28.0	34.1
3	40.1	26.0	28.0	34.2
4	40.2	25.1	25.5	31.2
5	35.3	24.2	27.4	35.0
6	39.6	26.6	24.5	26.4
7	39.9	26.7	27.4	23.3
8	37.4	27.5	27.4	27.4
9	35.5	23.5	24.3	30.2
10	39.6	24.3	24.2	28.1
11	39.3	22.1		27.3
Average	38.76	25.76	26.31	29.79
SD	1.83	2.18	1.59	3.96

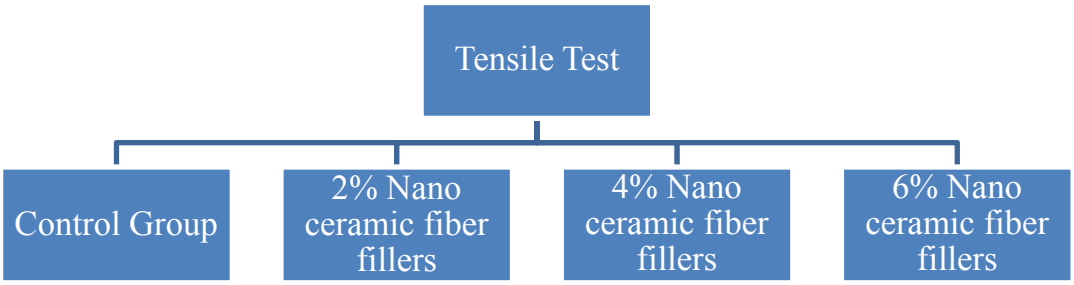

FIGURE 1. Experimental design.

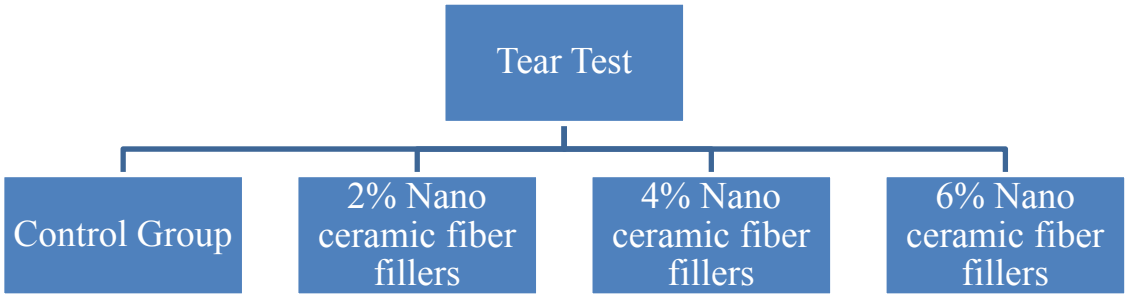

FIGURE 2. Experimental design.

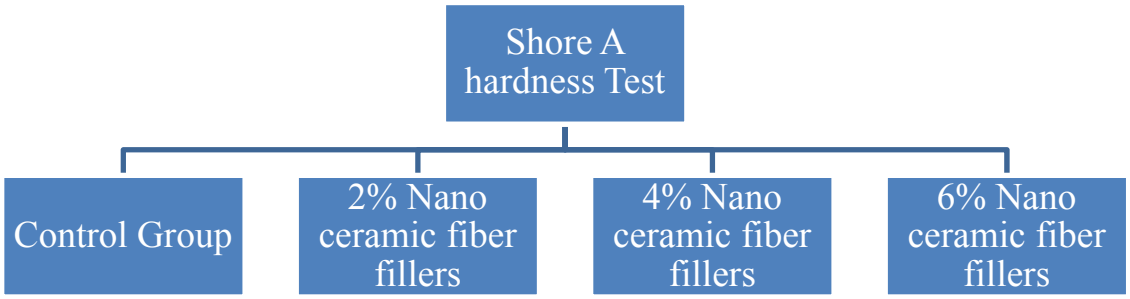

FIGURE 3. Experimental design.

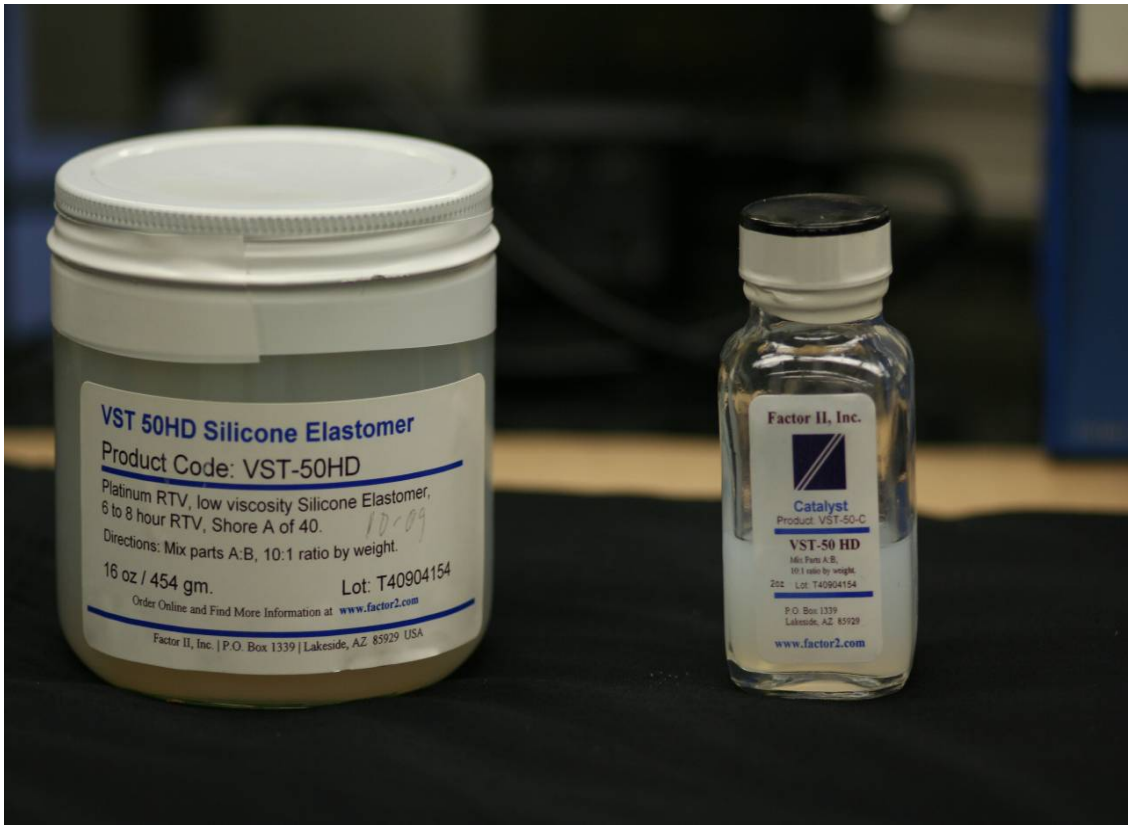

FIGURE 4. VST 50HD silicone elastomer used in the experiment.

FIGURE 5. Weight scale.

FIGURE 6. Pressure pot.

FIGURE 7. Silicone elastomer after being placed in the pressure pot.

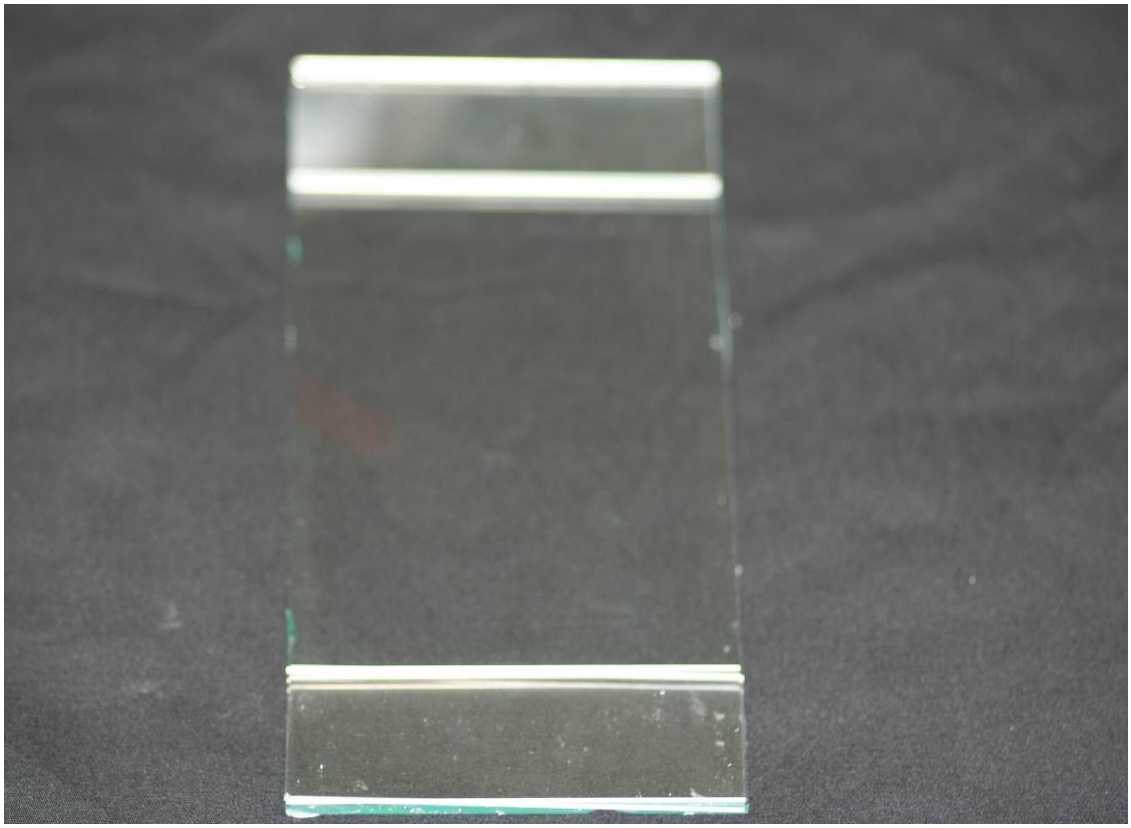

FIGURE 8. Sample preparation assembly (glass slab and glass spacer).

FIGURE 9. Vac-U-Mixer.

FIGURE 10. Vacuum power mixer.

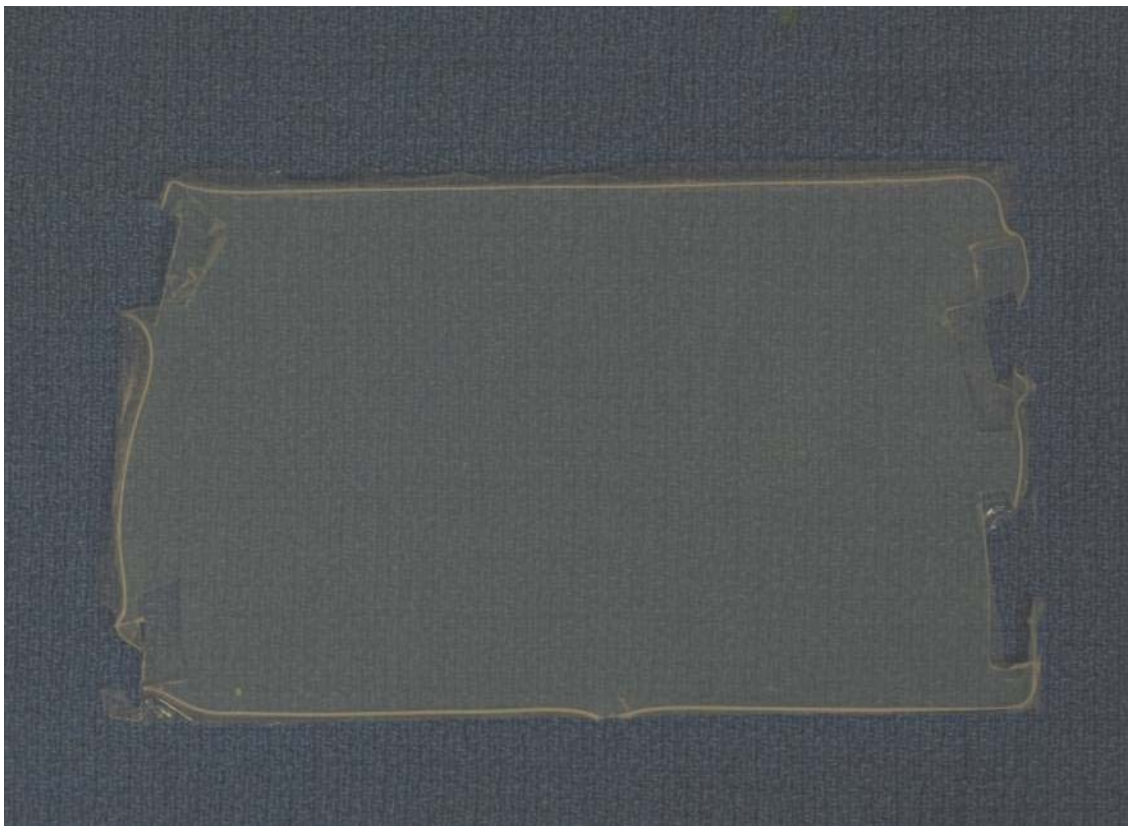

FIGURE 11. Control group sample.

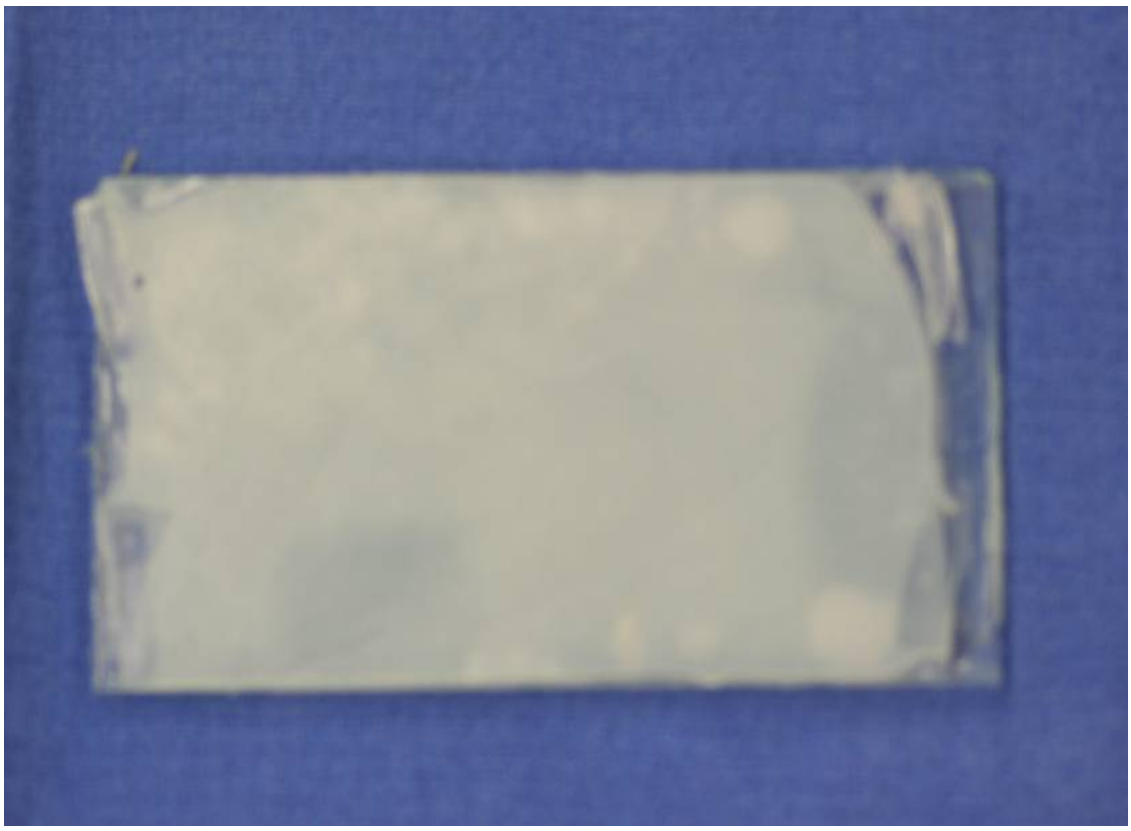

FIGURE 12. Sample with 2-percentreinforced nano alumina fibers.

FIGURE 13. Sample with 4-percent reinforced nano alumina fibers.

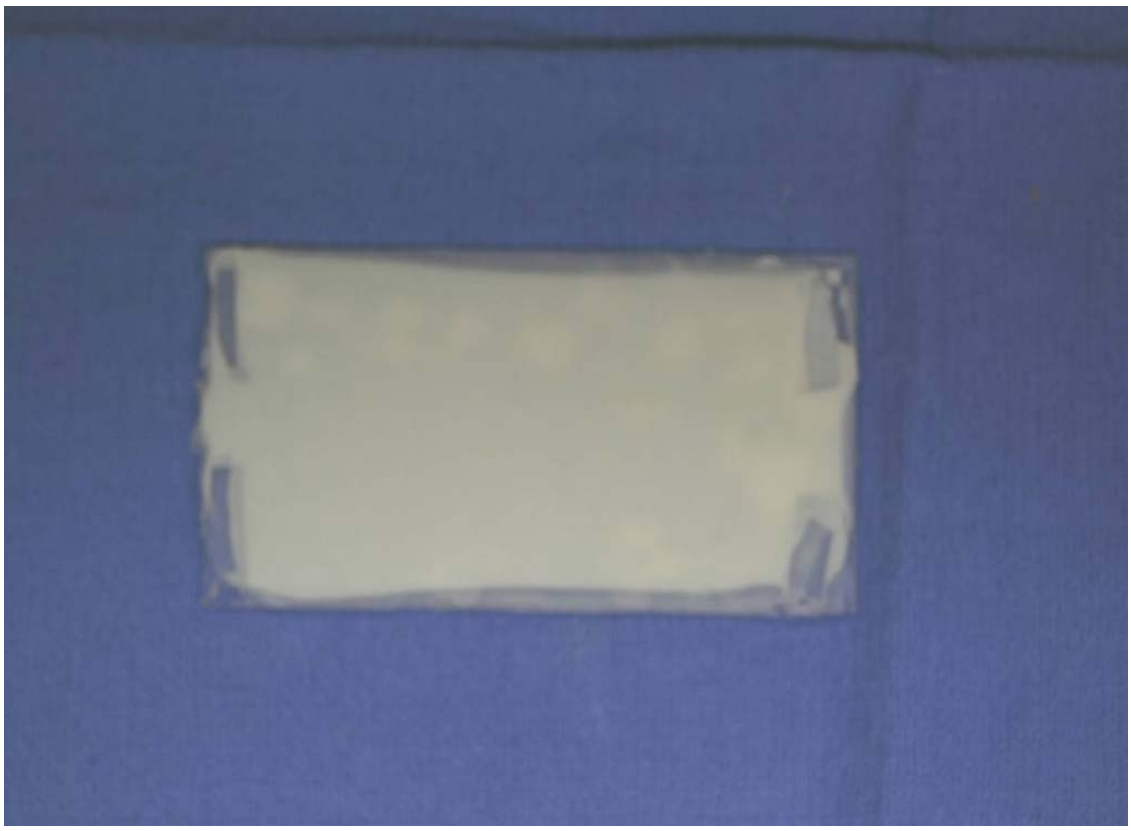

FIGURE 14. Sample with 6-percent reinforced nano alumina fibers.

FIGURE 15. Uniform distribution of nano fibers.

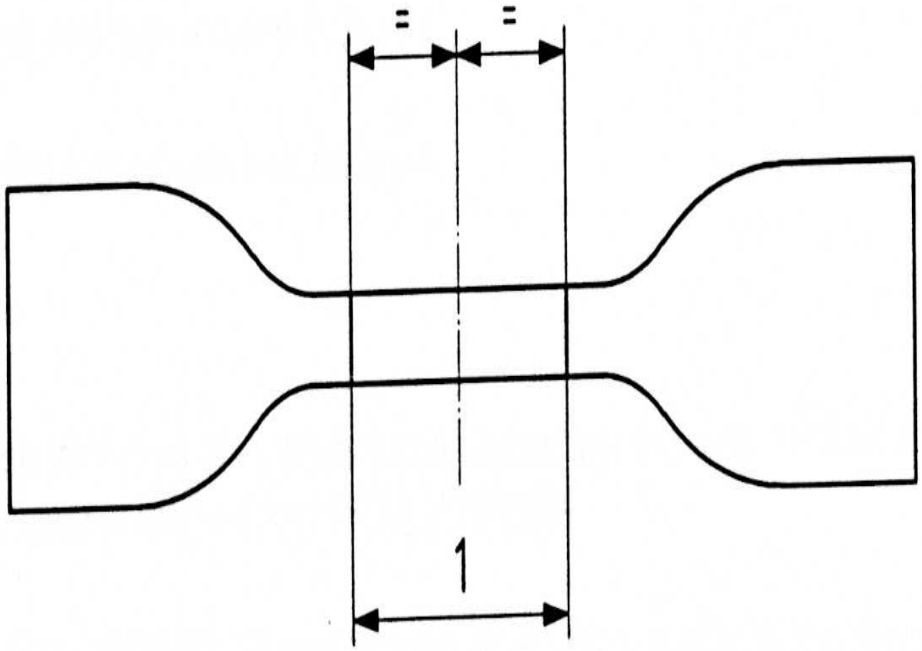

FIGURE 16. Shape of dumb-bell test pieces. The standard thickness of the narrow portion is 2.0 mm+/- 0. 2 mm for type 2. Test length is 20+/- 0. 5 mm.

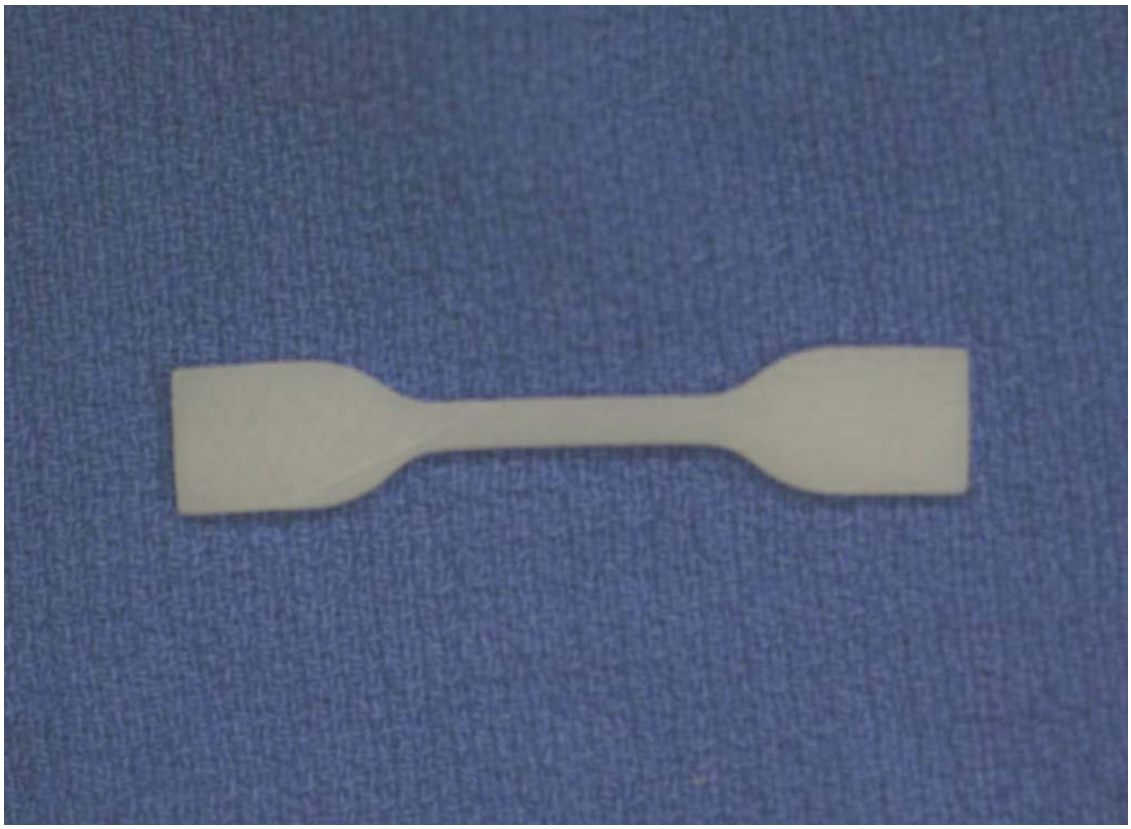

FIGURE 17. Dumb-bell test specimen.

FIGURE 18. Sample sheet and die cutter placed in the hydraulic compressor.

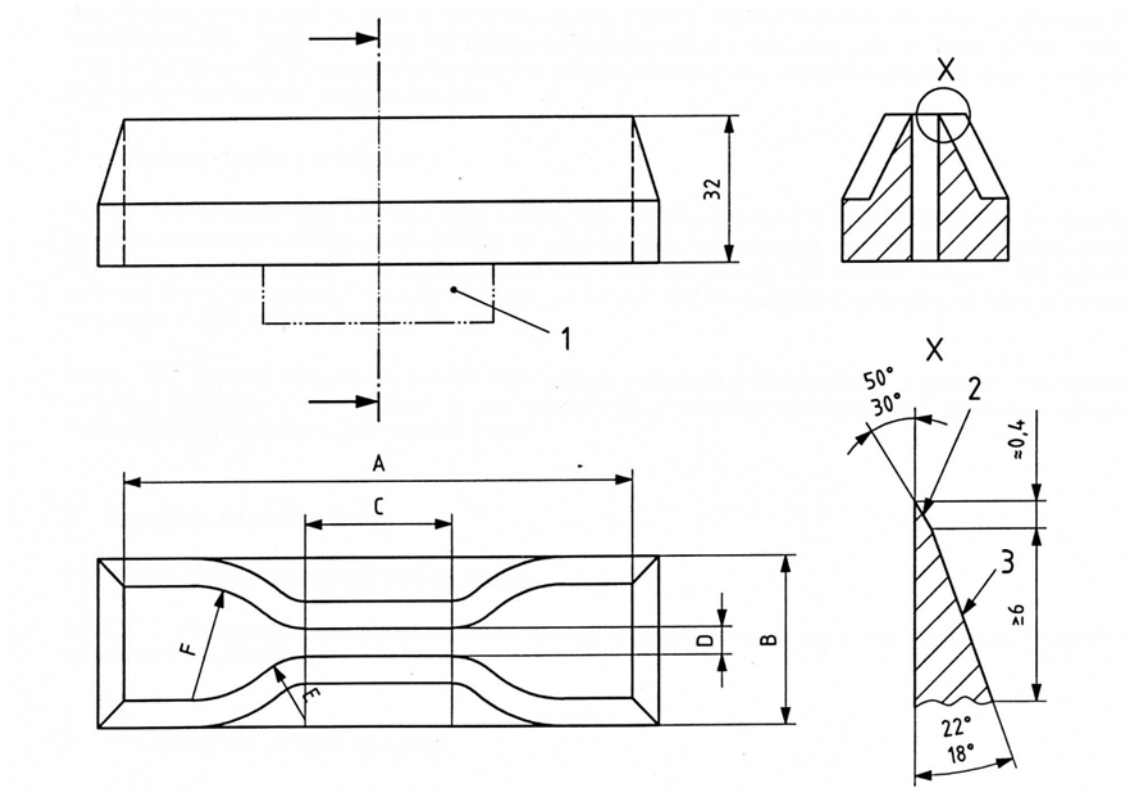

FIGURE 19. Die for dumb-bell test pieces: A) overall length 75mm, B) width of ends 12. 5+/-1 mm, C) length of narrow portion 25+/-1, D) width of narrow portion 4+/- 0.1, E) transition radius outside 4 +/- 0.1 mm, F) transition radius inside 8+/- 0.5 mm.

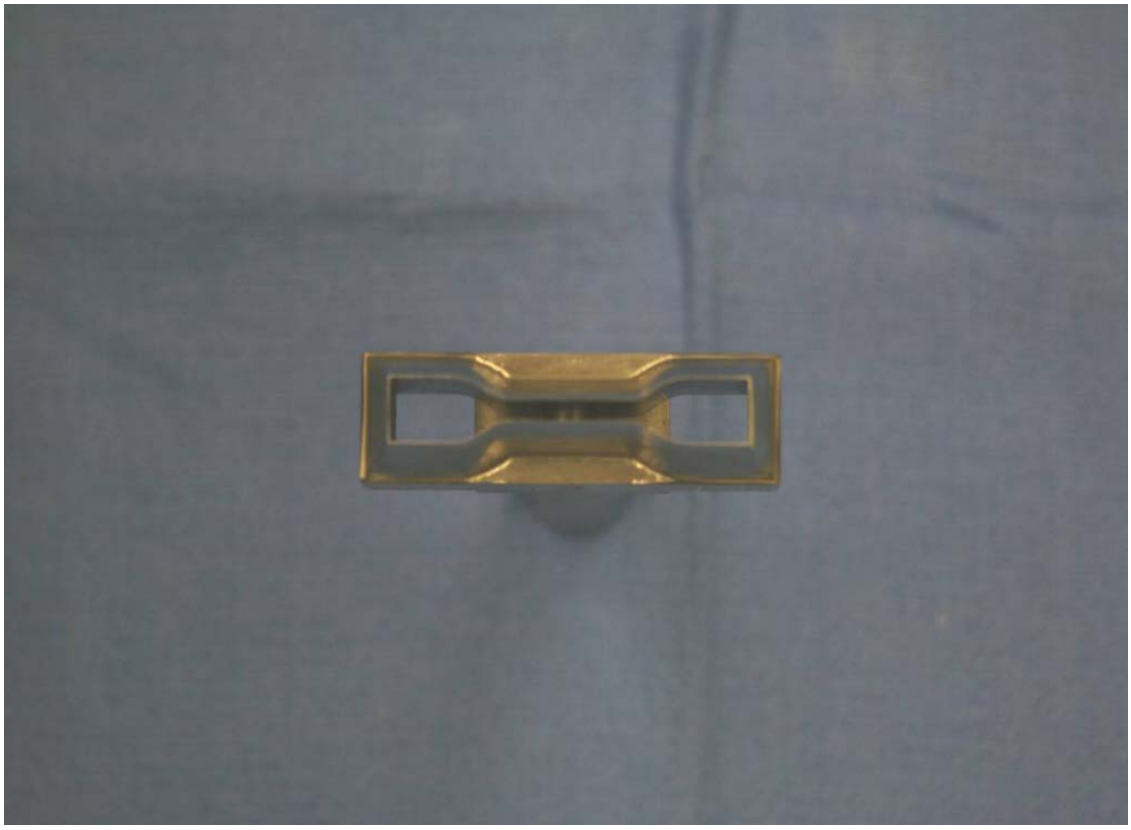

FIGURE 20. Die for cutting dumb-bell shaped samples.

FIGURE 21. Dumb-bell specimens inserted into the Universal testing machine.

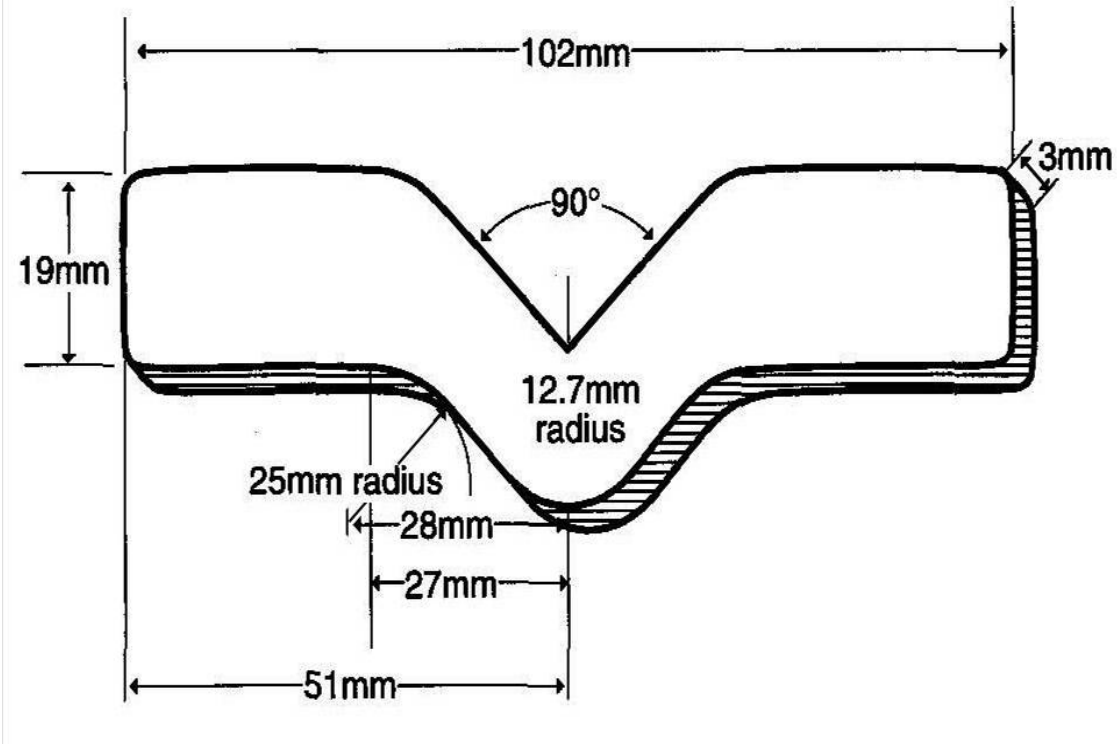

FIGURE 22. ASTM No. D624 (die C) specifications for trouser shaped specimen.

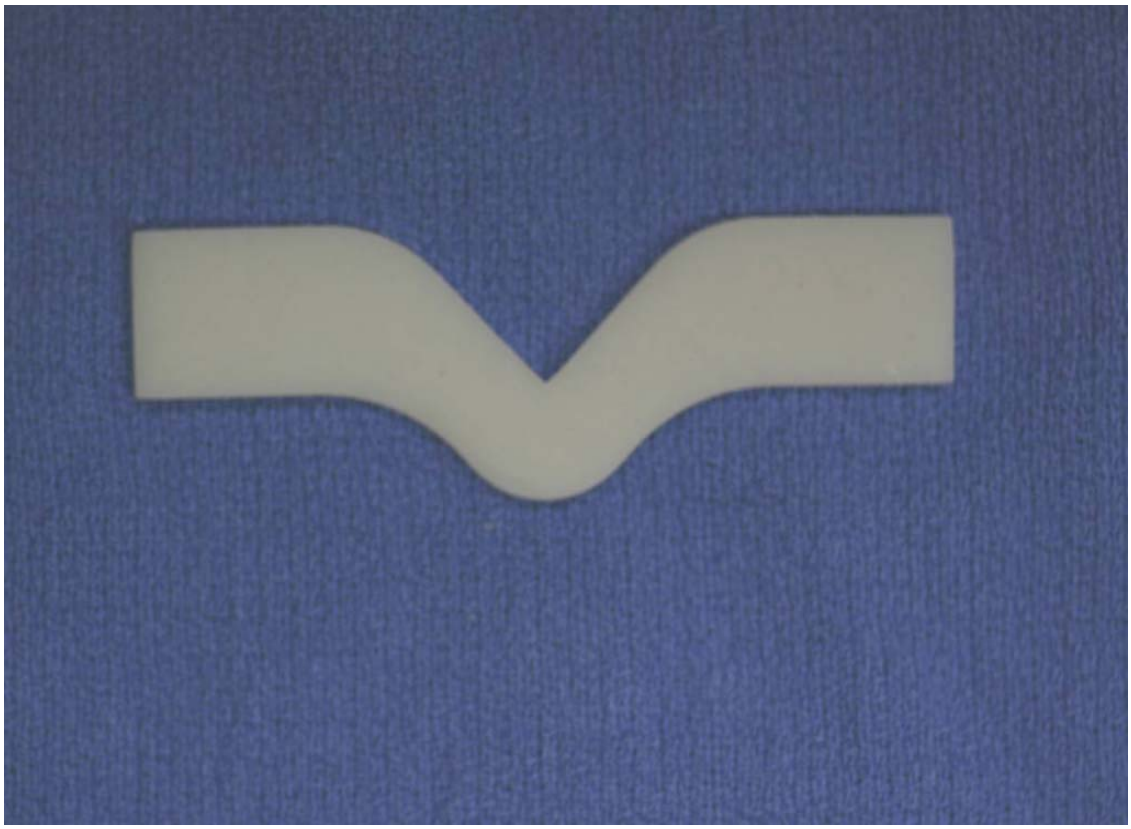

FIGURE 23. Trouser-shaped specimen.

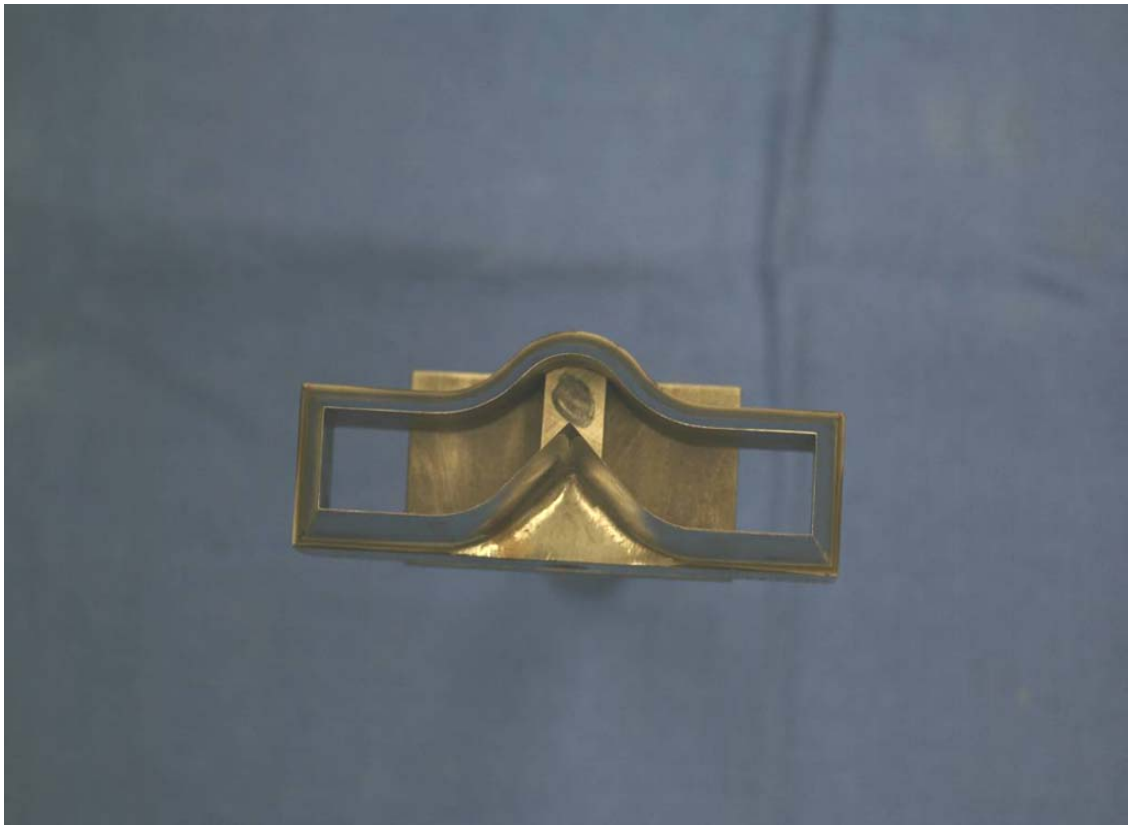

FIGURE 24. Die for cutting Trouser-shaped samples.

FIGURE 25. Trouser-shaped specimen inserted into the Universal testing machine.

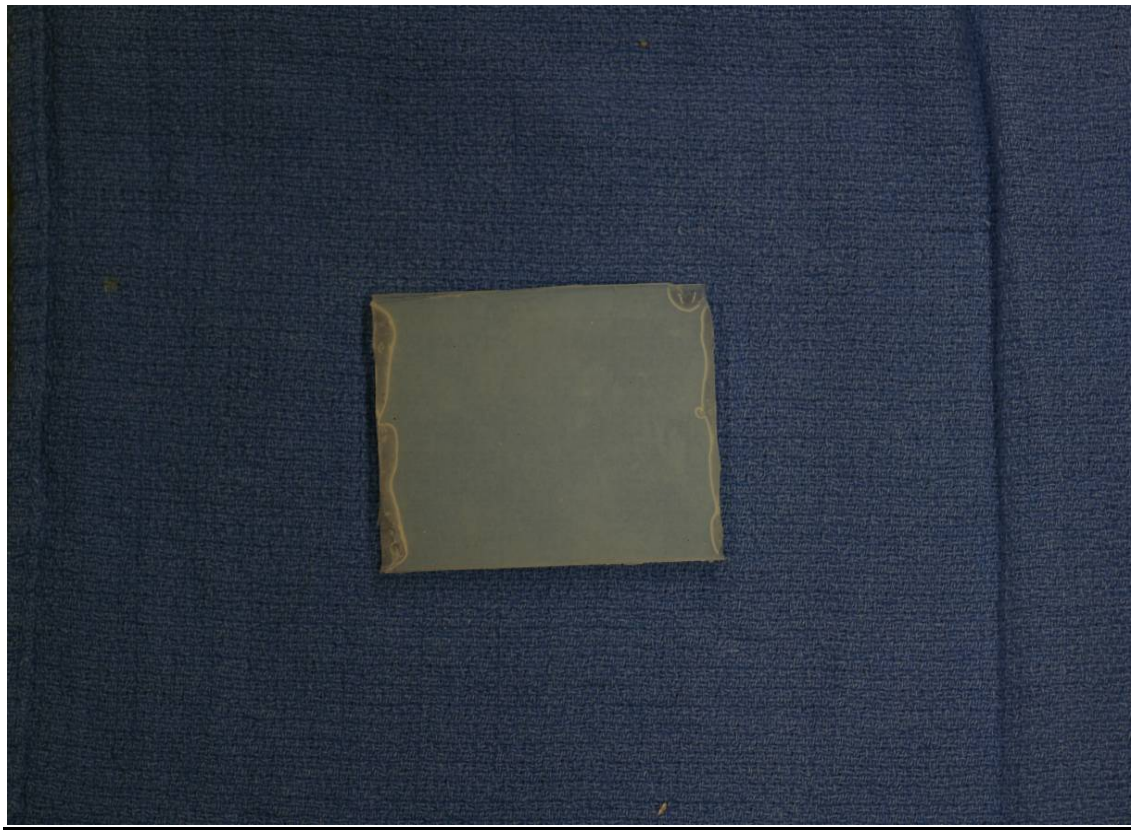

FIGURE 26. Specimen for Shore A hardness test.

FIGURE 27. Digital Shore A hardness tester .

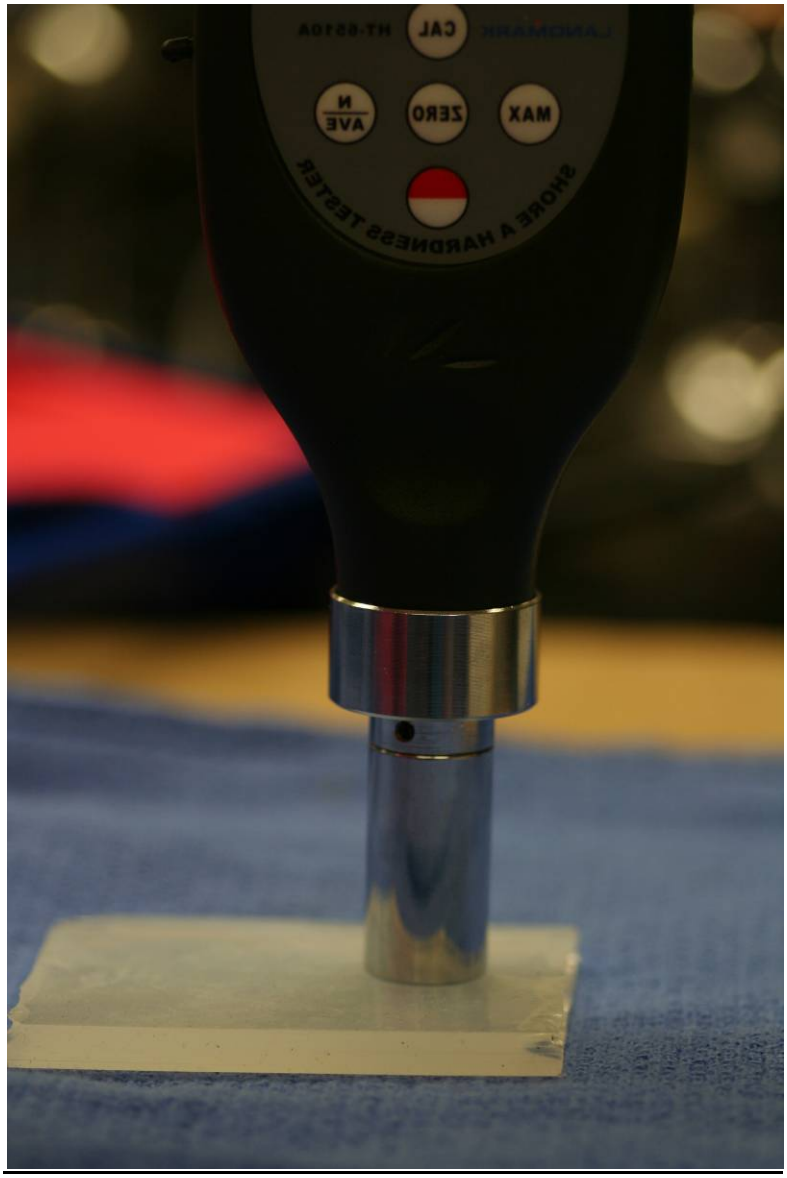

FIGURE 28. Digital Shore A hardness tester used to measure hardness on the control group sample.

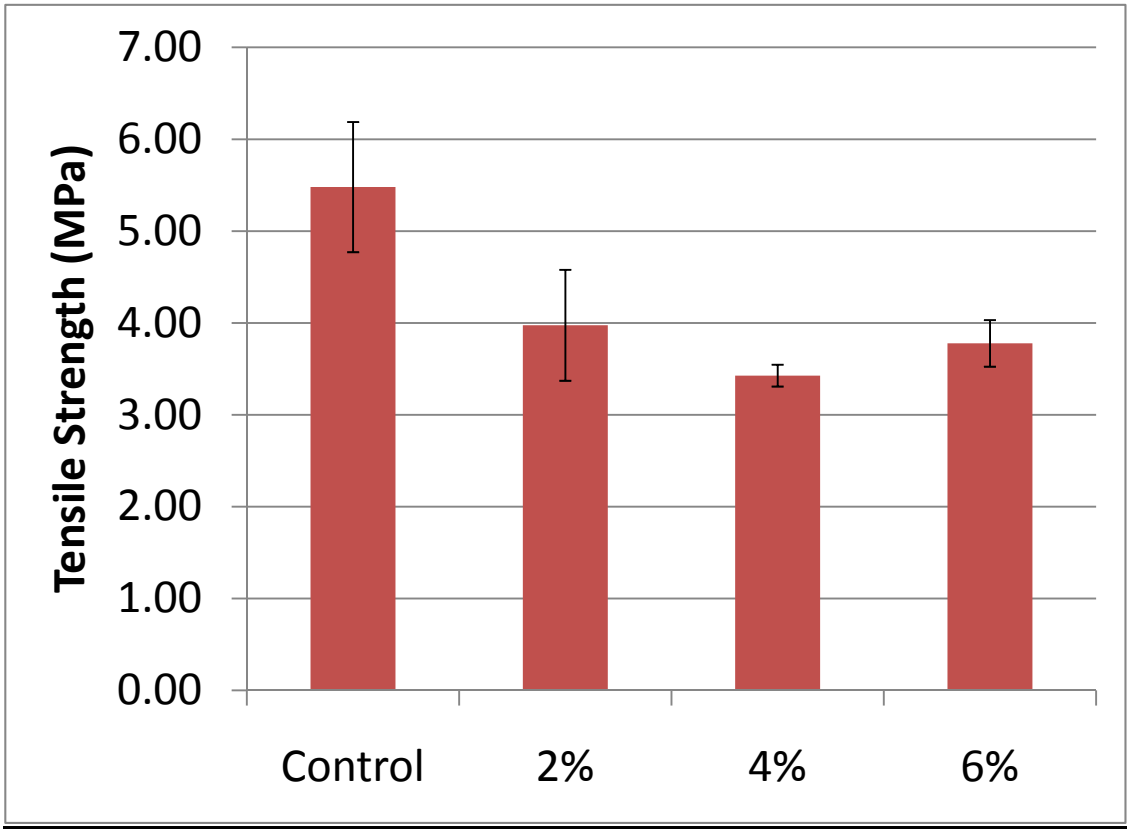

FIGURE 29. Tensile strength of control group, 2-percent, 4-percent, and 6-percent nano ceramic fiber fillers reinforced silicone maxillofacial material.

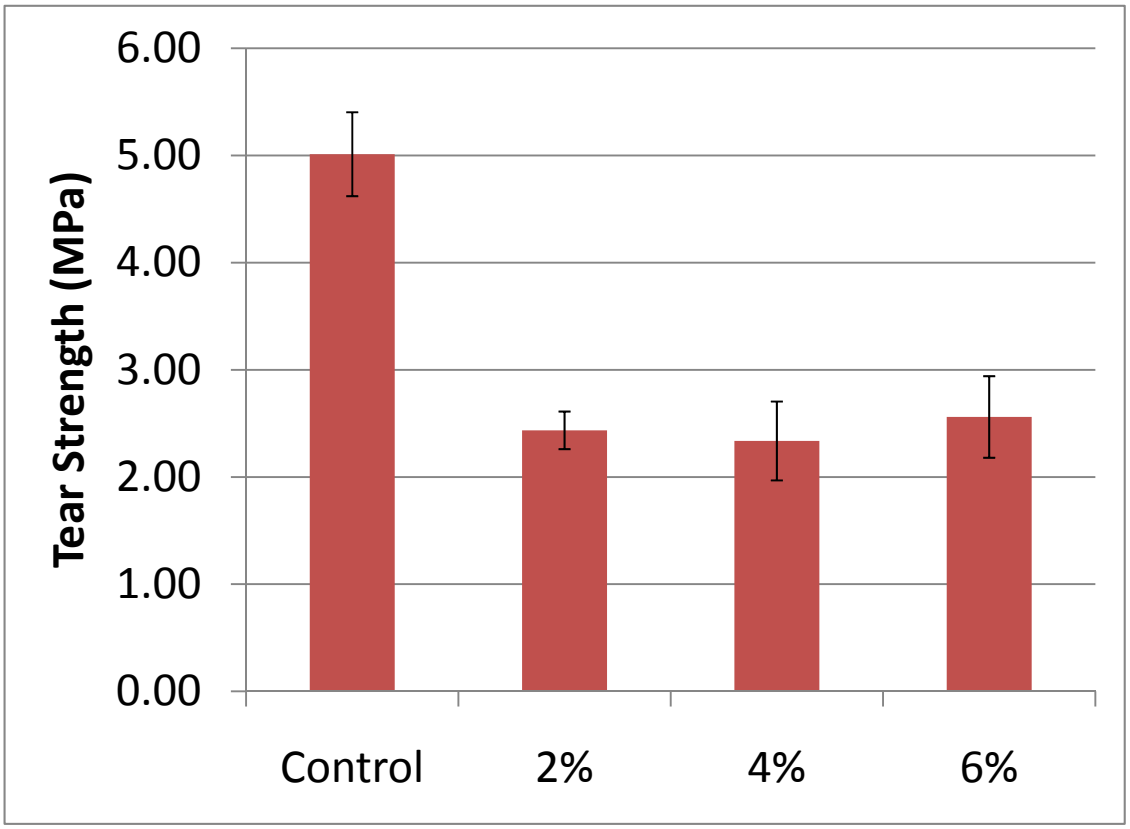

FIGURE 30. Tear strength of control group, 2-percent, 4-percent, and 6-percent nano ceramic fiber fillers reinforced silicone maxillofacial material.

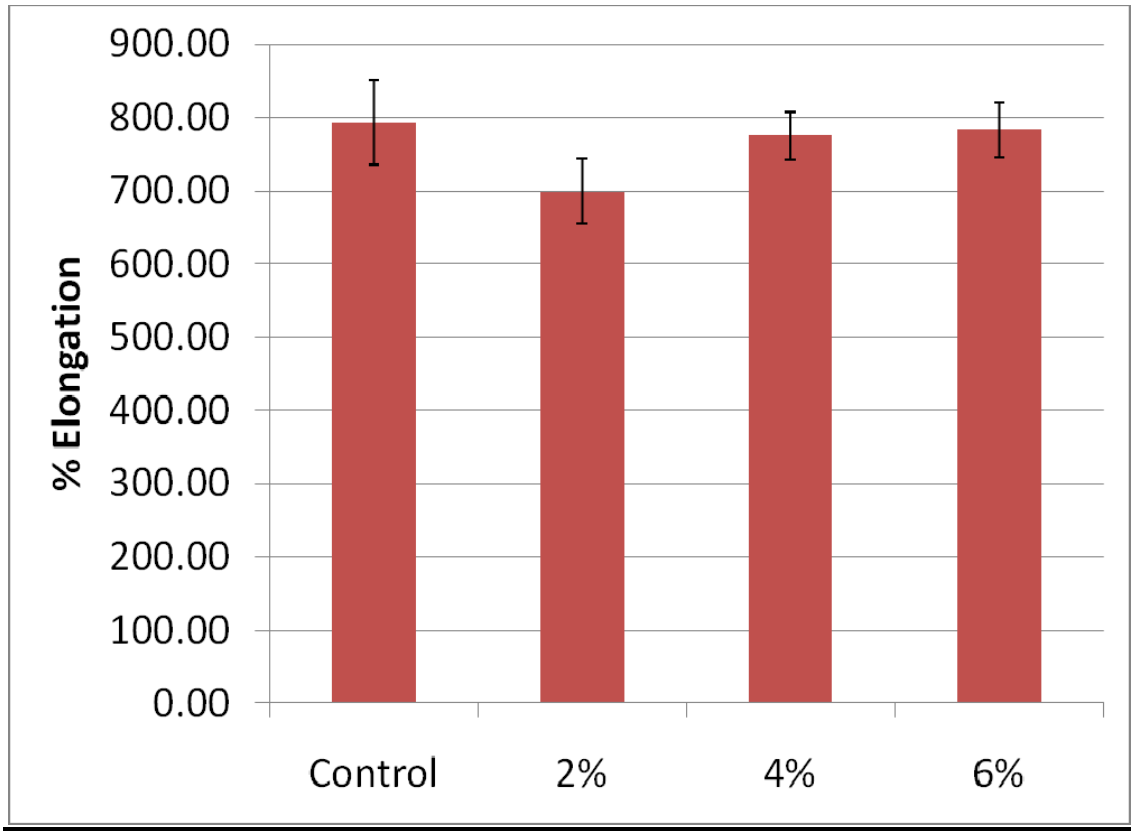

FIGURE 31. Percentage of elongation of control group, 2-percent, 4-percent, and 6-percent nano ceramic fiber fillers reinforced silicone maxillofacial material.

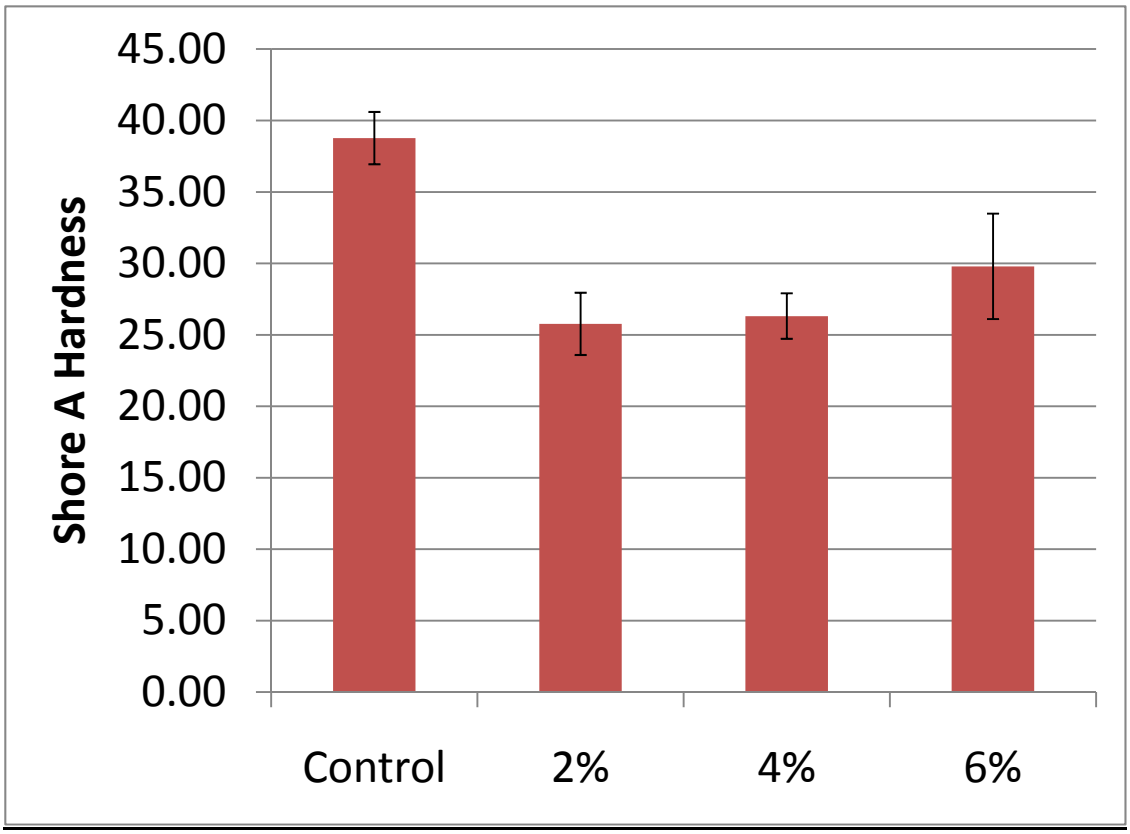

FIGURE 32. Shore A hardness of control group, 2-percent, 4-percent, and 6-percent nano ceramic fiber fillers reinforced silicone maxillofacial material.

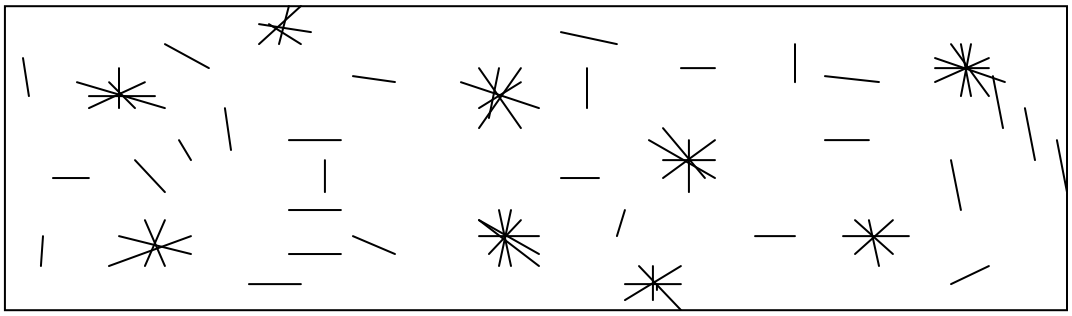

FIGURE 33. Agglomeration of nano ceramic fiber fillers in VST-50HD silicone material.

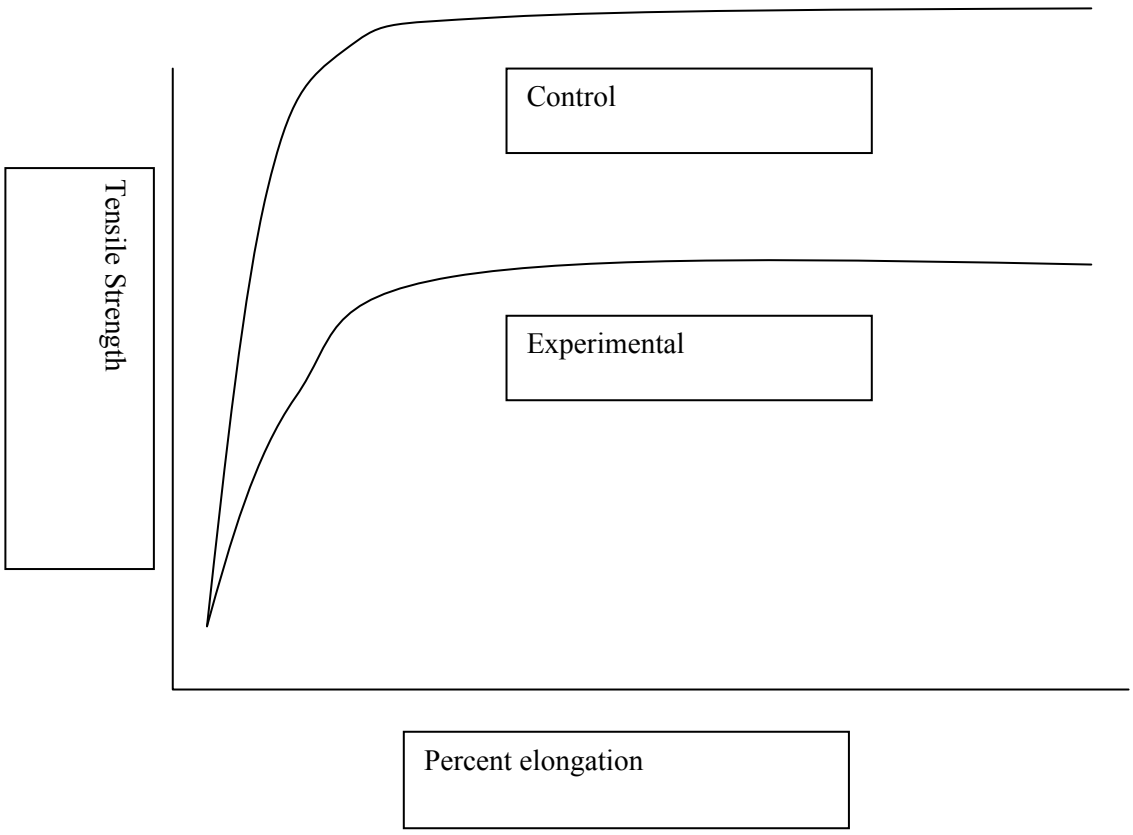

FIGURE 34. Tensile strength and percentage of elogation of control and experimental groups

DISCUSSION

Throughout the literature many attempts have been made to evaluate the physical and mechanical properties of different silicone maxillofacial material materials. Results of these studies have shown wide range of variation among tensile and tear strength, percentage elongation and Shore A hardness tests, in addition to the variation between different studies examining the same silicone maxillofacial material such as silicone MDX 4-421.[11, 13-20]

Tensile strength results of studies where Silastic MDX 4-4210 was used were high in some studies and low in others when similar methodologies of testing were conducted. Lewis et al.[20] reported a range of 3.24 to 7.04 MPa in the tensile strength of Silastic MDX 4-4210. Haug et al.[10, 15, 16] had three reports in three different studies: two results in 1999 showed comparable results with each other, with one study showing a result of 5 MPa, and the other one was slightly less with 4 MPa; while the earliest study in 1992 showed a lower result of 2.47 MPa. Bell et al.,[13] Farah et al.,[17] Haug et al.,[15] and Polyzois et al.,[18] showed results with an average tensile strength of 3.23 MPa, 1.24 MPa, 2.47 MPa, and 1.65 MPa respectively. And they conducted similar methodologies of testing, with both Farah et al.[17] and Polyzois et al.[18] reporting the lowest among Silastic MDX 4-4210 experiments.

Our data of VST-50 HD is in the range of MDX 4-4210 with average of 5.48 MPa.

Tear strength results of studies using Silastic MDX 4-4210 was also high in some studies and low in others when similar methodologies of testing were conducted.

Haug et al.[10, 15, 16] conducted three different studies measuring the tear strength of Silastic MDX 4-4210 maxillofacial material. Two studies in 1999 were similar with average of 7 MPa, while one earlier study in 1992 was slightly less with an average of 5.56 MPa. Polyzois et al.[18] reported a tear strength of 6.49 MPa. Lewis et al.[20] and Bell et al.[13] reported higher tear strength results with 21.07 MPa and 10.59 MPa respectively.

Our data on VST-50 HD is lower than MDX 4-4210 with an average of 5.01 (MPa).

Percentage of elongation of studies using Silastic MDX 4-4210 was also high in some studies and low in others when similar methodologies of testing were conducted. Lewis et al.,[20] Bell et al.,[13] Farah et al.,[17] and Polyzois et al.[18] showed percentage of elongation results of 410.0 percent to 514.0 percent, 430.4 percent, 296.0 percent, and 307.9 percent, respectively. Haug et al.,[10, 15, 16] showed results of 356.0 percent, 240.0 percent and 280.0 percent, respectively that have been reported in these three different studies, with Haug et al.[10] reporting the lowest and Lewis et al.[20] reporting the highest with 240.0 percent and 410.0 percent to 514.0 percent, respectively.

Our data on VST-50 HD is higher than MDX 4-4210 with average of 793.51percent.

An explanation for why there was a significant difference ($p < 0.001$) in the mean elongation at fracture between the 2-percent reinforced nano ceramic fiber VST-50HD silicone elastomer maxillofacial material and the control group, 4-percent, and 6-percent reinforced nano ceramic fiber fillers, would be the agglomeration of nano ceramic fibers (Figure 33). This would have two impacts: 1) creating a stress raiser at the surface of the specimen, which would cause an early failure of the material, and 2) failure of the

material from infiltrating into the accumulated nano ceramic fibers, which would result in a void that would make the elongation of fracture less than the other groups. The two reasons mentioned earlier may also explain why the control group, 4-percent and 6-percent nano ceramic fiber-reinforced groups might have the same elongation at fracture but lower tensile strengths (Figure 34). This may explain the reason for using an appropriate type and quantity of dispersing agent that will be discussed later in this study.

Shore A hardness of studies using Silastic MDX 4-4210 was also high in some studies and low in others when similar methodologies of testing were conducted. Bell et al.,[13] Farah et al.,[17] and Polyzois et al.[18] have shown Shore A hardness results of 31.60, 31.00, and 25.40, respectively. Haug et al.[10, 15, 16] demonstrated Shore A hardness results of 28.93, 27.00 and 28.00, respectively. Lewis et al.[20] reported the lowest Shore A hardness result of 15.00, while Bell et al.[13] showed the highest result of 31.60.

Our data on VST-50 HD is slightly higher than MDX 4-4210 with an average of 38.76.

The major deficiency in unfilled poly(dimethylsiloxanes) maxillofacial prosthesis is very low tear strength. Surface-treated silica fillers with an increased surface area and a small particle size is an important factor on the physical and mechanical properties of silicone elastomers, which made using silica fillers essential for enhancing tensile strength.

Assessment of the effect on varying the nano ceramic fiber fillers on hardness, tensile strength, tear strength, and elastic deformation on poly(dimethylsiloxanes) has been done in this study by laboratory experiments and comparison with VST-50HD silicone elastomer (Factor II Inc.) commercially-available silicone elastomer materials.

There was a significant difference ($p < 0.001$) in the mean tensile strengths between the control group VST-50HD silicone maxillofacial material and -percent, 4-percent, and 6-percent reinforced nano ceramic fiber fillers; however, there was not a significant difference ($p > 0.05$) between 2-percent, 4-percent, and 6-percent percent reinforced nano ceramic fiber fillers. Tensile strength results of our study suggest that reinforcing VST-50HD silicone maxillofacial material with 2-percent, 4-percent, and 6-percent nano ceramic fiber fillers did not improve tensile strength of our experimented upon material.

There was a significant difference ($p < 0.001$) in the mean tear strengths between the control group VST-50HD silicone maxillofacial material and 2-percent, 4-percent, and 6-percent reinforced nano ceramic fiber fillers; however, there was not a significant difference ($p > 0.05$) between 2-percent, 4-percent, and 6-percent - reinforced nano ceramic fiber fillers. Tear strength results of our study suggest that reinforcing VST-50HD silicone maxillofacial material with 2-percent, 4-percent, and 6-percent nano ceramic fiber fillers did not improve tear strength of our experimented material.

There was a significant difference ($p < 0.001$) in the mean elongation at fracture between the 2-percent reinforced nano ceramic fiber VST-50HD silicone maxillofacial material and control group, 4-percent, and 6-percent percent reinforced nano ceramic fiber fillers; however, there was not a significant difference ($p > 0.05$) between the control group, 4-percent, and 6-percent reinforced nano ceramic fiber fillers. Elongation at fracture results of our study suggest that reinforcing VST-50HD silicone maxillofacial material with 4-percent and 6-percent will have similar elongation at fracture as the control group, meaning that no effect on the elongation at fracture will occur.

Reinforcing VST-50HD silicone maxillofacial material with 2-percent nano ceramic fiber filler will result in reducing the elongation of fracture of the experimented upon material.

There was a significant difference ($p < 0.001$) in the mean Shore A hardness between the control group VST-50HD silicone maxillofacial material and 2-percent, 4-percent, and 6-percent reinforced nano ceramic fiber fillers; however, there was not a significant difference ($p > 0.05$) between 2-percent, 4-percent, and 6-percent -reinforced nano ceramic fiber fillers. Shore A hardness results of our study suggest that reinforcing VST-50HD silicone maxillofacial material with 2-percent, 4-percent, and 6-percent nano ceramic fiber fillers did not improve Shore A hardness in this experiment.

Surface-treated silica fillers with an increased surface area and a small particle size are an important factor to enhance the physical and mechanical properties of silicone elastomers, which made using silica fillers essential for enhancing tensile and tear strength, elongation at fracture, and Shoe A hardness test. Nano ceramic fiber fillers have a large surface area with 200 nm in length and 20 nm in width; however, they have not been investigated to reinforce silicone maxillofacial materials.

Enhancing the physical and mechanical properties of silicone elastomers by using fillers has been mentioned in the literature.[12, 23, 32]

Our study did not show any improvement by incorporating nano ceramic fiber fillers on the silicone maxillofacial material as was demonstrated in the study by Andreopoulos et al.[24] They reported that there was no improvement in tensile strength and modulus when fiber fillers were used. On the other hand, when particulate silica was used, improvements of tensile and tear strength were shown. However, Gunay et al.[22] showed a different trend. They investigated the effect of incorporating tulle in silicone

maxillofacial prosthesis. The results of their study showed that tensile and tear strengths were significantly higher with silicone maxillofacial prosthesis reinforced with tulle, than non reinforced silicone maxillofacial prosthesis. Andreopoulos et al.[25] later reported an increase in tensile and tear strength with increasing silica fillers up to 35 percent. We also compared our study with a study performed by Aziz et al.,[26] who studied the effect of three parameters on the development of new improved maxillofacial material C50. The parameters used were silica fillers, cross-linkage concentration, and ratio of high- and low-molecular weight polymers. Aziz et al.[26] demonstrated that increasing the 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 newly-developed maxillofacial material is relatively higher than the commercially-available materials. Han et al.[12] studied the effect of increasing nanosized oxide concentration on tensile and tear strength and percent elongation of maxillofacial material, and showed significant increase in tear and tensile strengths and percent elongation.

Studies on the behavior of different types of fillers with different kinds of materials in the engineering field may help us to understand the reasons behind having no improvements of the physical and mechanical properties of our reinforced silicone elastomer maxillofacial material.

Petsalas et al.[27] examined the effect of using aramid fiber to reinforce polyethylene. The main problem they found was making an adequate adhesive bond

between polyethylene matrix and aramid fiber. Fiber pretreatment was therefore done to the aramid fibers, which resulted with an increase in tensile strength with increasing the fiber volume. They also showed that there was a clear difference between the resultant forces between surface-treated aramid fibers and the non surface-treated fibers. The surface-treated aramid fibers showed a remarkable increase in strength.

Andreopoulos et al. in 1989[28] examined different surface treatments for aramid fibers to improve adhesion to polymeric matrices; either chemical modification performed by grafting, or by increasing the surface roughness of the aramid fibers. Results showed that methacryloyl chloride was the most favorable coupling agent with the least loss of tensile strength resulted from chemical treatment. Results have also shown than using the appropriate chemical treatment with the amount of chemical attack was very important in the resultant tensile strength.

Liu et al.[29] studied the effect of using up to 5 wt% nano SiO2 and TiO2 fillers on the mechanical properties of linear low-density polyethylene mixed with low-density polyethylene, with a fixed ratio of 80 wt% linear low-density polyethylene and 20 wt% low-density polyethylene. The study also has shown that using 91-percent resin matrix, 6-percent EVA dispersion factor, and 3-percent mixed nano Si02 and TiO2 fillers provided mechanical properties, processability, and environmental adaptability that were very balanced.

Abdelmouleha et al.[30] studied the effects of short natural fibers and coupling agents on the mechanical properties, absorbance behavior, and thermal properties of low-density polyethylene and natural rubber. Five different types of cellulose fillers with different average lengths were used and the effect of three different kinds of silane-

coupling agents on the physical properties of polymer matrixes were studied. Results showed that the mechanical properties of the composites significantly increased with increasing filler content, length, and with using γ-Methacryloxypropytrimethoxysilane and γ-Mercaptoproyltrimethoxysilane silane-coupling agents.

Frogley et al.[31] studied the effect of single-wall carbon nano tubes or vapor-grown carbon nano fibers on RTV silicone elastomers after dissolving the silicone elastomer in toluene (1mg/ml) so the viscosity could be reduced to help the dispersion of the fillers. They concluded that dispersion and interface of the filler in the matrix are the two major detrimental factors in usefulness of the fillers used for reinforcements.

Mirabedini et al.[32] studied the effect of TiO2 on the mechanical and adhesion properties of RTV silicone elastomer coatings. In order for the composite silicone elastomer material to exhibit improved physical properties during marine applications, the authors mixed it with the following materials: silicone elastomer ELSTOSIL (RTV-4511), TiO2 fillers, hardener (T-21), epoxy primer coating, amino silane compound (Silquset A-1170), and dispersing agent (EFKA-3232). Results showed that tensile stress, modulus, and abrasion resistance were increased with increasing the filler content up to 15.9 wt%. But to the contrary, elongation to fracture was decreased with increasing filler content. Results also showed that dispersing factor has an important effect on the physical properties of the material and also that hydrophobicity of the filler and matrix may have negative effect on the composite material.

From the previous engineering experiments, a number of factors may be contributed to the failure of enhancing the physical and mechanical properties of the nano ceramic fiber filler reinforced silicone maxillofacial material. These factors are:

1. Dispersion.
2. Hydrophobic or hydrophilic nature of the filler and matrix.
3. Coupling agent.

All these factors should be considered and examined on the reinforced silicone maxillofacial material with balanced quantities so the physical and mechanical behavior of silicone maxillofacial material can be improved.

SUMMARY AND CONCLUSIONS

This study investigated the physical properties of VST-50HD silicone elastomer maxillofacial material by using nano ceramic fiber fillers.

Nano alumina fibers at 2-percent, 4-percent, and 6-percent were mixed into the VST-50HD silicone elastomer (Factor II Inc.), a commercially-available poly(dimethylsiloxanes). Ten dumb-bell-shaped specimens have been used to determine the tensile strength according to ISO 37:2005. Ten trouser-shaped test pieces were used to determine the tear resistance according to ISO 34-1:2004. The Shore A test method was used to measure the hardness of the material. The data collected from all quantitative studies of the modified silicones was analyzed using one-way ANOVA with concentration of nano ceramic fiber as the main variable. The data was then compared to VST-50HD silicone elastomer.

Results showed no improvement in tensile and tear strength, elongation at fracture, and Shore A hardness after the VST-50HD was reinforced with 2-percent, 4-percent and 6-percent nano ceramic fiber fillers. Further studies need to be made to evaluate the effectiveness of dispersion agent, hydprophilicity of the filler, and coupling agent, with balanced amount to enhance the physical properties of the silicone maxillofacial material.

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ABSTRACT

NANO CERAMIC FIBER REINFORCED SILICONE MAXILLOFACIAL PROSTHES

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The purpose of this study was to investigate the effect of nano ceramic fiber fillers on the physical properties of VST-50HD silicone maxillofacial prosthesis. Nano alumina fibers at 2-percent, 4-percent, and 6-percent wt were mixed into the VST-50HD silicone elastomer (Factor II Inc., Lakeside, AZ), a commercially-available poly(dimethylsiloxanes). Ten dumb-bell-shaped specimens were used to determine the tensile strength according to ISO 37:2005 and elongation at fracture. Ten trouser-shaped test pieces were used to determine the tear resistance according to ISO 34-1:2004. Shore A test method was used to measure the hardness of the material. The data collected from all quantitative studies of the modified silicones were analyzed using one-way ANOVA with concentration of nano ceramic fiber as the main variable. Specimens from VST-50HD were also made and tested as control. Results: The mean values for tensile strength (MPa) of control group, 2-percent, 4-percent, and 6-percent reinforced nano

ceramic fiber fillers were from 3.43 ± 0.12 to 5.48 ± 0.71. Tear strength (MPa) were from 2.34 ± 0.37 to 5.01 ± 0.39. Elongations at fracture were from 699.66 ± 43.69 to 793.51 ± 57.27. Shore A hardness were from 25.76 ± 2.18 to 38.76 ± 1.83. Conclusion: There was a significant difference ($p < 0.001$) in the mean tensile, tear and Shore A hardness strengths between the control group and 2-percent, 4-percent, and 6-percent percent reinforced nano ceramic fiber fillers; however, there was not a significant difference ($p > 0.05$) between 2-percent, 4-percent, and 6-percent reinforced nano ceramic fiber fillers. There was a significant difference ($p < 0.001$) in the mean elongation at fracture between the 2-percent and control group, 4-percent, and 6-percent reinforced nano ceramic fiber fillers; however, there was not a significant difference ($p > 0.05$) between control group, 4-percent, and 6-percent reinforced nano ceramic fiber fillers. The properties of the experiment were all lower than the control. Further research is needed to determine the appropriate material and amount of dispersing agent, coupling agent, and determination of the hydprophilicity of the nano ceramic fiber fillers with great emphasis on the dispersing agent.

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