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Evaluation of tear strength of room temperature vulcanizing maxillofacial silicone by incorporating different materials - An In-Vitro Comparitive Study

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Abstract

Background: Maxillofacial prosthesis made of silicone elastomer gradually fades in colour or tears, especially at the edges. Therefore, the purpose of this study was to evaluate the tear strength of room temperature vulcanizing silicone by incorporating different materials to increase tear strength of the prosthesis for better longevity.

Method: Forty-eight M511 platinum silicone (Cosmesil) specimens were prepared according to ASTM D624 specification. Trouser shaped wax pattern with a length of 102mm, breadth of 19mm, thickness of 2mm and 90 degree angulation was invested, dewaxed and the mold was made. Cosmesil part A silicone and part B activator measured at a ratio of 10:1 for all the specimens was used. These specimens were divided into 4 groups Group 1) incorporation of tulle 2) incorporation of 20ppm of colloidal silver nanoparticle 3) incorporation of 1% polyamide (nylon 6) microparticle powder 4) control group. Mixing was done manually. Mixed elastomer was placed in the mold and cured at 100°C. Tear strength was evaluated by placing the specimen in the jaws of universal testing machine and stretched at rate of 500 ram/rain.

Result: The tear strength of Cosmesil incorporated with tulle showed higher tear strength (P=0.00) and longer elongation period (P=0.00)

Conclusion: Higher tear strength was seen with incorporation of tulle

Clinical Implication: Tulle can be incorporated to silicone elastomer in construction of maxillofacial prosthesis to increase the tear strength and longevity of the prosthesis.

Introduction

Acquired or Congenital defects of the face creates an unfortunate condition for an individual to lead a comfortable life. These defects require a maxillofacial prosthesis. Silicone elastomers also known as polydimethyl siloxane is the most successful maxillofacial prosthetic material used till date and new advances are being made to this material to overcome their weaknesses.[1] Depending whether the vulcanizing process uses heat or not, silicones are available as heat vulcanized (HTV) or room temperature vulcanized (RTV) and both have their own advantages and disadvantages.[1] Room temperature vulcanized (RTV) silicone is a translucent material characterized by a natural flesh-like appearance which makes it an ideal material to be used in facial prosthesis. As compared to room temperature vulcanized silicone (RTV) , heat temperature vulcanized (HTV) silicones are comparatively less used for maxillofacial prosthesis as it is white, opaque material with highly viscous, putty like consistency giving an unaesthetic result. Ease of manipulation, fabrication in stone molds, biological inertness and color stability are other advantages seen in RTV silicone material.[1] But the major disadvantage of using this material is its low edge strength. The outlines of the facial prosthesis are thinned at the edges to merge in with the surrounding skin. With the use of adhesives, colorants, cosmetic agents and repeated removal of the prosthesis, these edges tear off causing permanent deformation of the prosthesis.[2] Studies have shown that incorporating different materials in RTV silicone material has increased its edge strength.[2-5] But none of the study have evaluated if given a clinical scenario which would be a better material of choice out of all, to incorporate in RTV silicone to increase its tear strength. Hence, the purpose of this study is to evaluate and compare the tear strength of RTV silicone with the incorporation of different materials.

Materials And Method

Sample Size Estimation : A power analysis was established by G*power, version 3.0.1(Franz Faul universitat, Kiel, Germany). A sample size of 48 subjects (16 in each group) would yield 80% power to detect significant differences, with effect size of 0.47 and significance level at 0.05.

Sample Specification

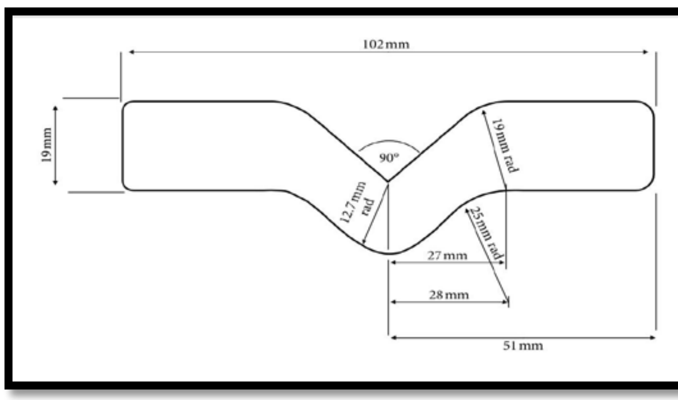

Fig 1: Dimensions of specimens based on ASTM D624 Specification

M511 Technovent platinum silicone elastomer (Cosmesil) was used for this study. Forty eight Cosmesil specimens were prepared according to ASTM D624 specification.(figure 1)[3]

Making of the stone mold

Figure a

Figure b

Figure c

Figure d

Figure e

Figure 2: Trouser shaped wax pattern of (a) length= 102mm, (b) breadth at the centre = 20mm, (c) 90° angulation, (d) wax pattern embedded in the stone mold, (e) Making of 6 dental stone molds

Trouser shaped wax pattern with a length of 102mm, breadth of 19mm, thickness of 2mm and 90 degree angulation was invested and dewaxed to create a mold.[3]

Groups

Specimens were divided into four groups-

Group 1 : Cosmesil Part A silicone and Part B activator was loaded in two 30 cc plastic syringe. To fulfil 10:1 ratio, 1ml of Part A was dispensed ten times while 1ml of part B was dispensed once onto the glass slab. Manual mixing was done with a stainless steel metal spatula. Tulle (No.1 – fine front and moustache lace, Nylon Art.2429, Kryolan GmbH, Berlin, Germany)[3] was trimmed according to the specimen specification. The mixture was loaded in the stone mold and trimmed tulle was placed onto it.[Figure 3(a)] Silicone elastomer was once again loaded onto the tulle [figure 3 (b)] The specimens were packed and polymerized for 1 hour at 100°C. The resultant samples obtained were marked green.[Figure 6(a)]

Figure 3 (a): placement of tulle in the mold

Figure 3 (b) loading of silicone elastomer onto the tulle.

Group 2: Cosmesil Part A silicone, Part B activator and colloidal silver nanoparticle (Mesosilver 20ppm) dispensed in the ratio 10:1:1 in 30cc plastic syringe mixed manually (figure 4) was packed in the stone mold and polymerized for 1 hour at 100°C. The resultant samples obtained were marked red. [4] [Figure 6 (b)]

Figure 4: dispensing of 20ppm colloidal silver nanoparticle in silicone elastomer.

Group 3: Cosmesil part A silicone, part B activator was loaded into two 30-cc plastic syringes respectively (10:1 ratio) and 1% by weight of polyamide microparticle powder (Goodfellow 588-184-71) was mixed manually, packed and polymerized for 1 hour at 100°C. The resultant samples obtained were marked blue. [5] [Figure 6 (c)]

Figure 5: dispensing of 1% by weight of polyamide microparticle powder in silicone elastomer.

Group 4 (Control group): Cosmesil part A silicone and Part B activator was loaded into two 30-cc plastic syringes respectively. 1ml of Part A was dispensed ten times while 1 ml of part B was dispensed once to fulfil 10:1 ratio in a glass slab. Manual mixing was done with a stainless steel metal spatula. This mixture was loaded to stone mold, packed and polymerized for 1 hour at 100°C. All the specimens obtained were marked black. [Figure 6 (d)]

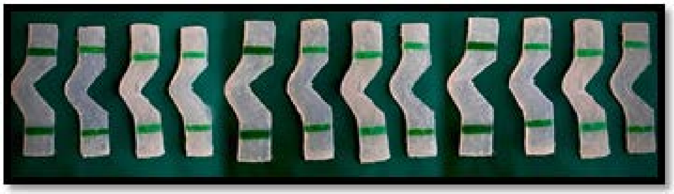

Fig 6 (a) : Silicone samples with tulle marked green

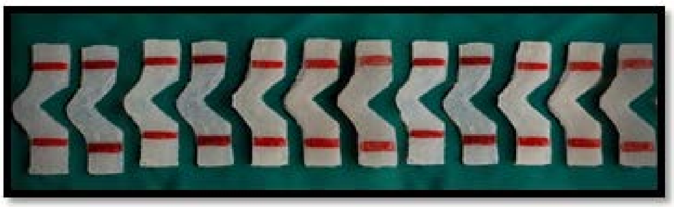

Figure 6 (b): Silicone samples with 20ppm colloidal silver nanoparticle marked red

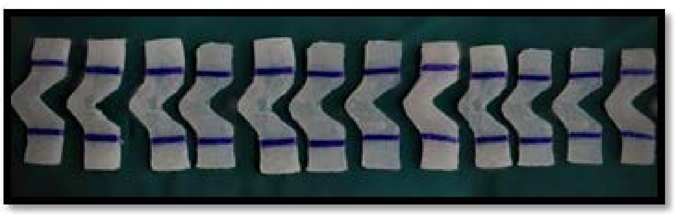

Figure 6 (c): Silicone samples with 1% by weight of polyamide microparticle powder marked green

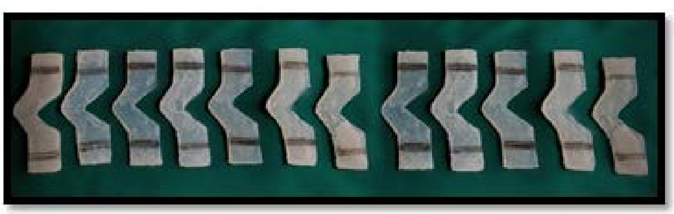

Figure 6 (d): silicone samples as control group marked black

Evaluation of tear strength

Specimens were placed at the jaws of Universal Testing Machine (Mecmesin) and stretched at a rate of 500 ram/rain. (Figure 7) Forces applied to tear each of the specimen apart were recorded. Tear strength (Ts) expressed in kilo Newton per meter of thickness (kN/m) was calculated according to equation [Ts=F/d] where F is the median force (N) calculated d is the median thickness (mm) of the test specimen.

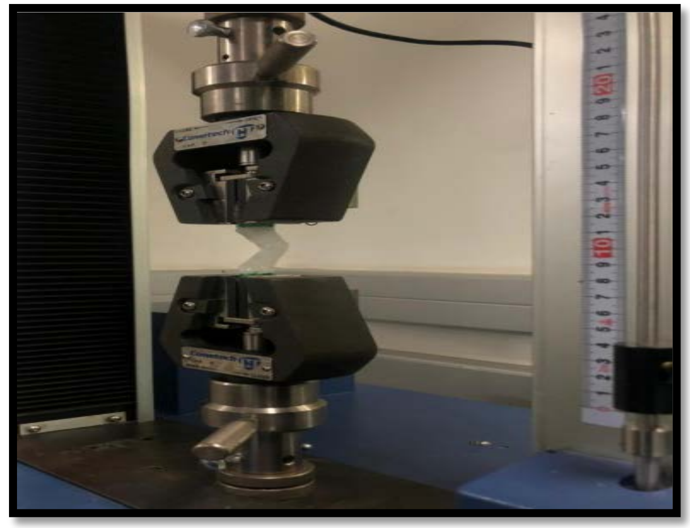

Figure 7: Specimens placed at the jaws of universal testing machine

Statistical Analysis

SPSS (Statistical Package For Social Sciences) version 20. [IBM SPASS statistics (IBM corp. Armonk, NY, USA released 2011)] was used to perform the statistical analysis. Data was entered in the excel spread sheet.. Descriptive statistics of the explanatory and outcome variables was calculated by mean, standard deviation for quantitative variables, frequency and proportions for qualitative variables.. Inferential statistics like ANOVA was applied to check the statistical difference among the groups with post-hoc Bonferroni for pair-wise comparison . The level of significance is set at 5%

Results

Data was subjected to normalcy test (Shapiro-wilk test). Data showed normal distribution. Hence parametric tests (ANOVA with post hoc Bonferroni) were applied.

Table 1

Tests of Normality						
	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	p value	Statistic	df	p value
Group 1	.167	12	.200*	.932	12	.398
Group 2	.129	12	.200*	.978	12	.972
Group 3	.137	12	.200*	.940	12	.504
Group 4	.124	12	.200*	.975	12	.957
*. This is a lower bound of the true significance.						
a. Lilliefors Significance Correction						

Table 2: Mean Tear Strength

Groups	Minimum	Maximum	Mean	Std. Deviation
Group 1	30.05	35.5	32.854	1.866
Group 2	24.05	29.5	26.567	1.566
Group 3	21	25.5	23.526	1.524
Group 4	16.05	21.5	18.967	1.684

Graph 1

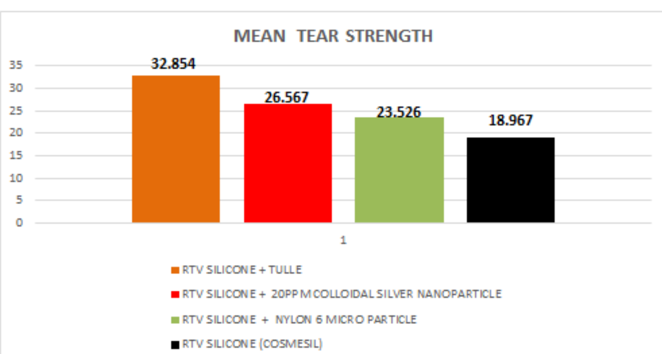

Table 3: Comparison of the tear strength among the groups using Anova

	F value	P value
Tear strength	146.81	0.00*

*significant

ANOVA test was applied to compare the tear strength among the groups. ANOVA test showed statistical significant difference among the groups (p=0.00).

Table 3: post-hoc bonferroni

Groups		Mean diff	p value
1	2	-6.287	.000*
	3	-9.328	.000*
	4	-13.887	.000*
2	3	-3.041	.000*
	4	-7.600	.000*
3	4	-4.559	.000*

*significant

Post-hoc Bonferroni test was applied to compare the tear strength between the groups. Statistical significant difference was seen between all the groups (p=0.00).

Result

After the statistical analysis was completed, it was found out that higher tear strength was recorded in GROUP 1 (RTV silicone incorporated with tulle) with a mean tear strength of 32.85 kN /m followed by GROUP 2 (RTV silicone incorporated with 20 ppm of colloidal silver nanoparticle) with a mean tear strength of 26.56 kN /m , GROUP 3 (RTV silicone incorporated with nylon 6 microparticle) with a mean tear strength of 23.52 kN /m and GROUP 4 (control group) with a mean tear strength of 18.96 kN /m.

Discussion

Maxillofacial silicone elastomers should have high tear resistance, high tensile strength and elongation at break, suitable hardness similar to the skin in the defective side and sufficient bonding to underlying retentive substrate.[5] Cosmesil M511 are a mixture of long and medium polymers chains with approx. 30% and 25% filler, respectively (Principality Medical Ltd, Newport, UK).[5] Tulle is a material used in theaters and operas to fabricate artificial beards and moustaches, whereby hair is sewn on flesh-toned, nylon tulle and the latter attached on the skin with prosthetic adhesives. Nonetheless, in a bid to increase the tear resistance of the margin of maxillofacial prostheses, tulle was incorporated in silicone elastomer in a recent research. [3] Addition of nanoparticles has become the new trend as nanotechnology has become one of the main growing sciences. [4] Gunay et al. in (2008)[5] reported improvement in the tear strength and other mechanical properties. After the addition of 1% by weight PA-6 micro fillers, the mean value of the tear strength test demonstrated high significant increase. This may be due to the nature of the fillers; the amide (-CO-NH-) groups within the filler structure are highly polar therefore PA-6 forms multiple hydrogen bonds among adjacent strands this may result in forming a 3-D network of fillers within the polymer matrix that lead to a change in the overall density and increase overall tearing resistance of the polymer.[5] This study evaluates tear strength of silicone elastomer by incorporating different materials under a standard method of testing. Forty eight M511 platinum silicone specimens were prepared according to ASTM D624 specification. Trouser shaped wax pattern were divided into four groups. Group 1 (RTV incorporated with tulle) showed highest tear strength followed by Group 2 (RTV incorporated with 20ppm nanoparticle)and then Group 3 (RTV incorporated with 1% polyamide microparticle powder) and Group 4 (control group). Thus, in clinical scenarios one can choose which among various materials incorporated would be the choice to improve the edge strength of the prosthesis. Within the limitations of this study, there was lack of metal mold for fabrication of wax pattern. Manual mixing was done over vacuum mixing. Edge strength of maxillofacial silicone may alter according to the body temperature, sweat, adhesives and several environmental factors which could not be analyzed in this invitro study. Further in-vitro and in-vivo studies should be conducted to prove the efficacy of the usage of maxillofacial silicone using RTV silicone incorporated with tulle for improved edge strength.

Conclusion

1) All the silicone elastomers tested showed enhancement in desirable properties of tear strength by incorporating different materials.

2) Incorporation of tulle exhibited highest tear strength followed by silver nanoparticle and nylon 6 micropowder**.**

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