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Comparative Evaluation of Mechanical Properties of Room Temparature Vulcanized Maxillofacial Silicone Material with and without incorporation of 1% Clotrimazole as an Antifungal Agent: An inVitro Study

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Abstract

Introduction: Antifungal agents such as 1% Clotrimazole can be included in maxillofacial prostheses for their antifungal properties. Despite a lack of literature evidence supporting this connection, we conducted this study to assess and compare the physical properties of vulcanized maxillofacial silicone material with and without the inclusion of 1% Clotrimazole as an antifungal agent.

Material and Method: Custom stainless steel molds were produced to assess mechanical properties (Tensile Strength, Elongation Percentage, Tear Strength, and Hardness). Three dies, compliant with ISO and ASTM standards, were crafted for silicone test specimens. To ensure even dispersion, 1% Clotrimazole, an antifungal agent, was added to part B of room temperature vulcanized maxillofacial silicone material (VST-30, Versiltal silicone).

Results: Regardless of whether room temperature vulcanized maxillofacial silicone material included 1% Clotrimazole as an antifungal agent, all specimens displayed statistically insignificant changes in mechanical properties, including Tensile Strength, Elongation Percentage at break, and Tear Strength. However, a notable difference in Hardness was observed in the maxillofacial silicone material when comparing samples with and without 1% Clotrimazole. Samples with the antifungal agent exhibited improved mechanical properties (Tensile Strength, Elongation Percentage at break, Tear Strength, and Hardness) compared to those without the antifungal agent.

Conclusion: Adding an antifungal agent to maxillofacial silicone elastomer is a viable option to enhance prostheses by reducing fungal activity. Additionally, it improves the mechanical properties (Tensile Strength, Elongation Percentage at break, Tear Strength, and Hardness) of medical-grade maxillofacial silicone material, extending the longevity of the prosthesis.

Keywords: Maxillofacial Silicone; Clotrimazole; Antifungal; In-Vitro; Physical Properties.

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INTRODUCTION

Restoration of maxillofacial defects caused due to facial injuries such as trauma or congenitally missing facial parts are a possibility today.[1] Throughout history, a diverse range of materials has been utilized in the creation of maxillofacial prostheses. However, the properties of all previously

employed materials fell short of the ideal standards.[2] Bulbulian AH first described the use of soft and flexible material for maxillofacial prosthesis[3] introduction of silicone rubber as maxillofacial prosthesis material was a breakthrough in field of prosthodontics.[4] Silicone polymers currently stand as the most commonly employed materials for maxillofacial prostheses, attributed to their favourable characteristics like chemical stability, ease of production, biocompatibility, and durability. Nevertheless, these materials have not fully met the ideal requirements for maxillofacial prostheses, primarily due to certain drawbacks, especially in terms of mechanical properties.[5] The overall strength of the silicone elastomer is determined by its 'Tensile Strength,' while 'Elongation' provides insight into the flexibility of the prosthesis. A prosthesis with high elongation at break is preferred, especially when removing a nasal or eye prosthesis from facial tissue. Additionally, the 'Hardness' of the maxillofacial material serves as a gauge for flexibility, and it is crucial to match the hardness of the material to the missing facial tissue for optimal results.

The prevalence of oral infections attributed to Candida species is increasing, possibly due to a rising population of individuals with compromised immune systems, as well as favourable conditions in the oral cavity, often associated with the use of removable prosthetic appliances.[6] the adherence of candida albicans on the surface of maxillofacial prosthesis depends on the surface contact angle.[7] Common signs and symptoms of candida infestation are Inflammation of the oral mucosa, tongue redness, tongue burning, taste disturbances, tongue coating, and dryness of the mouth.[8]

Antifungal agents like 1% Clotrimazole can be incorporated in the maxillofacial prosthesis to function as an antifungal agent. Although literature lacks evidence of this association. Hence, we conducted this study with the aim of comparing the physical properties of vulcanized maxillofacial silicone material with and without incorporation of 1% Clotrimazole as an antifungal agent.

MATERIAL & METHODS

This prospective, experimental in-vitro study was conducted in the Department of Prosthodontics Crown and Bridge and Laboratory. An ethical clearance was obtained from the institutional ethics committee (IEC). The sample size was calculated to be 90. There were 6 groups in total, each of 15 specimens. A single operator randomly selected samples for the control and test group.

Study group comprised of:

(Group 1) - Maxillofacial silicone elastomer with the incorporation of 1% Clotrimazole as an antifungal agent.

(Group 1a) - Maxillofacial silicone elastomer with the incorporation of 1% Clotrimazole as an antifungal agent to evaluate and compare tensile strength and percentage elongation. (Group 1b) - Maxillofacial silicone elastomer with the incorporation of 1% Clotrimazole as an antifungal agent to evaluate and compare tear strength.

(Group 1c) - Maxillofacial silicone elastomer with the incorporation of 1% Clotrimazole as an antifungal agent to evaluate and compare hardness.

Control group comprised of:

(Group 2) - Maxillofacial silicone elastomer without incorporation of 1% Clotrimazole as an antifungal agent.

Group 2a) Maxillofacial silicone elastomer without incorporation of 1% Clotrimazole as an antifungal agent to evaluate and compare tensile strength and percentage elongation.

Group 2b) Maxillofacial silicone elastomer without incorporation of 1% Clotrimazole as an antifungal agent to evaluate and compare tear strength.

Group 2c) Maxillofacial silicone elastomer without incorporation of 1% Clotrimazole as an antifungal agent to evaluate and compare hardness.

The maxillofacial prosthesis material used was Room temperature vulcanized maxillofacial silicone material, (VST- 30) Versiltal silicone; Lot No. R 531221LKB, Technovent U.K

Antifungal agent used was 1% Clotrimazole by weight, Glenmark Pharmaceuticals Ltd

Inclusion criteria

Specimens of specified dimensions and shapes were included.

Exclusion criteria

Specimens with defects and porosities were excluded.

Specimens not having specified dimensions or shapes were excluded.

A universal testing machine and Shore A hardness tester was used for the sample evaluation.

Custom stainless steel molds were produced to assess mechanical properties (Tensile Strength, Elongation Percentage, Tear Strength, and

Hardness). Three dies, compliant with ISO and ASTM standards, were crafted for silicone test specimens:

Tensile Strength and Elongation: Dumbbell shaped mold (115 mm x 25 mm x 3 mm).

Tear Strength: Trouser-shaped mold (102 mm x 19 mm x 3 mm).

Hardness: Rectangle-shaped mold (25 mm x 25 mm x 6 mm).

Tensile Strength and Elongation Percentage at 100% elongation were measured using a computer-operated Universal Testing Machine (Star Testing System, India, Model No. STS 248). The specimen's thickness, determined with a digital calliper (Mitutoyo, Tokyo, Japan) at three points, was averaged for cross-sectional area calculations.

With a 20 mm separation between tensile grips, specimens were symmetrically inserted, ensuring even tension distribution. The test was conducted at a crosshead speed of 300 mm/min. Excluded were specimens breaking outside the narrow portion or yielding beyond the test length.

The tear strength test for both main test groups used moulded trouser-shaped specimens. Each specimen, with a 40mm-long cut at its centre, was symmetrically inserted into grips and aligned axially. Ensuring a secure grip, specimens were inserted to a depth of 30 mm and tested at a 300 mm/min strain rate using a computer-operated Universal Testing Machine (Star Testing System, India, Model No. STS 248).

Indentation hardness for both main groups was determined using a Shore A Hardness Tester on rectangular specimens (25×25×6 mm) fabricated to meet ASTM specification D224034. The Shore A durometer, held vertically, applied pressure parallel to the specimen surface, and readings were taken 5 seconds after firm contact. Nine readings per specimen were recorded, maintaining a 6-mm distance between each reading and the specimen edge, and the average value was calculated. After trimming and finishing, specimens were dried, and each silicone sample underwent mechanical properties measurement using a Universal Testing Machine and Shore A Hardness Tester.

To ensure even dispersion, 1% Clotrimazole, an antifungal agent, was added to part B of room temperature vulcanized maxillofacial silicone material (VST-30, Versiltal silicone). This concentration was achieved by dissolving 1 gm of Clotrimazole in 100 ml of part B. After mixing Part A with Part B, the mixture was placed into moulds. The mould assembly underwent compression at 0.75 kg/cm2 using a Hydraulic compressor machine (Unident) and was cured at room temperature for 30 minutes. This method aligns with the technique proposed by Pigno et al. in 1994 for incorporating an antifungal agent into the 10:1 mixture of part A and part B.

OBSERVATION & RESULTS

The objective of this research was to assess and compare the mechanical characteristics (including Tensile Strength, Percentage Elongation, Tear Strength, and Hardness) of medical-grade silicone elastomer with and without the inclusion of antifungal agents. The quantitative test data gathered from all test samples were subjected to a statistical analysis utilizing the 'Unpaired t-test'. A significance level of 0.05 was employed for all conducted tests. The results derived from the statistical analysis are as follows:

In Group 1 (Maxillofacial silicone elastomer with 1% Clotrimazole) consisting of 15 samples, the Tensile Strength ranged from a minimum of 2.74 to a maximum of 4.10, with a mean value of 3.4353 ± 0.35502 N/mm^2.

In Group 2 (Maxillofacial silicone elastomer without 1% Clotrimazole) with 15 samples, the Tensile Strength varied from a minimum of 2.66 to a maximum of 3.89, and the mean Tensile Strength was 3.3460 ± 0.37605 N/mm^2. (Table 1).

Table 1: Descriptive Statistics for Tensile Strength (N/mm2) among two groups

Descriptive Statistics					
Group	**N**	**Minimum**	**Maximum**	**Mean**	**Std. Deviation**
Group 1: Maxillofacial silicone elastomer with 1 % Clotrimazole	15	2.74	4.1	3.435	0.355
Group 2 : Maxillofacial silicone elastomer without 1 % Clotrimazole	15	2.66	3.89	3.346	0.376

In Group 1, the Elongation (%) ranged from a minimum of 467.07 to a maximum of 605.38, with a mean value of 543.4927 ± 39.16878.

For Group 2, the Elongation (%) varied from a

minimum of 425.38 to a maximum of 644.46, with a mean Elongation (%) of 549.8407 ± 51.41478.(Table 2)

In Group 1, the Minimum Maximum Load (N) ranged from 60.95 to a maximum of 109.76, with a mean value of 81.6940 ± 13.96057.

Table 2: Descriptive Statistics for Elongation (%) among two groups

Descriptive Statistics					
Group	**N**	**Minimum**	**Maximum**	**Mean**	**Std. Deviation**
Group 1: Maxillofacial silicone elastomer with 1 % Clotrimazole	15	467.07	605.38	543.493	39.169
Group 2: Maxillofacial silicone elastomer without 1 % Clotrimazole	15	425.38	644.46	549.841	51.415

For Group 2, the Minimum Maximum Load (N) varied from 59.68 to a maximum of 90.25, with a mean Maximum Load of 75.8793 ± 9.85280. (Table 3)

In Group 1, the Tear Strength (N/mm) ranged from a minimum of 20.31 to a maximum of 36.58, with a mean value of 27.2273 ± 4.65254.

Table 3: Descriptive Statistics for Maximum Load (N) among two groups

Descriptive Statistics					
Group	**N**	**Minimum**	**Maximum**	**Mean**	**Std. Deviation**
Group 1: Maxillofacial silicone elastomer with 1% Clotrimazole	15	60.95	109.76	81.694	13.961
Group 2: Maxillofacial silicone elastomer without 1% Clotrimazole	15	59.68	90.25	75.879	9.853

For Group 2, the Tear Strength (N/mm) varied from a minimum of 19.89 to a maximum of 30.08, with a mean Tear Strength of 25.2900 ± 3.28419. (Table 4)

The minimum Hardness among Group 1 (Maxillofacial silicone elastomer with 1 % Clotrimazole) (n=15) was 26, maximum 32, with mean 28.67 ± 1.447.

Table 4: Descriptive Statistics for Tear Strength (N/mm) among two groups

Descriptive Statistics					
Group	**N**	**Minimum**	**Maximum**	**Mean**	**Std. Deviation**
Group 1: Maxillofacial silicone elastomer with 1 % Clotrimazole	15	20.31	36.58	27.227	4.653
Group 2: Maxillofacial silicone elastomer without 1 % Clotrimazole	15	19.89	30.08	25.29	3.284

The minimum Hardness among Group 2 (Maxillofacial silicone elastomer without 1% Clotrimazole) (n=15) was 22, maximum 31, with mean 27.20 ± 2.336. (Table 5)

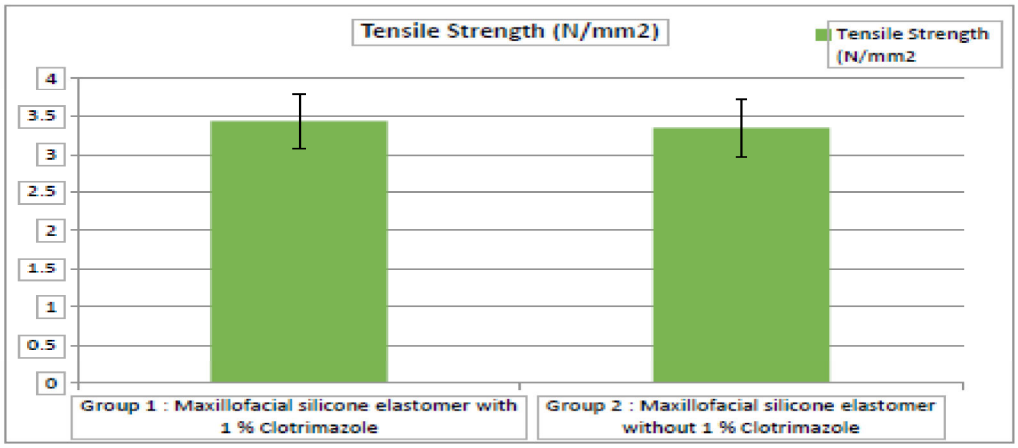
Table 5 : Descriptive Statistics for Hardness among two groups

Descriptive Statistics					
Group	**N**	**Minimum**	**Maximum**	**Mean**	**Std. Deviation**
Group 1: Maxillofacial silicone elastomer with 1 % Clotrimazole	15	26	32	28.67	1.447
Group 2: Maxillofacial silicone elastomer without 1 % Clotrimazole	15	22	31	27.2	2.336

The mean difference in Tensile Strength (N/mm^2) between Group 1 (Maxillofacial silicone elastomer with 1% Clotrimazole) (3.4353 ± 0.35502) and Group 2 (Maxillofacial silicone elastomer without 1% Clotrimazole) (3.3460 ± 0.37605) was 0.08933. This difference was determined to be statistically insignificant, as evidenced by a p-value of 0.509. (Table 6, Graph 1)

Table 6: Comparison of mean Tensile Strength (N/mm2) between Two groups by Unpaired 't' Test

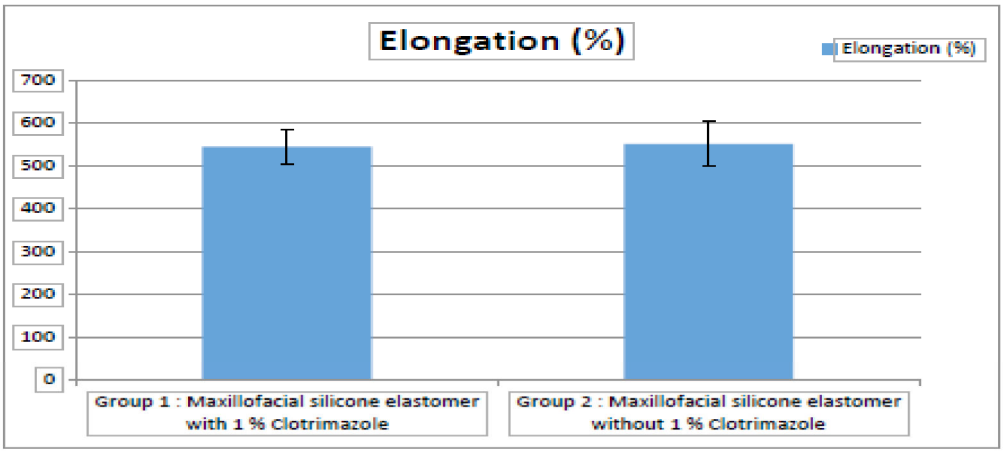
Group 1 vs Group 2	t	df	Sig. (2-tailed)	Mean Difference	Confidence Interval (CI)	
					Lower	Upper
3.4353 ± .35502 3.3460 ± .37605	0.669	28	0.509	0.089	-0.184	0.363



Graph 1: Comparison of mean Tensile Strength (N/mm2) between Two groups

Table 7: Comparison of mean Elongation (%) between Two groups by Unpaired 't' test

Group 1 vs Group 2	t	df	Sig. (2-tailed)	Mean Difference	Confidence Interval (CI)	
					Lower	Upper
543.4927 ± 39.16878 549.8407 ± 51.41478	-0.38	28	0.707	-6.348	-40.533	27.837

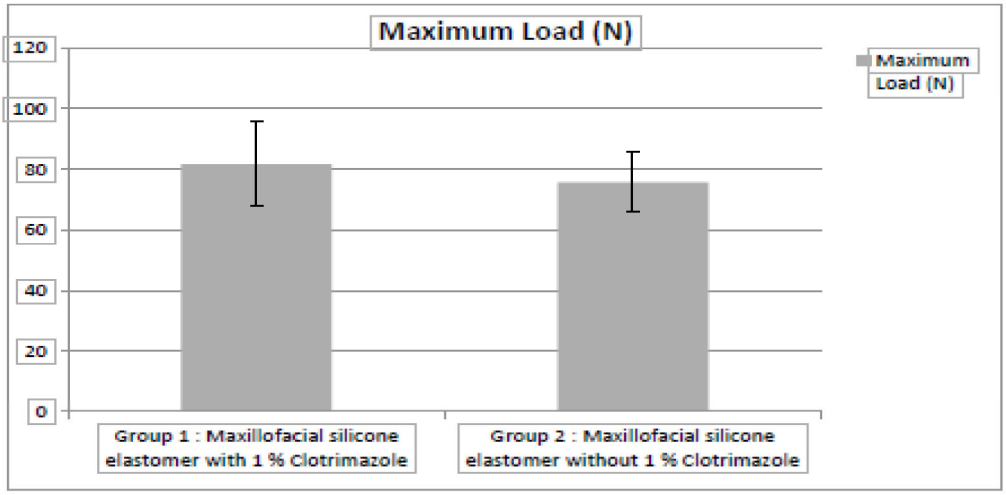


Graph 2: Comparison of mean Elongation (%) between Two groups

The mean difference in Elongation (%) between Group 1 (Maxillofacial silicone elastomer with 1% Clotrimazole) (543.4927 ± 39.16878) and Group 2 (Maxillofacial silicone elastomer without 1% Clotrimazole) (549.8407 ± 51.41478) was -6.34800. This difference was determined to be statistically insignificant, as indicated by a p-value of 0.707. (Table 7, Graph 2)

Table 8: Comparison of mean Maximum Load (N) between Two groups by Unpaired 't' Test

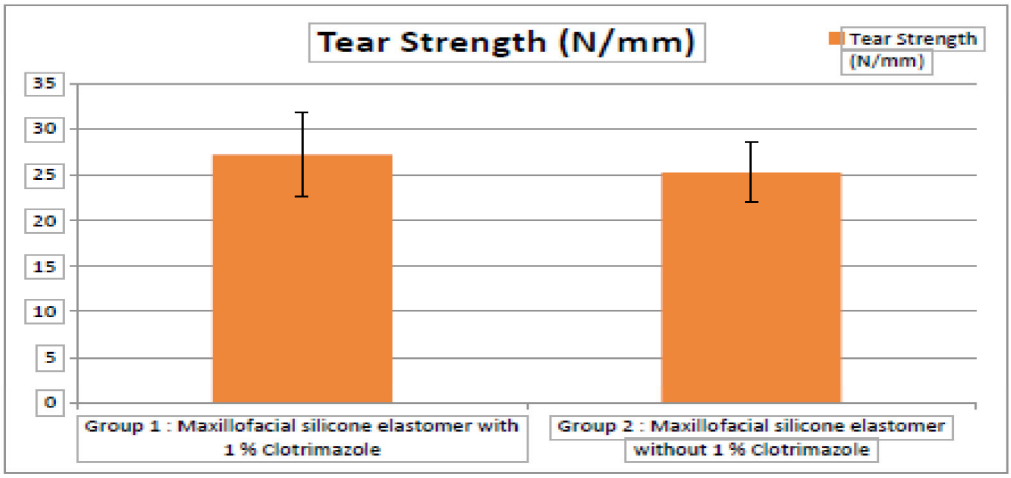
Group 1 vs Group 2	t	df	Sig. (2-tailed)	Mean Difference	Confidence Interval (CI)	
					Lower	Upper
81.6940 ± 13.96057 75.8793 ± 9.85280	1.318	28	0.198	5.815	-3.223	14.852



Graph 3: Comparison of mean Maximum Load (N) between Two groups

Table 9: Comparison of mean Tear Strength (N/mm) between Two groups by Unpaired 't' Test

Group 1 Vs Group 2	t	df	Sig. (2-tailed)	Mean Difference	Confidence Interval (CI)	
					Lower	Upper
27.2273 ± 4.65254 25.2900 ± 3.28419	1.318	28	0.198	1.937	-1.075	4.949



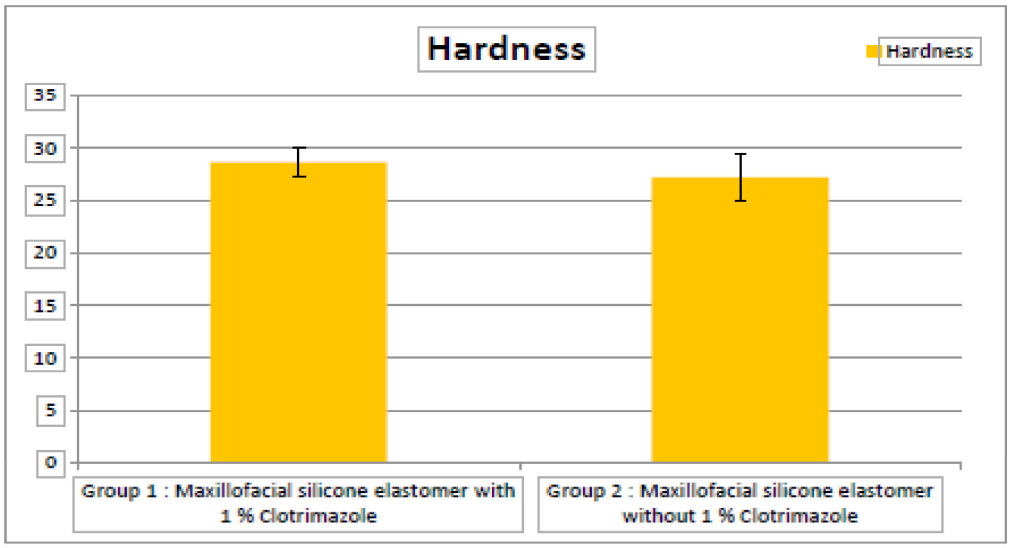
Graph 4: Comparison of mean Tear Strength (N/mm) between Two groups

The mean difference in Maximum Load (N) between Group 1 (Maxillofacial silicone elastomer with 1% Clotrimazole) (81.6940 ± 13.96057) and Group 2 (Maxillofacial silicone elastomer without 1% Clotrimazole) (75.8793 ± 9.85280) was 5.81467. This difference was deemed statistically insignificant, as evidenced by a p-value of 0.198. (Table 8, Graph 3)

The mean difference in Maximum Load (N) between Group 1 (Maxillofacial silicone elastomer with 1% Clotrimazole) (27.2273 ± 4.65254) and Group 2 (Maxillofacial silicone elastomer without 1% Clotrimazole) (25.2900 ± 3.28419) was 1.93733. This difference was determined to be statistically insignificant, as indicated by a p-value of 0.198. (Table 9, Graph 4)

Table 10: Comparison of mean Hardness between Two groups by Unpaired 't' Test

Group 1 vs Group 2	t	df	Sig. (2-tailed)	Mean Difference	Confidence Interval (CI)	
					Lower	Upper
28.67 ± 1.447	2.067	28	.048*	1.467	0.013	2.92
27.20 ± 2.336						



Graph 5: Comparison of mean Hardness between Two groups

The mean difference in Hardness between Group 1 (Maxillofacial silicone elastomer with 1% Clotrimazole) (28.67 ± 1.447) and Group 2 (Maxillofacial silicone elastomer without 1% Clotrimazole) (27.20 ± 2.336) was 1.467. This difference was determined to be statistically significant, with a p-value of 0.048*, and a confidence interval (CI) of 0.013 to 2.920. (Table 10, Graph 5)

DISCUSSION

The literature clearly indicates efforts to assess the physical and mechanical characteristics of various silicone maxillofacial materials. Findings from these studies reveal significant variations in tensile similar testing methodologies. Lewis et al. found a range of 3.24 to 7.04 MPa for the Tensile Strength of Silastic MDX 4 - 4210.17. Haug et al. conducted three studies with differing outcomes: two 1999 reports showed comparable results, one at 5 MPa and the other slightly lower at 4 MPa, while the earliest 1992 study reported a lower result of 2.47 MPa. Other studies indicated Tensile Strength averages of 3.23 MPa, 1.24 MPa, 2.47 MPa, and 1.65 MPa, respectively.[9,16,17] The current study showed the mean difference for Tensile Strength (N/mm 2) between Group 1(Maxillofacial silicone elastomer with 1% Clotrimazole) (3.4353 ± .35502) and Group 2 (Maxillofacial silicone elastomer without 1% Clotrimazole) (3.3460 ± .37605) was .08933 which was found statistically insignificant with p>0.509.

and tear strength, percentage elongation, and Shore A hardness tests. Additionally, disparities emerge among studies investigating the same silicone maxillofacial material.[9–11]

In a clinical context, the paramount physical characteristic is the 'Tear Strength' of the material. The Tear Strength of a PDMS maxillofacial material holds exceptional significance, especially in the thin margins surrounding nasal, ear, and eye prostheses. The margins of facial prosthesis are usually thin and they are glued to the patients skin. So there are chances of it tearing when they are removed at nigh for cleaning etc.[2]

The silicone elastomer's strength relies on its 'Tensile Strength,' and 'Elongation' indicates. prosthesis flexibility. A prosthesis with high elongation is preferred for ease of removal from facial tissue, especially for nasal or eye prostheses. Matching the 'Hardness' of maxillofacial material to missing facial tissue is crucial for optimal results.

While widely utilized, they fall short of being ideal. The lifespan of maxillofacial prostheses relies on both the material used and the patient's approach to the prosthesis and the functioning of prosthesis in achieving its purpose.[12] Many studies author have agreed in unison that maxillofacial prosthesis need to be replaced every 6-18 months due to degrading mechanical properties and discoloration.[13,14]

The black discoloration is caused by fungal growth. With nasal prosthesis, this is attributed to moist air and secretions. Adding Clotrimazole to silicone specimens in vitro effectively inhibited fungus growth in disk diffusion tests. The Clotrimazole specimens exhibited consistent inhibition upon repeated testing, suggesting stability. When stored at room temperature, Clotrimazole specimens displayed ongoing inhibition of fungal growth for several months, indicating sustained antifungal effectiveness.[15]

In this study, we compared room temperature vulcanized maxillofacial silicone with and without 1% Clotrimazole. We evaluated various physical properties like Tensile strength, Percentage elongation, Tear strength, and Hardness. The control group specimens had part A and part B mixed in a 10:1 ratio. For the test group, 1 gm of 1% Clotrimazole was mixed into 100 ml of part B to ensure even dispersion, and then part A and part B were mixed in a 10:1 ratio.

The 'Tensile strength' values of maxillofacial silicone varied across studies, with some reporting high values and others reporting low values under

Plenty studies have evaluated the 'percentage elongation' of maxillofacial materials. In a study the percentage elongation of heat vulcanized silicone (HTV) was found to be 441 and room temperature vulcanized (RTV) silicone was found to be 445.[18] Different types of silicone also have variations. In 2007, Li Xiao and colleagues assessed the mechanical characteristics of Cosmesil M511 maxillofacial elastomer, juxtaposing it against A-2186 elastomer. The findings indicated that Cosmesil M511 exhibited a greater percentage of elongation compared to A-2186.[19]

The 'Elongation Percentage' values obtained in this investigation ranged from 543.4927 ± 39.16878 percent to 549.8407 ± 51.41478 percent, showing a difference of -6.34800. Notably, there was variability in the percentage of elongation among specimens with antifungal incorporation compared to those without. However, the observed differences were not statistically significant ($p > 0.05$). The findings regarding elongation at fracture in this study suggest that reinforcing silicone maxillofacial material with antifungal incorporation does not significantly impact elongation at fracture, indicating similar outcomes to the group without antifungal incorporation.

High percentage elongation and high tear strength make the ideal prosthesis material.[20] The 'Tear Strength' values in this study varied from 36.58 N/mM to 30.08 N/mM. Although there was a slight improvement in Tear Strength for specimens with antifungal incorporation compared to those without, the observed differences were not statistically significant ($p > 0.05$). These variations likely originate from differences in the structural stability of PDMS chains, attributed to varying cross-linking densities and conditioning types.

In many studies authors have mentioned addition of different particles to increase the tear strenghth such as tulle,[21,22] silica fillers,[23] POSS-pohedralsilsesquioxane.[24] However there is lack of studies evaluating tear strength after addition of antifungal agents.

In a study A-2000 and A-2006 Room Temperature Vulcanized (RTV) silicone elastomers were tested for Shore A hardness. Silane treated silica, fumed silica, and titanium dioxide nanoparticles were employed as fillers in the maxillofacial silicone elastomers, each at a concentration of 10% by volume. The A-2000 group containing fumed silica exhibited the lowest hardness values after storage. Nevertheless, there was no notable difference observed between the control group and the one with fumed silica.[25]

A significant difference ($p < 0.001$) was found in the average 'Shore A Hardness' between specimens with and without antifungal incorporation, ranging from 28.67 ± 1.447 to 27.20 ± 2.336. This suggests that specimens with antifungal agents displayed higher hardness levels. Further investigations are needed to delve into this aspect.

In 2018, Lee et al. explored the antifungal activity of tissue conditioners containing chitosan. Their findings indicated that chitosan and quaternized chitosan nanoformulations did not impact the viability of human gingival epthelial cell/ fibroblasts.[26]

The results of the aforementioned study reveal variations in mechanical properties following the inclusion of 1.5% (w/w) zinc pyrithione and silver nano particles. Tensile strength and percentage elongation at break values for metal incorporated specimens showed no significant changes compared to the standard compounds (tensile - $p=0.47$; elongation at break $p=0.09$). However, there was a notable difference ($p<0.05$) in the modulus, density, and hardness values of zinc pyrithione incorporated compounds when compared to standard and silver nanoparticles compounds. This discrepancy may be attributed to the polypropylene fraction in the master batch present in the zinc pyrithione additive, which possesses higher modulus, density, and hardness than the styrene-ethylene/butylene-styrene copolymer (SEBS). Further exploration of various fillers and materials in the engineering field may provide insights into the factors influencing changes in the physical and mechanical properties of medical grade maxillofacial silicone elastomer material.

CONCLUSION

All specimens, whether room temperature vulcanized maxillofacial silicone material was incorporated with or without 1% Clotrimazole as an antifungal agent, showed statistically non-significant changes in mechanical properties, including Tensile Strength, Elongation Percentage at break, and Tear Strength. A statistically significant difference in Hardness was observed in the maxillofacial silicone material when comparing specimens with and without 1% Clotrimazole incorporation.

Specimens with the incorporation of an antifungal agent displayed improved mechanical properties (Tensile Strength, Elongation Percentage at break, Tear Strength, and Hardness) compared to those without the antifungal agent. Integrating an antifungal agent into maxillofacial silicone elastomer emerges as a viable option to enhance prostheses, significantly reducing fungal activity. Moreover, it enhances the mechanical properties of the medical grade maxillofacial silicone material, contributing to the extended longevity of prostheses.

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