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Effect of Incorporation of Thymol Powder on the Tensile Strength, Elongation Percentage, and Surface Roughness of Room-Temperature Vulcanised Maxillofacial Silicone Material: An In Vitro Study

Manar Hussein Ramadhan[1,2*], Faiza Mohammed Hussein Abdul-Ameer[1]

1. Department of Prosthodontics, College of Dentistry, University of Baghdad, Baghdad, Iraq
2. Department of Prosthodontics, College of Dentistry, Mustansiriyah University, Baghdad, Iraq

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**** Corresponding author:***
1- Department of Prosthodontics, College of Dentistry, University of Baghdad, Baghdad, Iraq
2- Department of Prosthodontics, College of Dentistry, Mustansiriyah University, Baghdad, Iraq

Email: mannar.hussein.ramadhan@uomustansiriyah.edu.iq

A B S T R A C T

Objectives: Silicone facial prostheses are replaced after a relatively short period of clinical service, mainly due to the decline in their physical and mechanical properties. This study aimed to investigate some mechanical and physical properties of VST-50 maxillofacial silicone after incorporating thymol micro-powder into its matrix.

Materials and Methods: In this in vitro study, room-temperature vulcanised VST-50 maxillofacial silicone and thymol micro-powder were used to prepare the study specimens according to the findings of a pilot study. Sixty specimens were prepared and assigned equally and relevantly to three tests (tensile strength/elongation percentage test, and surface roughness test). Each test encompassed three groups (n=10). According to thymol content percentage, the study groups were customised as: group A: control (without additive), experimental groups B and C with 0.75wt% and 1wt.% thymol additive, respectively. An Instron universal testing machine was used to investigate the tensile strength and elongation percentage, and a profilometer was used to test the surface roughness. ANOVA and post-hoc test were used to analyze the results (alpha 0.05).

Results: Statistically, group B showed a significantly higher mean tensile strength (mean difference: -3.055 N/mm^2; P<0.001) and elongation percentage (mean difference: -157.9885%; P=0.003). However, group C showed a significantly lower surface roughness (mean difference: 0.1172µm; P<0.001).

Conclusion: According to the results of this in vitro study, thymol micro-powder appears to be a promising additive that could reinforce some physical and mechanical properties of medical-grade maxillofacial silicone.

Keywords: Maxillofacial Prosthesis; Mechanical Tests; Silicone Elastomers; Thymol

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INTRODUCTION

Maxillofacial defects are usually the outcome of either surgical removal of a tumor, trauma, or a birth defect [1]. Maxillofacial prosthetic replacement is highly important as it helps patients return to their previous life before the defect occurred, restore their normal self-image, enhance their self-confidence, and relieve their psychological pressure by avoiding possible bullying and staring [2]. Thus, such prosthesis should possess certain physical, mechanical, biological, and esthetic characteristics to be comfortable and satisfactory for patients [3].

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There are various materials used for the fabrication of prosthetic replacements that integrate into patients' face to substitute the missing part, but silicone is the most widely used material for this purpose due to its favorable characteristics such as easily matching facial complexion through coloring dyes and characterization of minute details, optimal biocompatibility, and relatively low cost [4]. Additionally, it has high tensile strength and elongation percentage which make the silicone flex in a more natural manner during muscular activities like laughing and frowning, giving it a more realistic appearance [5].

Surface roughness is the degree of irregularity on the outer surface of a given material. These irregularities could be nucleation areas for crack initiation; thus, a smoother surface is more resistant to crack propagation [6].

Various studies evaluated the mechanical properties of silicone and reported that they were not suitable enough to meet the optimum requirements during service time and the intended longevity of prostheses [7,8]. Generally, silicone prostheses serve for a relatively short period of about 1.5–2 years before they fail and need to be replaced with a new one [9]. Therefore, further experimental studies should be conducted to improve the properties of this material [7].

The physico-mechanical properties of elastomers depend on the type and amount of fillers, which can be optimized to achieve the desired characteristics of silicone prosthesis [10].

Thymol powder, the primary active constituent of thymol oil extracted from *Thymus vulgaris* (*T. vulgaris*), is a natural monoterpenoid phenol that appears as a colorless crystalline material with a distinctive aroma. It is a perennial fragrant herbaceous plant characterized by its compact size, extensive branching, and woody nature. It belongs to the botanical family Lamiaceae (mint family) [11]. It exhibits antioxidant, anti-inflammatory, and antimicrobial activities [12].

During the Black Death in the late 1340s, thymol served as the primary component of medicinal mixtures and ointments that were administered topically to the blistered skin [13]. Recently, thymol has become well known as a potent antiseptic that is used in acne medications, hand sanitizers, and mouthwashes [12]. Various studies used thymol to develop anti-foul food packaging [14-16].

To our knowledge, the effects of incorporating thymol extract into maxillofacial silicone elastomers on their physical and mechanical properties have not been previously reported. Thus, this study aimed to evaluate selected physical and mechanical properties of room-temperature vulcanized (RTV) VST-50 maxillofacial silicone following the incorporation of thymol micropowder into the silicone matrix. In this study, the null hypothesis was that there would be no significant difference in the tested physical and mechanical properties of thymol-modified maxillofacial silicone material.

MATERIALS AND METHODS

In this in vitro study, thymol powder (DHA, Denmark) was added to VST-50 maxillofacial silicone (Factor II Inc., USA) matrix to fabricate the study specimens and investigate the mechanical and physical properties of thymol-modified silicone.

Thymol powder was first milled using a planetary ball mill (Fritsch, Idar-Oberstein, Germany) to obtain thymol particles as small as possible. This step seemed mandatory to enhance the homogeneity of the thymol-silicone mixture and surface smoothness of the specimens. Next, the particle size was measured using a particle size analyzer (Brookhaven, USA).

Pilot study:

A pilot study was carried out to determine the optimal concentrations of thymol micropowder for incorporation into maxillofacial silicone. To assess the effect of thymol addition, the tensile strength and elongation at break of VST-50 silicone specimens were measured and compared with unmodified control group. The results indicated that incorporating 0.75wt.% and 1wt.% thymol enhanced both mechanical properties, suggesting that these concentrations may provide improved performance for maxillofacial applications.

Main study:

The main study was conducted based on the findings of the pilot study to evaluate the tensile strength, elongation at break, and surface roughness of thymol-modified VST-50 maxillofacial silicone.

Each test involved three groups (n=10) of specimens according to the thymol percentage with 0wt.% (group A), 0.75wt.% (group B), and 1wt.% (group C) thymol addition. The tensile strength and elongation at break were measured using the same set of specimens, resulting in a total of 60 samples prepared for the main study. The control groups were included as reference standards to assess the effect of thymol micropowder on physical and mechanical properties of silicone elastomer.

Fabrication of molds:

Transparent acrylic sheets (Perspex cell-cast acrylic; Clairevaux les Lacsrance, France) were used for the fabrication of molds. They were designated using AutoCAD-2013 (Autodesk Inc., San Rafael, CA, USA), and subsequently manufactured with a computer numerical control milling machine (JL-1612; Jinan Link Manufacture and Trading Co., Ltd., China) [17]. The molds used to fabricate specimens for tensile strength and elongation at break tests were dumbbell-shaped (type 2) according to ISO 37:2017 [18]; while those used for the fabrication of specimens for the surface roughness test were designated according to ISO 7619-1:2010 specifications [19] with dimensions of 25mm×25mm×6mm (length×width × thickness) (Fig. 1).

Specimen fabrication and storage:

The control silicone specimens were fabricated according to the manufacturer's instructions by adding the catalyst to the base in 1:10 weight ratio. They were then mixed by a vacuum mixer (Manfredi, Italy) for 5 minutes at 360rpm and -10 bar pressure [9].

Specimens of the experimental groups were fabricated by the same method as the control group specimens, but with an additional step of adding thymol powder to the silicone base at the specified weight percentages and mixing by the mixer for 3 minutes without vacuum to avoid powder suction, then mixing for an additional 5 minutes under vacuum power to release air bubbles. The rest of the process was continued as mentioned above [2].

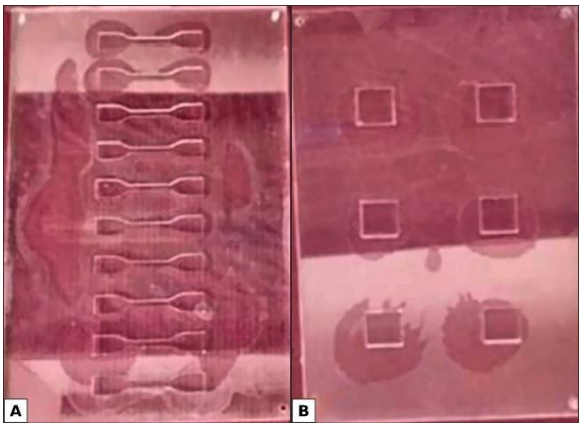


Fig 1. Transparent acrylic molds: (A) molds for tensile strength and elongation percentage specimens, and (B) molds for surface roughness specimens.

A thin layer of separating medium (BMS Dendal, Italy) was applied to all parts of the mold and allowed to dry, then the silicone mixture was poured into the mold. The pouring was performed under controlled conditions, with a relative humidity of 50%±10% and a temperature of 23±2°C [20,21].

After allowing 4–6 hours for setting in accordance with the manufacturer's instructions [22], the specimens were removed from the molds and kept in a storage box away from light exposure and under standard conditions of 50±10% relative humidity (RH) and 23±2°C temperature. The time interval between fabrication of specimens and testing had to be at least 16 hours (Fig. 2) [20].

Tensile strength and elongation percentage test:

Every dumbbell-shaped specimen was held in an Instron computerized universal testing machine (WDW-20; Laryee Technology Co., Ltd., Beijing, China) and stretched automatically at a constant rate of 500mm per minute until failure. Then, the maximum force at failure was recorded by the machine's software. The tensile strength was calculated according to ISO 37:2017 [18] using the following equation:

$$UTs = \frac{f_m}{w_t}$$

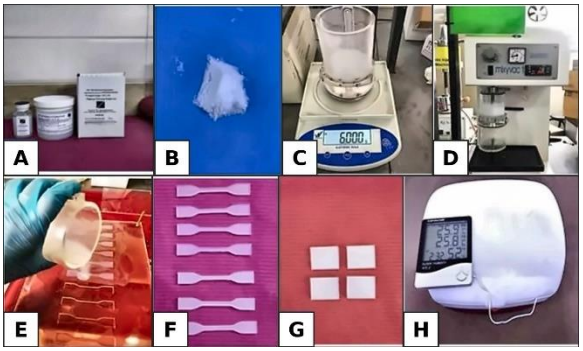


Fig 2. Specimen fabrication: (A) silicone, (B) thymol powder, (C) thymol, base, and catalyst in the mixing jar, (D) vacuum mixer, (E) pouring silicone mixture into the mold, (F) tensile strength and elongation percentage specimens, (G) surface roughness specimens, and (H) storage box.

UTs: ultimate tensile strength (Newtons per square millimeters).
F_m: maximum force recorded at break (Newtons).
W_t: original cross-sectional area of the specimen (in square millimeters).
The elongation percentage prior to failure was measured synchronously with the tensile strength; it was calculated according to ISO 37:2017 [18] using the following equation:

$$E_b = 100 \times \frac{(L_b - L^{\circ})}{L^{\circ}}$$

E_b: elongation percentage at break (%).
L°: original length (millimeters).
Lb°: extension at failure (millimeters).
A permanent marker was used to place two reference points at both ends of the narrow part of the dumbbell-shaped specimens, equidistant from the center. Then, the original length of the dumbbell-shaped specimens was measured (before testing) between these two points by using a digital vernier (Guilin Guanglu Measuring Instrument Co., Ltd, Guilin, China) with 0.01mm accuracy, while the universal testing machine's computer software automatically measured the length of the specimen at failure (Fig. 3).

Surface roughness test:

A portable digital profilometer (Time Group Inc., Beijing, China) with 0.001µm accuracy was used to examine the surface roughness of the specimens. The profilometer was mounted on a stand, while the test specimen was placed on a flat, stable surface. Then, the sensible diamond tip of the profilometer device was placed in contact with the specimen's surface, and 10 randomly selected points on the surface of each specimen were examined to obtain Ra parameter readings; this parameter is the average of a set of single measurements of a surface's peaks and valleys [23]. The mean value of the 10 readings represented the roughness value (Fig. 4).

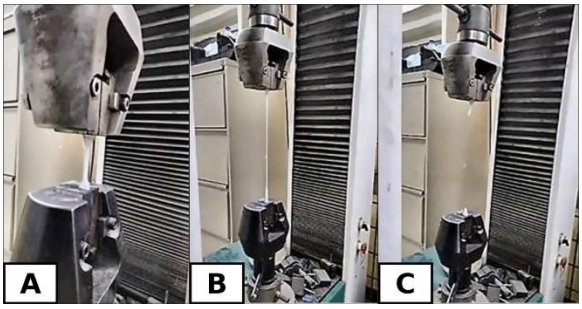


Fig 3. Tensile strength and elongation percentage tests: (A) Specimen mounted in the Instron universal testing machine, (B) maximum strain of specimen before failure, and (C) failed specimen.



Fig 4. Surface roughness test using a profilometer.

Scanning electron microscopy (SEM):

Scanning electron microscopy (SEM; Inspect S50, FEI Company, Hillsboro, OR, USA) was used to examine the surface topography of the specimens and the homogeneity of the silicone-thymol mixture. The polymeric nature of silicone renders the samples an insulating medium for the SEM electron beam, producing a mirror-like effect. To increase electrical conductivity, the sample surfaces were coated

with a 1 nm gold film using the device's coating system [17]. SEM images were captured for the control group (A) and the two experimental groups (B and C) at 300×magnification.

Particle size analysis:

A particle size analyzer (90Plus, Brookhaven Instruments Corporation, Holtsville, New York, USA) was utilized to measure the particle size of thymol powder, where thymol powder was dispersed in distilled water and sonicated for 3 min at low power to minimize temperature rise. Particle size was determined by dynamic light scattering (DLS), which estimates the hydrodynamic diameter of particles from temporal fluctuations in the intensity of scattered laser light caused by Brownian motion [24].

Statistical analysis:

The collected data were analyzed using SPSS version 25 (SPSS Inc., IL, USA). The results were expressed by inferential statistics, where Levene's test for homogeneity of variances used and showed non-homogeneous variance for tensile strength (P=0.046), and homogeneous variance for elongation percentage (P=0.466) and surface roughness (P=0.087).

In addition, one-way ANOVA used to explore whether the additive powder made a significant impact on the tested silicone properties, thereby evaluating the variance in the mean values of the tested groups. Finally, the Games-Howell and Bonferroni tests were used to compare the mean values of each tested group against all other groups. P<0.05 was considered statistically significant.

RESULTS

SEM imaging results:

SEM images of VST-50 maxillofacial silicone specimen without thymol additive showed considerable irregularities on the specimen surface. Furthermore, SEM micrographs showed homogeneously distributed thymol powder particles within the silicone matrix and progressively less irregularities on the silicone specimens with 0.75wt.% and 1wt.% thymol powder additive, respectively, as shown in Figure 5.

Particle size:

Particle size analysis revealed an average particle size of approximately 2µm.

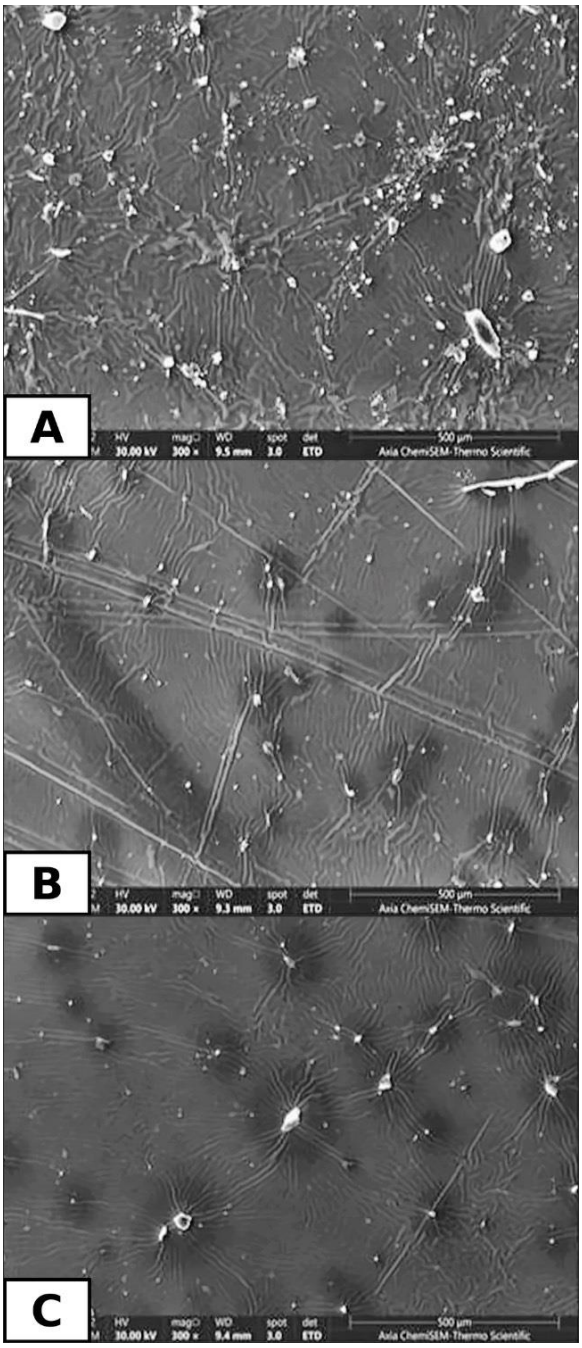


Fig 5. SEM micrographs of (A) a control specimen (0wt.% thymol content), (B) a specimen from group B (0.75wt.% thymol content), and (C) a specimen from group C (1wt.% thymol content).

Inferential statistics:

ANOVA showed significant effects of thymol micropowder on the tensile strength (P<0.001), elongation percentage (P=0.004), and surface roughness (P<0.001) of maxillofacial silicone elastomer as detailed in Table 1.

Table 1. Results of one-way ANOVA regarding the comparison of physico-mechanical properties of the groups

Mechanical/ physical property	Groups	Sum of squares	Df	Mean square	F	P-value.
Tensile strength (N/mm2)	Between groups	47.494	2	23.747	14.255	<0.001*
	Within groups	44.978	27	1.666		
	Total	92.471	29			
Elongation percentage (%)	Between groups	124906.129	2	62453.065	6.902	0.004*
	Within groups	244305.465	27	9048.351		
	Total	369211.594	29			
Surface roughness (µm)	Between groups	0.082	2	0.041	12.645	<0.001*
	Within groups	0.088	27	0.003		
	Total	0.170	29			

*Significant at P<0.05, df: Degree of freedom.

Table 2 presents the post-hoc pairwise comparisons for all study groups. The Games-Howell test was applied for tensile strength. Group A showed significantly lower tensile strength than both group B (P<0.001) and group C (P=0.004), while the difference between groups B and C was not significant (P=0.207).

The Bonferroni test was applied for elongation percentage and surface roughness. For elongation percentage, group B showed a significantly higher mean than group A (P=0.003), while the differences between groups A and C (P=0.267) and between groups B and C (P=0.185) were not significant. For surface roughness, group A showed significantly higher values than both group B (P=0.001) and group C (P<0.001), while the difference between groups B and C was not significant (P=1.000).

DISCUSSION

According to the results of this study, the null hypothesis was rejected as thymol powder added as a filler to VST-50 maxillofacial silicone matrix significantly enhanced tensile strength, elongation percentage, and surface smoothness. Higher values of tensile strength and elongation percentage are desired to fabricate a more natural-looking facial prosthesis that is capable of flexing in a more natural manner during smiling, laughing, and frowning. This could help in delaying fatigue and extending the service life of maxillofacial prosthesis. Additionally, a facial prosthesis

Table 2. Post-hoc test results for pairwise comparisons of the groups

Mechanical/ physical property	Type of multiple comparisons test	(I) Group	(J) Group	Mean difference (I-J)	Standard. error	P-value
Tensile strength (N/mm2)	Games-Howell	A	B	-3.055	0.577	<0.001*
		A	C	-1.880	0.477	0.004*
		B	C	1.175	0.661	0.207**
Elongation percentage (%)	Bonferroni test.	A	B	-157.988	42.540	0.003*
		A	C	-75.038	42.540	0.267**
		B	C	82.949	42.540	0.185**
Surface roughness (µm)	Bonferroni test.	A	B	0.103	0.0255	0.001*
		A	C	0.117	0.0255	<0.001*
		B	C	0.0135	0.0255	1.000**

*Significant at P<0.05, **Non-significant at P>0.05.

with a smoother surface may be more hygienic in terms of less retention of microorganisms, easier cleansing, and being gentler on the underlying vital tissues.

Statistically, tensile strength showed a significant increase in both experimental groups B and C as compared to the control group (group A). Thymol powder micro-particles increased the density of the polymer matrix, being physically imbedded within the polymer chain networks; when tensile force is applied, these micro-particles could facilitate the gliding movement between the adjacent polymer chains with less chance for separation in comparison to the control group [25]. In agreement with the present results, an earlier study found a significant increase in tensile strength after the addition of polyamide-6 micro powder to the room-temperature vulcanised maxillofacial silicone [2]. In contrast, the results of a study conducted to investigate the effect of adding chitosan micro-filler to the maxillofacial silicone matrix reported a reduction in tensile strength [26]. Another study evaluated addition of a composite of polyamide-6 microparticles and silicon dioxide nanoparticles to a maxillofacial silicone matrix and reported that it decreased the tensile strength [27]. These disagreements can be attributed to the use of different types of fillers and silicones with different percentages.

The elongation percentage test showed a statistically significant increase in experimental group B specimens as compared to group A. When tensile force is applied to the filler-reinforced silicone specimen, articulation movements between the polymer chains and the filler micro-particles occur, which could aid in protecting the polymer chains from breakage. Moreover, a filler-reinforced polymer matrix could convert the energy of the applied tensile force into thermal energy, which dissipates the tensile force and therefore decreases the chance of polymer chain fracture [28]. The results of this study agreed with the results of an earlier study, in which the elongation percentage of VST 50F maxillofacial silicone experienced a significant increase after the incorporation of titanium dioxide nanoparticle fillers into the silicone [29]. Both nanofillers used in the above-mentioned study and micro-fillers used in the present study act as fillers to reinforce the elongation percentage property of the tested silicone material. In contrast, these results disagreed with the results of a study that investigated the effect of incorporating a composite of polyamide-6 microparticles and silicon dioxide nanoparticles into the maxillofacial silicone matrix, which indicated a significant decrease in the percentage of elongation in the tested specimens [27]. This disagreement could be attributed to the use of different types of fillers and silicone at different percentages.

Surface roughness showed a statistically significant reduction in experimental groups B and C. Thymol is hydrophobic by nature [16]. Likewise, polydimethylsiloxane exhibits hydrophobic behavior due to the presence of methyl groups in the side chains [30]. The surface of hydrophobic materials has low surface energy and high surface tension [31]. Therefore, the hydrophobicity of the thymol-silicone mixture could yield a higher surface tension, which in turn could align the molecules at the surface layer of the unset silicone into a tighter, smoother raw; this may result in a decrease in surface roughness of the set silicone, as shown on SEM micrographs.

Furthermore, the low melting point of thymol crystals (49–51Cº) may further decrease due to the process of thymol milling, which makes thymol powder particles smaller with increased surface area. Hence, it readily melts, integrates, and fits into the irregularities on the surface of the cured silicone. However, in contrast to these results, an earlier study recorded an increase in the surface roughness mean value of maxillofacial silicone when a composite of polyamide-6 microparticles and SiO_2 nanoparticles was incorporated [27]. These disagreements may be due to the use of different types of fillers.

Since the use of thymol in the food industry or as a wound dressing is promising [32,33], and according to the results of the present study, it seems that this material can be used more in dentistry in the future. Further studies are recommended on the thymol-modified

silicone to investigate biocompatibility potential, environmental-related factors, and the aging of modified silicone material in order to improve the quality of life of patients with maxillofacial defects.

This study was an in vitro experiment, which indicates that patient-related factors were not taken into consideration; thus, biocompatibility tests should also be performed on thymol-containing maxillofacial silicone.

CONCLUSION

Thymol micropowder could present promising potential in the field of maxillofacial silicone improvement. The highest tensile strength mean value was seen in the 0.75wt.% thymol addition group, which makes the silicone resistant to forces attempting to create plastic deformation.

The elongation percentage of the silicone was highest with 0.75wt.% thymol addition which enables the silicone to match the surrounding soft tissue movement during function. The lowest mean roughness value was recorded in the 1wt.% group, which can decrease the chance for microbial aggregation and colonization on the silicone surfaces.

CONFLICT OF INTEREST STATEMENT

None declared.

GENERATIVE AI IN SCIENTIFIC WRITING

None declared.

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