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Effect of Wool Fiber Incorporation into RTV Maxillofacial Prosthetic Silicone Elastomers

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Abstract

The estimated lifespan of silicone maxillofacial prostheses under clinical use is 1.5–2 years, necessitating the fabrication of new prostheses after expiration. The most common reason for prosthesis remanufacturing is the deterioration of the mechanical properties of silicone. This study aimed to evaluate the tensile and tear resistance properties of RTV silicone used in maxillofacial prostheses after the addition of wool fibers. A specific methodology was followed in this study, which involved incorporating wool fibers (red and dark blue) as a sintering layer in VST-30 RTV silicone. Eighteen samples were equipped and splatted into two groups based on the tests performed; 40 samples per test were used. Each group was further divided equally into two subgroups: Group A (n=20), which was characterized by the absence of wool fibers (control group), and Group B (n=20), which was characterized by the presence of wool fibers. Descriptive statistical analysis was used to analyze the data and the t-test. Ultimately, a set of results was obtained. The samples containing wool fibers as filler exhibited significantly higher tear and tensile strength than those in the control group. This resulted in improved mechanical properties, specifically a substantial increase in tear and tensile strength, when wool fibers were incorporated into RTV VST-30 silicone.

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Introduction

Maxillofacial prostheses are produced and provided as an alternative treatment when surgical rectification of maxillofacial defects is unfeasible [1]. From a technical standpoint, silicone elastomers can be used extensively in most cases because they possess a distinctive set of physical, mechanical, and biological properties that effectively cover the studied field [2]. One of the most important applications of silicone elastomers is in the design of skin-like prosthetics; however, this application has several shortcomings, such as mechanical wear, discoloration, and short prosthesis lifespan [3]. The primary elements influencing the outcomes of prosthetic treatment are the characteristics of the synthetic materials selected. Mechanical characteristics can be considered the primary drivers of maxillofacial prosthesis redesign [4]. Accuracy in color, texture, translucency, and shape is the most important factor influencing the clinical success of maxillofacial prosthesis reconstruction. To actualize these findings, it is essential to incorporate color into silicone by either external or internal methods [5]. Pigments used to color prostheses can be classified as internal or external. Internal pigments, which determine the desired color and transparency, are less affected by processing and environmental conditions but are more likely to significantly influence the properties of the mixture [6]. Numerous studies have assessed the impact of internal pigments on the mechanical characteristics of prostheses, utilizing various silicone elastomers incorporated into maxillofacial surgery, including diverse hues to enhance material characteristics and durability [7,8]. To address this issue, various sizes and types of organic and inorganic filler particles have been incorporated into silicone elastomer matrices. These filler particles increase the durability of maxillofacial silicone, enabling it to withstand most normal functions and weather conditions [9]. Tear strength, tensile strength, and colorfastness are among the most important mechanical properties of prostheses; however, these properties, like others, deteriorate over time, which is why we look for a mechanism to compensate for them [10,11]. The main component of wool fiber, polyamide, can be obtained from molecules of different amino acids in a definite order (as in wool or silk). The amino acids in wool are predominantly large, whereas silk contains mainly small amino acids. Therefore, wool is considered a relatively amorphous material. Consequently, the polymer system in wool was highly amorphous, with an amorphity rate of up to 75%. When studying the structural composition of large wool macromolecules, we found that they consist of 18 amino acids arranged not randomly but in a specific, defined order. Therefore, we can conclude that the resulting polyamide is a protein called keratin. Thus, keratin is a fibrous material in wool, like cellulose in cotton. The dimensions of wool fibers vary widely. When studying the structural composition of fine wool fibers, we found that their lengths ranged from approximately 38 to 125 mm (5 to 5.5 in). The width or fineness of high-quality Merino wool fibers averages approximately 17 µm. Productively, finer wool varieties yield wool that is typically used to make thicker and softer yarns, which can be used for knitting and embroidery. Based on existing studies, it can be concluded that the effects of wool fibers, commonly used in the manufacture of maxillofacial prostheses, on the tear resistance and tensile strength of commonly used mechanical materials in this industry have not yet been examined. Therefore, the aim of this study was to develop a suitable silicone material for prostheses that mimics the appearance of natural skin and to evaluate the effect of adding wool fibers on the tear resistance and tensile strength of the flexible material RTV silicone VST-30.

Materials and Methods

The current research aimed to evaluate the tear and tensile strengths of ambient-temperature-cured VST30 silicone ("Factor II Inc., USA") under two conditions: before and after the addition of wool fibers and using two colors (red and dark blue) as sintering agents. Approximately 80 samples were prepared and divided into two groups of 40 samples each based on the tests performed. The design process involved creating custom acrylic sheets with specific dimensions of 2±0.05 mm and 4±0.05 mm in thickness, using Autodesk AutoCAD 2019 (Autodesk, San Rafael, California, USA). After the design phase, the production process commenced; a CNC machine was employed to shape the fundamental component of the mold into which the material was cast. The depth of the mold cavity for the 2±0.05 mm sheets matched the thickness of the samples to be produced for every test, while the 4±0.05 mm sheets were utilized for forming the cover and bottom [12,13]. Based on the manufacturer's guidance, the VST-30 silicone base was mixed with wool fiber (SWF) at a ratio of 10:1 for the base and catalyst. The red and blue wool fibers were first weighed using an electronic digital scale balance (10:1), and a precise weight of silicon (part A) was added to prevent fiber dispersion. The next stage of this work will consist of several phases. First, the same individual used a clean, solid metal spatula with a flat end to physically stir the combination with the base for a duration of five minutes and five seconds, allowing for a range of five seconds. Subsequently, the mixture was mixed for a duration of five minutes and five seconds, using a mechanical mixer, inside a glass beaker. A vacuum chamber was used to evacuate the mixture that was collected from the experimental groups. After that, the mixture was allowed to rise to its maximum capacity and then settle to the lowest point of the mixing beaker. To remove all air bubbles from the mixture, the vacuum was maintained for an additional 5 ± 1 min. Following the manufacturer's recommendations, the vacuum pressure was set at 28 inches Hg of mercury. The intended benefit of removing air at this stage is to reduce the time required to obtain a pore-free mixture after adding the catalyst [14]. After providing the mold with a coating of a separating substance, it was allowed to dry. In the subsequent step, the silicone mixture was cast, and the mold was secured with screws and clamps in the form of a G [13]. According to the directions provided by the manufacturer, the silicone should be kept undisturbed for a period of twenty-four hours at a temperature of 23 ± 2 °C and a relative humidity of 50% ± 10% until it has fully hardened (Figure 1).

After hardening, a silicone sheet (15 × 15 mm) was formed [15]. After hardening, when the specified time elapsed, the piece was cut after being detached from the mold (Figure 2) using appropriate cutting dies with the aid of a specially designed sample-cutting press. The press comprised a 3-ton hydraulic jack (Lezaco, Syria) mounted on metal plates; this type of cutting makes the surfaces smooth and defect-free [13]. After the cutting and completion of all the production steps, it was placed inside a vaccine preservation box (Polare Bag, China) for a minimum of sixteen hours under circumstances that were adequate for testing [16,17,18]. All manufactured and ready-to-test specimens were tested using an automated testing device (WDW-20, Laryee Technology Co., Ltd., China) with a fast-moving head at up to 500 mm/min [19]. According to ISO 37 [20]. Moving on to the strength and tensile testing stage, forty Type II dumbbell-shaped specimens were manufactured (according to ISO 2010). Twenty specimens were used as a control group to evaluate the tensile strength, while the remaining 20 were fabricated from silicone with the addition of wool fibers. Finally, the specimens were placed in a programmable testing device apparatus with a spacing of 25 ± 0.5 mm between them [19]. It was confirmed that the tensile strength test was conducted in accordance with ISO 37 (International Organization for Standardization) [20]. We arrive at the mathematical and computational expression of the applied force model, where we can calculate the ultimate tensile strength by dividing the maximum tensile strength at fracture (in Newton) by the first cross-sectional measurement of the specimen (in mm^2), according to the following equation: (Standard and ISO, 2010).

$$Tensile\ strength\ (MPa) = \frac{\text{Force recorded at break (N)}}{\text{Original cross sectional area of the sample (mm}^2\text{)}} = \frac{\text{F}}{\text{A}}$$

Based on another international standard, ASTM D624 (ISO, 2010), 40 Type C specimens were manufactured. These samples were characterized as being unlit at a right angle (90°) on one side, in addition to specimens with retractable ends [21]. The purpose of these specimens was to measure the initial tear strength. Twenty specimens served as the control group, while the remaining 20 specimens were made of silicone with added wool fibers. The specimens were placed in a computerized universal testing apparatus with a spacing of 30 ± 0.5 mm between samples [22]. Based on this program, the device calculated the tearing strength according to the following equation to calculate the maximum load:

$$Tear\ strength = \frac{\text{Maximum force required for specimen breaking,(kN)}}{Median\ thickness\ of\ specimen\ (m)} = \frac{F}{D}$$

Finally, we present the statistical analysis of the data obtained from the experiments. This was performed using SPSS version 24.0 from IBM (Chicago, Illinois, USA). Descriptive statistics were calculated using the mean and standard deviation, whereas inferential statistics were analyzed using an independent t-test (a considerable gap between the two separate $p < 0.05$). The null hypothesis tested in this study was that adding wool fibers to this type of silicone elastomer used in maxillofacial surgery does not produce significant differences in tear or tensile strength.

Results

The findings indicated that the *p*-value, being less than 0.05, led to the rejection of the initially accepted null hypothesis, rendering the acquired result statistically significant. The tear strength test results demonstrated a statistically significant difference ($p < 0.01$) between the two groups (Table 1). The group that received wool fibers when they were introduced to the silicone elastomer had a considerably higher mean value of tear strength ($p < 0.01$) compared to the control group. This was a statistically significant difference.

There was a very statistically significant difference ($p < 0.01$) between the two groups that were examined, as shown by the results of the tensile strength test, described in Table 2. The mean value of the tensile strength of the group to which wool fibers were added to the silicone elastomer was clearly higher than that of the control group, with a high level of confidence ($p \leq 0.01$).

Figure 2 shows a 30-RTV silicone elastomer with added wool fibers (red and dark blue); the red fiber indicated the artery color, and the dark blue fiber indicated the vine color at the end. These fibers were mixed with the intrinsic color of the skin, and the result appeared similar to human skin symmetry.

Discussion

Limited clinical trials have been conducted, but few have been able to evaluate the mechanical properties of silicone elastomers used in maxillofacial surgery [14,15]. This means that laboratory studies are the primary reference to be consulted when making clinical decisions regarding silicone elastomers used in maxillofacial surgery, and that these decisions should be made with reference to laboratory studies [23,24]. Manufacturers that do not use pigments, fillers, or additives report only the mechanical properties of silicone. This, in turn, does not provide a complete picture of the true clinical performance of silicone, especially when used in extra-oral prosthetics. This presents a major challenge for anaplastologists and maxillofacial prosthodontists: to carefully consider the values offered by manufacturers, which, as we have mentioned, are insufficient, especially when using any material to make prosthetic facial devices [25]. Based on the above, it is important to clarify the most clinically significant properties of silicone elastomers used in maxillofacial surgery, along with the values suggested in earlier research (tear strength 5.25-17.51 N/mm and tensile strength 6.90-13.8 MPa) [26, 27]. We come to the most important specifications and characteristics that must be achieved when manufacturing artificial facial prostheses; it can be said that the properties of tear and tension resistance are among the most important characteristics [10]. By delving deeper into this fact, it can be verified that the selection and determination of mechanical properties constitute a very important step towards modifying the existing material or adopting a new one [19]. The main objective of the research is to verify the tear strength and stretch resistance of the silicone material used in maxillofacial surgery, which can only be achieved by adding wool fibers, which have become somewhat necessary because unfilled interlocking wool fibers have very low mechanical properties [1,28]. The tests showed that adding 1% wool fibers per weight significantly increased the average tear strength value compared to that of the control group. This could be because of the characteristics of the synthetic wool, primarily known as acrylic fiber, which is a synthetic textile made from fossil fuel-based polymers (petrochemicals) designed to mimic the warmth, soft texture, and loft of natural wool. The previous addition changed the overall density and increased the polymer's resistance to tearing, as this property has led to the formation of a three-dimensional network of fibers within the polymer matrix [29]. From a statistical standpoint, and as is evident from the statistical analysis, the average value of the tensile strength test increased significantly after adding 1% wool fibers by weight, compared to the control group. This improvement is due to the formation of multifunctional crosslinks, which strengthen and stiffen the polymer by increasing its overall crosslink density after the fibers are added. To rephrase, the polydimethylsiloxane chains prevent breakage under tensile forces [30]. During the testing process, a large amount of energy was supplied to achieve the desired deformation. This phenomenon occurs because some of the energy is dissipated as heat when the polymer network is broken [31]. In contrast, a significant increase in the mean value of the tensile strength was recorded compared to that in the control group. Clinically, the most important property of silicone used in maxillofacial surgery is its tear resistance, which indicates the integrity of the thin edges and the durability of maxillofacial prostheses [32]. When analyzing the tear strength test results, a large increase in tear strength ($p > 0.01$) was observed after the addition of wool fibers (Table 1). This increase in tear strength after the addition of wool fibers may be attributed to the fibers acting as impurities that besmear the catalyst, thus reducing the degree of hardening [33]. It was also observed that the tear and tensile strength values were high because of the increased crosslinking density and conversion rate in silicone elastomers, resulting from the evaporation of the polymer component [23,33,34]. Ultimately, it is difficult to compare the extracted results directly, as the existing research in the field of manufacturing prosthetic materials for maxillofacial prosthetics has varied, which has been tested with various types of silicone elastomers that have undergone extensive evaluation, laboratory testing procedures, standards for preparing test samples, and standards used to control simulated aging conditions [1]. Accordingly, the values adopted for comparison in the study are those obtained from wool fiber samples as standard values.

Conclusion

The data from this study showed a change in the mechanical properties and a clear improvement in tear and tensile strengths when wool fibers were incorporated into RTV silicone VST-30. This study also produced a model of silicone skin containing hair, which has an appearance like that of natural human skin.

Conflict of Interest

The authors declare no conflicts of interest in this article.

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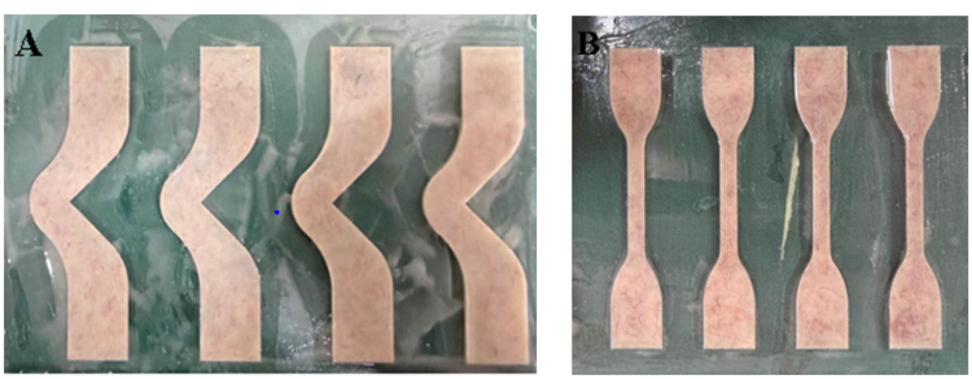

Figure 1. Sample's preparation through cutting of the silicone sheet after injection of the silicone material [A, tear specimens; B, tensile specimens].

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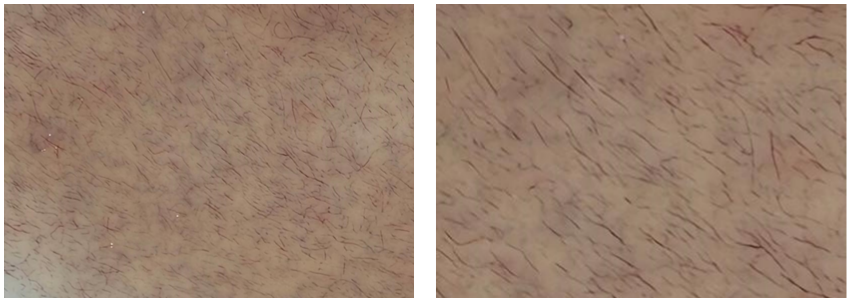

Figure 2. A 30-s RTV silicone elastomer with added wool fibers (red and dark blue) mixed with skinned intrinsic color, yielding results like human skin symmetry.

Table 1. Descriptive statistics for tear strength in kN/m.

Tear (kN/m)				
Variable	Mean	SD	t statistic (df)	*P*-value*
Control group	18.906	0.792	-4.377 (106)	< 0.01
SWWF	28.268	1.358		

*Independent *t* test

Table 2. Descriptive statistics for tensile strength test in (MPa).

Tensile strength (MPa)				
Variable	Mean	SD	t statistic (df)	*P* =-value*
Control group	30.580	0.579	-5.257 (86)	< 0.01
SWWF	31.640	0.615		

*Independent *t* test