

MECHANICAL PROPERTIES OF 3D PRINTED FACIAL PROSTHESES COMPARED TO HANDMADE SILICONE POLYMER PROSTHESES

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Abstract

Purpose: To evaluate the mechanical properties of the 3D printed starch models infiltrated with maxillofacial silicone polymers used for fabrication of maxillofacial prostheses compared to the mechanical properties of pure silicone polymer models.

Materials and methods: The test and control specimens were designed according to industry standards ASTM specifications using SolidWorks 2008 software for testing tensile strength tear strength, percentage elongation and hardness properties of starch infiltrated silicone polymer. Ten Dumbbell-shaped specimens and ten Trouser-shaped specimens with four hardness test specimens were printed by Zcorp 510 3D printer and infiltrated with Sil-25 maxillofacial silicone polymer. Whereas, control samples made from pure Sil-25 silicone polymers using a stainless steel mould and following a similar specification of test specimens. Lloyd LRX tensile instrument; load rating 100 N at a constant crosshead speed of 25 mm/min for testing tensile, tear strength and percentage elongation and Hardness Tester (England) was used to measure shore A durometer hardness.

Results: Silicone polymer infiltrated starch (test) specimens demonstrated significantly lower tensile strength, tear strength and percentage elongation than the pure silicone polymer (control) samples ($p<0.05$). However, a significant increase ($p<0.05$) in the hardness of the printed specimens was recorded against the pure silicone samples.

Conclusion: The 3D printed soft tissue prostheses – the final product showed significantly different mechanical properties compared to the handmade prostheses; they were significantly harder and reported lower mechanical properties.

Keywords: Mechanical properties, maxillofacial silicone polymer, Silicone polymer infiltrated starch, 3D colour printing, Sil-25, Z Corp Printer

Introduction

Soft tissue facial prostheses are artificial appliances used to repair facial deformities as interim or definitive substitutes. Furthermore, these appliances can support patients' social life by improving their self-esteem after restoring aesthetical and functional demands (Haug et al., 1999). Nevertheless, Periodic replacement of these prostheses requires exhaustive fabrication schedules, which burden both the patient and anaplastologist. Achieving patient's compliance and satisfaction about the prosthesis requires a highly skilled anaplastologist that is able to reproduce the patients' morphology and colour details. Although aesthetic option is the patients' prime concern and the key elements for satisfaction, however, the short service life is also considered one of the patient's chief complaints following delivery of the prosthesis (Chang et al., 2005). While in service, the prosthesis loses its elastic properties and become rigid especially at the borders, this ending up with marginal tearing following daily application and removal of a medical adhesive for retention. Therefore, the prostheses must be fabricated from highly characterised materials which possess suitable mechanical properties that enable the prosthesis to resist chemical and physical deterioration (Farah et al., 1987, Mancuso et al., 2009b, Mancuso et al., 2009a). Most of the current maxillofacial elastomers don't meet the ideal properties; however, they shown some biocompatibility and mechanical properties that keep them in service for some time. The prosthesis should have a high tear strength and a low hardness properties (Chalian and Phillips, 1974). Tensile strength indicates overall strength characteristic of the prosthesis (Waters et al., 1997). Whereas, marginal integrity of the prosthesis based on tear strength property of the material used (Aziz et al., 2003). Hardness determines the flexibility and softness of the final prostheses, Moreover, tear resistance during maintenance and overall flexibility is the

matter of percentage elongation of the applied material (Lewis and Castleberry, 1980).

The use of 3D additive manufacturing technology offers the best possibility for the automated manufacture of facial prostheses. In this project, a seamless, fully automated process was developed and utilised to produce a patient specific (geometry and colour), soft, lightweight and biocompatible soft tissue facial prosthesis (Figure 1). The project employed a 3D photogrammetry system for 3D data capture and data manipulation in a bespoke 3D CAD package for designing the prostheses and finally the manufacturing process adopted by layered printing using a Z510-3D colour printer (Zardawi et al., 2015). Zcorp printer is printing in starch, the printed models are solid but fragile; they are robust enough to be manipulated but must be handled carefully prior to infiltration. The infiltrated silicone rubber provides them with strength and elasticity.



Figure 1: Photograph of a silicone infiltrated 3D printed powdered construct used to manufacture a bespoke nasal soft tissue prosthesis. Geometry and colour data were translated throughout the CAD/CAM design and manufacturing process.

The mechanical properties of the 3D printed prostheses and the final product quality are influenced by type of powder and particle size used in printing, that are primarily bounded together by the printing binder to form a delicate shell. This shell is acting as a scaffold for the infiltrant (SP). The infiltrant is considered the main binder for the 3D printed facial prosthesis; moreover it renders soft and flexible models.

The aim of this study was to evaluate the mechanical properties of the starch printed models infiltrated with maxillofacial silicone polymer (SPIS), and compare them to the existing maxillofacial materials used (SP).

Materials and Methods

Silicone Infiltrated Starch Specimens

Test specimens were designed using SolidWorks 2008 software and then printed by the Z-Corp printer. The test specimens were printed in starch and allowed a 24 hours post printing “dry” and then infiltrated with Sil-25 maxillofacial SP under 3 bar pressure in a pressure vessel for 25 min in order to achieve total infiltration (Zardawi et al., 2015). The specimens were left for 24 hours in order to achieve complete set before performing the mechanical tests.

Test designs and measurements

The test specimens were designed according to industry standards and set out to evaluate key mechanical properties.

Tensile strength

Ten dumbbell shaped specimens were produced for testing tensile strength and percentage of elongation in accordance with ASTM-D412/ISO (ASTM-D412, 1981), (Figure 2A). Tensile strength testing was conducted using a Lloyd LRX tensile instrument; load rating 100 N at a constant crosshead speed of 25 mm/min (Figure 3-A). The tensile strength was calculated using the following equation: $\sigma_f = F/A$, where: σ_f = tensile strength (MPa), F = force at failure (N) and A = original cross-sectional area (mm^2).

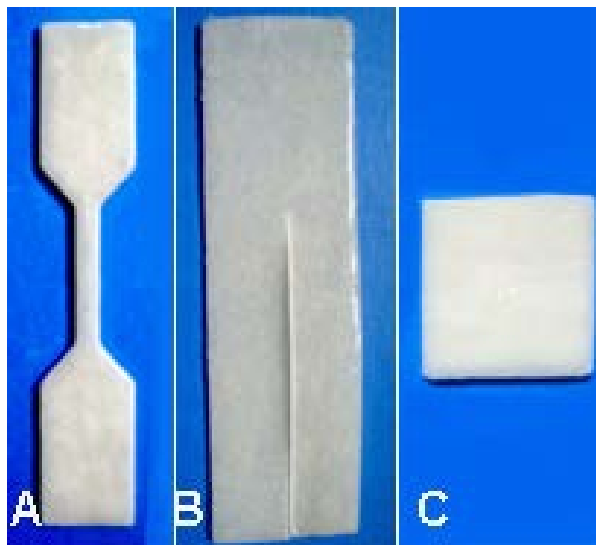


Figure 2: Mechanical properties test specimens, starch infiltrated silicone polymers (SPIS), A- Dumbbell-shaped specimens ASTM-D412/ISO34, B- Trouser-shaped specimens ASTM-D624-07/ISO34 and C- Hardness test specimens ASTM-D1415-06/ISO48

Tear strength

Ten test specimens, in accordance with ASTM D624-07/ISO34 (trouser leg) ^(ASTM-D624, 1981) for testing tear strength, were fabricated for this test (Figure 2B). Tear strength was conducted using a Lloyd tensile tester (Figure 3B) and calculated by the following equation: $T=F/D$, Where: T is tear strength (N/mm), F is the force required to break the specimen (N) and D is thickness of the specimen (mm).

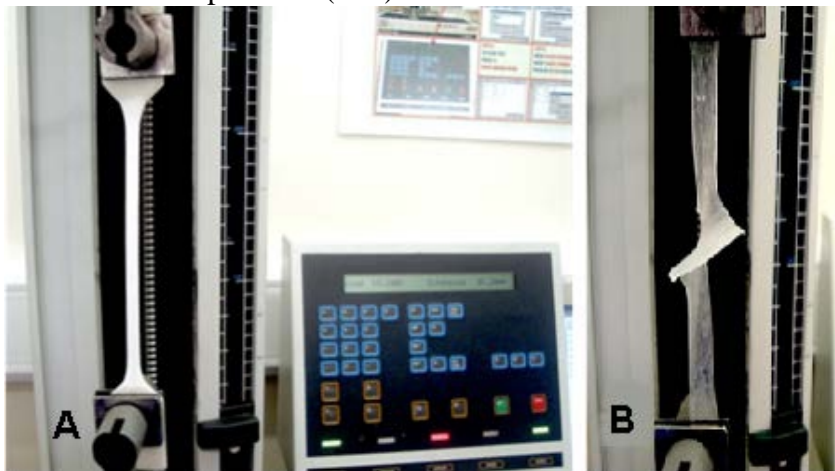


Figure 3: Lloyd LRX tensile instrument used for testing, (A) tensile strength on dumbbell shaped specimens, (B) tear strength on trouser leg specimens

Percentage elongation

Elongation prior to failure was performed at the time of measuring tensile strength. Ultimate elongation was calculated using the following equations:

% Elongation = $100 \times (L - L_0) / L_0$: where: L represents extension at break and L_0 represents the original length.

Hardness

Test specimens, in accordance with ASTM D1415-06 ISO48 (solid blocks) for testing Shore A Durometer hardness, were produced. Four specimens were fabricated for this purpose (Figure 2C) and the hardness test carried out using a Shore Scale Durometer, Hardness Tester (England), with 6 mm measurement course, 6 mm distance between the measurements and keeping 6 mm away from the border. 12 measurements were undertaken on each block, a total of 48 measurements were collected for hardness test.

Silicone/Control Specimens

Control specimens were produced from pure SP (Sil-25) In order to provide a comparison. The control samples were manufactured to the exact

dimensions as the test samples using custom made stainless steel moulds (Figure 5A). These were designed according to ASTM specifications and were made specifically for this study. Ten dumbbell shaped specimens were fabricated for testing tensile strength and percentage elongation, 10 trouser leg tear strength specimens and 4 hardness specimens were fabricated by mixing the two 2 components of the SP, Sil-25 (10:1) for one minute – as per the manufacturer’s instructions. The mix was then poured into the stainless steel mould, pressed and left under pressure at room temperature for 24 hours (Figure 5B).

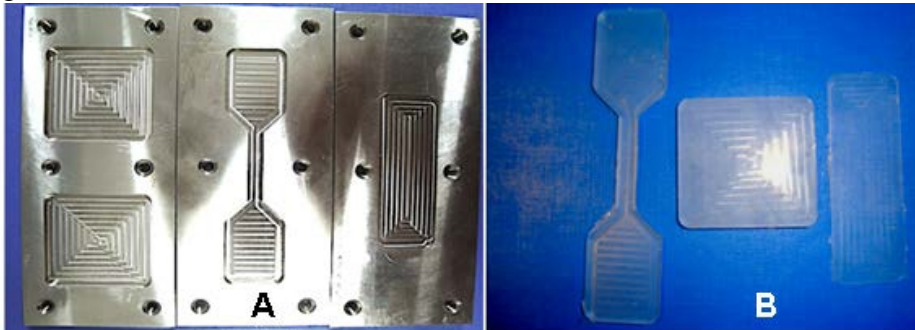


Figure 4: Control specimens (SP) and mould, A- Stainless steel moulds designed according to ASTM specifications for production of tensile, tear, hardness and percentage elongation test, B- SP (Sil-25) specimens for tensile, tear, hardness and elongation testing.

Statistical Analysis

The entire resultant data was collected and subjected to PASW statistics 18 in order to make the comparison between the test group (SPIS) and the control group pure (SP). Independent sample T test was employed for the analysis.

Results

Table 1 shows average and standard deviation values of different mechanical properties (Tensile strength, tear strength, hardness and percentage elongation) and their measurement units for the control (SP) and printed (SPIS) specimens. As the table reveals and following testing the SPIS specimens, results demonstrated significantly lower tensile strength and tear strength and percentage elongation than the pure SP test samples ($p < 0.05$). The average tensile strength reduced from 3.5 ± 0.3 MPa for SP specimens to 1.2 ± 0.2 MPa for SPIS samples. Tear strength also recorded a significant reduction with SPIS samples from 12.2 ± 1.5 N/mm for the SP specimens to 8.5 ± 1.1 N/mm for the SPIS printed samples. Subsequently percentage elongation had also recorded a significant reduction for SPIS specimens from $(511 \pm 57.5\%)$ to $(244 \pm 36.1\%)$ respectively. However, a significant increase ($p < 0.05$) in the hardness of the printed specimens SPIS was

recorded against the pure silicone samples SP this was demonstrated by increasing the Shore (Durometer) hardness A from (30.9 ± 0.7) to (62.8 ± 2.8) respectively (Table 1).

Table 1: Average, standard deviation and standard error mean values for different mechanical properties tests and their measurement units for the control (SP) and printed (SPIS) specimens.

Mechanical test	Group	Measurement unit	Sample No.	Value	Std Dev	Std Error Mean
Tensile	SP	MPa	10	3.48*	0.36	0.11
	SPIS	MPa	10	1.24	0.20	0.06
Tear	SP	N/mm	10	12.22*	1.47	0.47
	SPIS	N/mm	10	8.47	1.10	0.35
Elongation	SP	%	10	511.50*	18.1	18.19
	SPIS	%	10	244.1	36.14	11.42
Hardness	SP	Shore A	4 [‡]	30.90*	0.71	0.10
	SPIS	Shore A	4 [‡]	62.73	2.80	0.41

*P Value was significant at $P < .05$

[‡]Four samples – total 48 measurements

Discussion

In the present study, assessment of the mechanical properties of the printed specimens performed by testing tensile strength, tear strength, hardness and percentage of elongation according to ASTM standards. The specimens infiltrated with Sil-25 maxillofacial silicone polymer which is a traditionally used material for fabrication of facial prosthesis. There are no technical problems could be expected in the methodology applied since these standards were followed. However, it could be argued that there was some reservation about the elongation percentage appraisal as this was measured from the extension of the tensile machine at the time of measuring tensile strength rather than an extensometer, which may not present a fully accurate measurement of extension. During the measurement some of the materials may pull out of the grips and this may lead to disproportion degree of extension and not the true extension.

The current study also aimed to follow previous works in terms of selection of the properties measured, which would provide good characterisation of the materials evaluated and how these properties would be compared with the measurements undertaken by other researches (Polyzois et al., 2000, Eleni et al., 2009, Hatamleh and Watts, 2010, Li et al., 2007).

Discrepancy in the results of the mechanical data was obvious between the test samples SPIS and control samples SP, which is most probably be due to the large amount of starch that is used by Zprinter to produce the shell models. Starch powder constitutes up to 40% of the total

weight of the SPIS samples (Zardawi et al., 2015). Inevitably the presence of a filler material is going to affect the properties of the samples produced. However, these changes may be irrelevant – or may even be an advantage. As detailed, the presence of filler tended to increase the hardness of the samples whilst reduce the tensile and tear strength. The SP is extremely hydrophobic with very low surface energy (Waters et al., 1999), while starch is extremely hydrophilic, this leads to lack of integration between the starch particles and the SP, in other word the starch within the samples can be consider as a potential space inside the silicone rubber which weaken the final product (Jayasekara et al., 2004). Thus, it was expected that this would lower the values of the mechanical data especially tear strength, tensile strength and elongation of the test printed (SPIS) samples compared to control (SP) samples. It was also expected that there would be an increase in the (Shore A) hardness due to the mount of starch within the printed parts.

These characteristics may, in part, be dictated by the material used. We know the SPs are not “ideal”, but are the best available at present. In this study we used SP as an infiltrant because it is the material always used for producing soft tissue facial prostheses, moreover we considered it a control group for comparison purposes despite not being the ideal material, and thereby the material we used could have characteristics are potentially more favourable - the mechanical properties of the printed samples could be entirely adequate or in some respects better when compared to traditional SP.

In these investigations hardness test values increased and the samples had lost some flexibility in the SPIS (printed) when compared to pure SP (control group). However, hardness itself is not the only determination criteria for the “overall” toughness of the printed parts; the design can also influence the flexibility of the prostheses. In this project we utilised CAD/CAM principles to design and manufacture soft tissue facial prostheses. Unlike the handmade prostheses, CAD allows the production of shell prostheses which are lighter and more flexible than those produced by hand (Ciocca et al., 2010) (Figure 5B). Due to technical limitations, the maxillofacial technicians are not always able to produce shell prostheses. Therefore, despite the higher values of (Shore A) hardness for the SPIS samples compared to the pure SP samples, the prostheses produced by applying CAD/CAM technology can be more flexible than the handmade SP prostheses.

Tear strength values for the printed samples reduced after infiltration with SP about 30%. However, this is not a critical problem since the 3D printed prostheses in this project were designed to be infiltrated with silicone rubber which would extend to the peripheries to achieve a feathered edged prosthesis in order to blend the margin of the prosthesis with the patient’s natural skin tissues (Figure 5A). Tears usually start at the flange which is

finished with pure silicone rubber and the prosthesis is going to tear there during cleaning and removal of the adhesive from the margin. Therefore, as with a traditional prosthesis a tear will start in the silicone rubber at the periphery and not in the starch itself. It may well become an issue when the feathered edge has torn through the silicone into the starch, but it could be argued that by that stage the prosthesis should be replaced anyway. Hence, the reduction in tear strength is not a critical point especially with implant retained prostheses when no adhesive is required for retention.

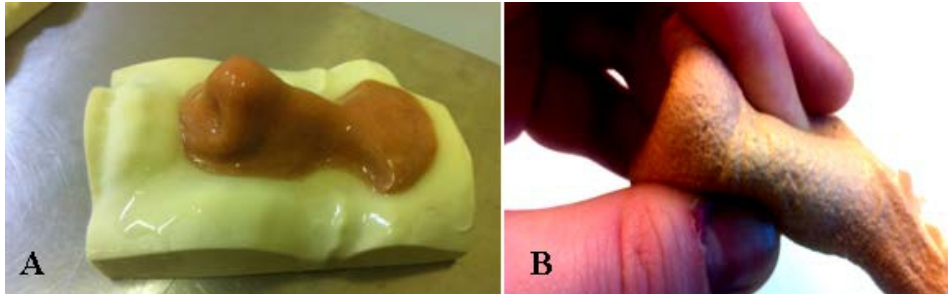


Figure 5: A- A 3D printed Nasal prosthesis designed to be infiltrated with silicone rubber which would extend to the peripheries to achieve a feathered edged prosthesis in order to blend the margin of the prosthesis with the patient's natural skin tissues, B- Nasal Prosthesis produced using CAD/CAM principles to design and manufacture a prosthesis that allows the production of shell prosthesis which is lighter and more flexible than handmade prosthesis. The drawback in tensile strength and percentage of elongation values will not be a critical problem if the patient looked after his/her prosthesis properly. It would be dependent on how the patient follows the instructions of maintenance and how to take care of the prosthesis in order to optimise service life. Indeed the patient may not have to stretch the prosthesis for maintenance purposes and during placement and removal. As a matter of fact very high tear strength is not required for facial soft tissue prostheses unless the patient manipulates the prosthesis harshly. Our results of mechanical properties were found to be significantly different from the control samples. This does not necessarily mean that the present material would be worse or better. Indeed we really don't know because it is yet not clear what the optimal properties are for making facial prostheses. The ideal properties have not been standardised yet in terms of the mechanical properties. Therefore, there is nothing to suggest that these prostheses shouldn't last as long as the existing handmade silicone prostheses. Moreover, the natural feel and handing characteristics of the new material appear as good as if not better as the existing silicone rubber prostheses. Although it is acknowledged that this is a subjective evaluation.

Conclusion

SPIS specimens showed significantly different mechanical properties to those made of pure SP. There is a significant increase in Shore (A) hardness, but a significant decrease in tensile strength, tear strength and percentage elongation. However the recorded mechanical data for the printed models - starch infiltrated silicone polymer is sufficient for interim prostheses.

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