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EXPERIMENTAL ASSESMENT OF THE MECHANICAL BEHAVIOR OF IMPRESSION MATERIAL FOR ANAESTHESIOLOGY USE: A PRELIMINARY STUDY

Thomková B.[*], Hrubanová A.[**], Košková O.[***], Richtrová M.[†], Skácel P.[††], Štourač P.[†††], Marcián P.[‡]

Abstract: *This study examines a silicone material designed for a high precision impressions. We explore the possibility of using this material for creation of patient specific obturator for soft tissue protection of upper jaw while intubating neonatal patients with cleft palate. The biaxial tensile tests were performed to examine the material properties of the selected silicon material. Specimen were compressed in 2-part mold made by 3D printing technology. The preliminary results suggest isotropic properties (p-value 0.198), showing no statistically significant differences between measured directions. The study also suggests potential viscoelastic behavior since the slowest deformation speed showed slightly different behavior compared to the higher strain rate. However, this is just a preliminary study thus, to strengthen the study's reliability, further validation on larger datasets is recommended.*

Keywords: Cleft, silicone material, biaxial tensile test, stiffness.

1. Introduction

Neonatal patients with a cleft palate are operated on as soon as possible after birth to ensure not only an airway but also a better intake of food. However, performing intubation in such young patients is often challenging due to the danger of damaging the patients soft tissue of upper jaw. A protective obturator made of silicone material can be used for these intubations (Richtrová et al., 2023). The aim of this study is to examine the mechanical behavior of the selected silicone material. To do so, series of biaxial tensile tests were performed to explore the isotropic and viscoelastic nature of this material.

[*] Ing. Barbora Thomková: Institute of Solid Mechanics, Mechatronics and Biomechanics, Faculty of Mechanical Engineering, Brno University of Technology, Technická 2896/2, 616 69 Brno, Czech Republic; CZ, barbora.thomkova@vutbr.cz

[**] Ing. Anna Hrubanová: Institute of Solid Mechanics, Mechatronics and Biomechanics, Faculty of Mechanical Engineering, Brno University of Technology, Technická 2896/2, 616 69 Brno, Czech Republic; CZ, anna.hrubanova@vutbr.cz

[***] MUDr. Olga Košková, PhD.: Department of Burns and Plastic Surgery, Faculty of Medicine, Masaryk University, Jihlavská 340/20, 625 00 Brno, Czech Republic; CZ, koskova.olga@fnbrno.cz

[†] MUDr. Michaela Richtrová: Department of Paediatric Anaesthesiology and Intensive Care Medicine, Masaryk University, Černopolní 212/9, 662 63 Brno, Czech Republic; CZ, 60032@mail.muni.cz

[††] Ing. Pavel Skácel, PhD: Institute of Solid Mechanics, Mechatronics and Biomechanics, Faculty of Mechanical Engineering, Brno University of Technology, Technická 2896/2, 616 69 Brno, Czech Republic; CZ, skacel@fme.vutbr.cz

[†††] Prof. MUDr. Petr Štourač, PhD., MBA, FESAIC: Department of Paediatric Anaesthesiology and Intensive Care Medicine, Masaryk University, Černopolní 212/9, 662 63 Brno, Czech Republic; CZ, stourac@med.muni.cz

[‡] Ing. Petr Marcián, PhD.: Institute of Solid Mechanics, Mechatronics and Biomechanics, Faculty of Mechanical Engineering, Brno University of Technology, Technická 2896/2, 616 69 Brno, Czech Republic; CZ, marcian@fme.vutbr.cz

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2. Methods

2.1. Specimen preparation

The study tested Zhermack Elite HD+ putty, a two-component silicone material used for orthodontic purposes. The mixed material (ratio 1:1), was inserted into a mold and cured for 3.5 minutes.

The mold (Fig. 1a) for sample preparation was created using additive 3D printing technology (Prusa i3 MK3S+) with polylactic acid (PLA). The mold, featuring an outlet channel for excess material removal, maintained its stiffness during sample production without deformation. Each specimen, sliced to 18 × 18 mm after molding (Fig. 1b), was labeled with black markers for deformation tracking (Fischer et al., 2023). Eight marks on each specimen's sides ensured consistent clamp spacing across all tests (Fig. 1c). In total, 24 specimens were prepared for the study. Note that 4 specimens had to be excluded from the analysis because a pre-existing defect in the specimen prior to testing or because the initial damage during the clamping process.

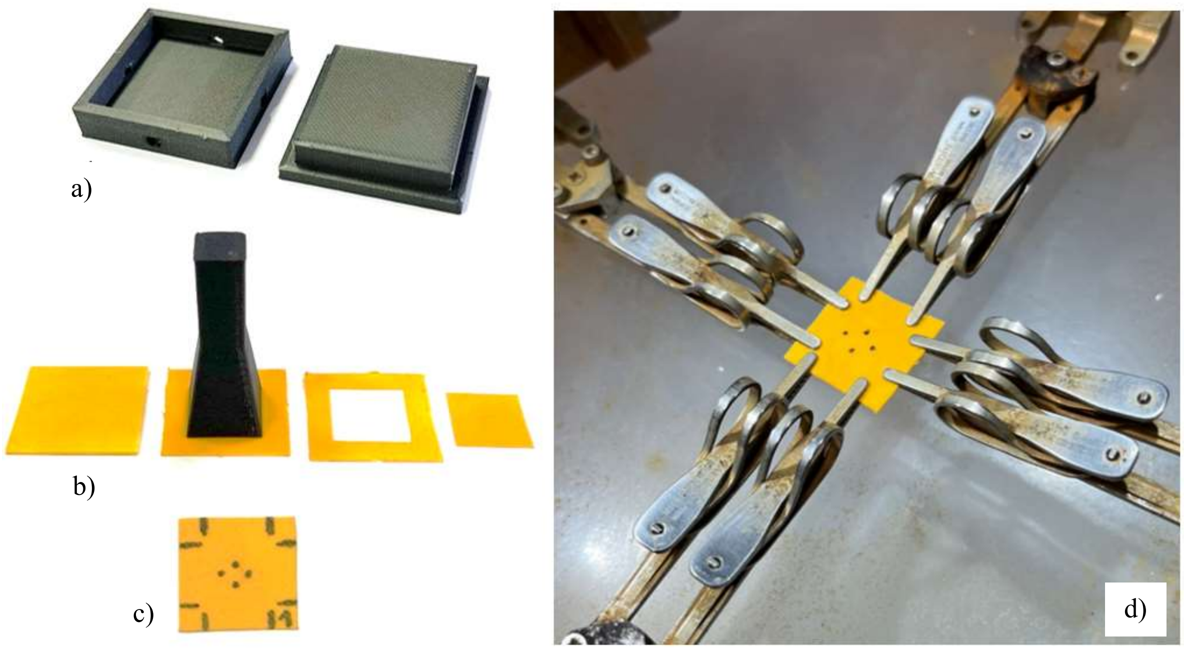

Fig. 1: a) 3D printed mold; b) the process of cutting the final 18 x 18 mm specimen; c) final specimen used for testing with markers for deformation evaluation (center) and markers for clamp spacing (outer boundary); d) the specimen mounted in the biaxial tensile device ready for the testing.

2.2. Testing and evaluation

All mechanical tests were performed on a testing device (Camea, s.r.o., CZ). The device consists of 2 perpendicular axes with linear-stepped motors realizing the mechanical displacement of clamps. In case of biaxial testing, two motors are used, and the specimen is attached by eight spring clamps (Fig. 1d) with serrations preventing the slipping of specimen during testing. The forces are measured by load cells with nominal capacity of 20 N mounted on both actuator axes providing the controlled displacement. The area of the specimen is captured by CCD camera (sampling frequency of 8–33 Hz) with 0.02 mm/pixel resolution mounted perpendicularly to the testing area. To ensure high contrast images, the measured area is illuminated by two external lights. The sample clamped in the testing device is shown in Fig. 1d. The sample thickness was measured by dial indicator (MarCator 1075, produced by Mahr, Germany, accuracy 0.01 mm, pin diameter 4.1 mm) at 5 locations of each specimen; the mean value is used for further analysis. After clamping a pre-tension of 0.1 N was applied to each specimen to ensure its flatness (Lisický, 2021). The testing is displacement controlled; three different displacement speeds of 0.167; 0.33 and 0.667 mm/s (8 specimen per speed) were employed to explore the potential viscoelastic behavior of the material.

The evaluations of the testing area are done in software Tibixus (Turčanová et al., 2023) from the images captured by CCD camera. The first captured image is taken as a reference and the deformation is determined by digital image correlation (DIC) techniques, tracking the relative position of the contrast markers on specimen marked on it prior to testing, and calculating the corresponding strain values. The first Piola-Kirchhoff stress is calculated as follows:

$$\sigma = \frac{F_{exp}}{b\,T}, \tag{1}$$

where F_{exp} is the force measured by the load cell, b and T are the measured initial (undeformed) dimensions of the specimen (width and mean thickness, respectively).

The initial parts of the obtained stress-strain curves were cut off - due to experimental errors at extremely low stresses/strains (caused by 3D effects from clamping, specimen planarity imperfections, parasitic effects of gravity, etc.) Thus, only the rest of the stress-strain curves with stabilized progression are considered and fitted by first order polynomial function; the slope represents the given initial stiffness.

3. Results

The resulting stiffnesses of 20 specimens in x and y direction are summarized in Tab. 1:

Def. speed [mm/s]	**S_x [MPa]**	**S_y [MPa]**	**Def. speed [mm/s]**	**S_x [MPa]**	**S_y [MPa]**	**Def. speed [mm/s]**	**S_x [MPa]**	**S_y [MPa]**
0.167	11.249	10.690	0.333	19.427	10.604	0.667	15.653	15.441
0.167	11.395	12.285	0.333	15.674	8.5102	0.667	10.748	10.434
0.167	11.944	9.822	0.333	10.301	13.616	0.667	11.176	19.383
0.167	12.538	10.086	0.333	17.680	14.635	0.667	17.560	14.614
0.167	9.343	10.065	0.333	22.703	11.990	0.667	11.330	9.5393
0.167	21.285	10.133	0.333	16.648	14.837	0.667	13.304	18.771
Median (Q1;Q3)	11.67 (10.77;14.72)	10.11 (10.00;11.09)	0.333	19.536	19.390	0.667	7.380	11.541
			Mean ± SD	17.42 ± 3.89	13.37 ± 3.49	**Mean ± SD**	12.45 ± 3.38	14.25 ± 3.92

Tab. 1: The stiffness in both measured direction with given deformation speed used during equibiaxial testing.

The subsequent statistical analysis was performed using software Minitab 15; statistical significance assumed if $p < 0.05$. The stiffnesses were compared for x and y direction for entirety of 20 specimens by Wilcoxon signed rank test since the normality of distribution was not confirmed for all datasets (Anderson Darling test). Then, the same comparison was made for distinctive deformation speeds to eliminate the potential influence of viscoelastic effects. The resulting p-values are summarized in Tab. 2.

Statistical test	**All**	**0.167 mm/s**	**0.333 mm/s**	**0.667 mm/s**
Wilcoxon signed rank test	0.198	0.295	0.108	0.554

Tab. 2: The p-values for statistical analysis comparing the stiffness in X and Y direction for all specimens and for the three distinctive deformation speeds.

Based on the statistical significance levels, as indicated by the p-values presented, an evidenced deduction affirming the isotropic nature of the material can be drawn. Subsequently, the stiffnesses for three deformation speeds can be compared to determine the possible viscoelastic behavior. Analogously, Anderson-Darling test was performed, the normality of data was not confirmed for all datasets thus the Mann-Whitney test was used. The p-values are displayed in Tab. 3.

Statistical test	**0.167 vs 0.333 mm/s**	**0.167 vs 0.667 mm/s**	**0.333 vs 0.667 mm/s**
Mann-Whitney	0.019	0.190	0.161

Tab. 3: The stiffness in both measured direction with given deformation speed used during equibiaxial testing.

These results show that there is a significant difference between the 0.167 and 0.333 mm/s deformation speeds indicating possible viscoelastic behavior.

4. Discussion

The study results reveal no statistically significant differences between the two measured directions, confirming material isotropy. However, limitations must be acknowledged. The thinness of specimens (approximately 0.25 mm) ensured biaxial strain conditions but led to premature fractures during clamping, restricting maximal strain to no more than approx. 6 % for most specimens. Consequently, the dataset primarily captures the initial stress-strain curve, presenting challenges in strain evaluation due to reference zero strain determination and clamp micro adjustments.

Moreover, the dataset size is insufficient for robust statistical analysis, particularly for nonparametric tests. Data at 0.167 mm/s deformation rate did not meet normal distribution criteria, possibly influenced by clamp-induced damage during the longer test duration. Further statistical analysis indicated significant differences in low deformation, suggesting potential viscoelastic behavior. All conclusions drawn should be validated on larger datasets.

Despite being a preliminary study, it supports the assumption of isotropic behavior and highlights potential viscoelastic effects.

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