Mechanical Properties of 3D Printed Resorbable Material for Manufacturing of Vascular Replacements

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Abstract: Modern additive manufacturing methods offer the ability to achieve high geometric complexity, allowing for the production of tubular implants with intricate anatomical details that were previously unattainable. Specifically, the manufacturing process enables the accurate fabrication of structures such as the aortic arch and its branches, which display significant inter-individual geometric variability. In this study, the mechanical properties of a 3D-printed material composed of polylactic acid (PLA) and polyhydroxybutyrate (PHB) were investigated. This material holds the potential for additive manufacturing of such implants. The results of uniaxial tensile tests conducted on PLA-PHB are compared with the mechanical behavior of GORE tubes, currently utilized as vascular grafts in clinical practice. Our findings reveal that, within the range of linear elasticity, the mechanical response of PLA-PHB strips closely resembles that of circumferentially cut GORE-TEX vascular graft strips. Conversely, longitudinally oriented GORE-TEX strips exhibit greater compliance compared to the 3D-printed PLA-PHB material.

Keywords: Additive manufacturing; Bioresorbable material; Elasticity; PLA-PHB; Uniaxial tensile test; Vascular graft

1 Introduction

Bioengineering focused on tissue engineering and tissue replacements development is an emerging field providing innovations in medical technology. Bioengineering uses multidisciplinary concepts of materials science and life sciences that together lead to the development of regenerative treatments and replacements, thereby improving the function of tissues damaged by injury, disease or congenital disorders [1]. In the field of 3D printing and bioprinting of tissue substitutes, materials science focuses on obtaining compatible materials suitable for the fabrication of so-called scaffolds, which are structures whose properties at the macroscopic and microscopic level promote the formation of new tissue and colonization by recipient cells [2]. Natural and synthetic polymers most commonly used for vascular grafts and vascular replacement include collagen, silk, gelatin, expanded polytetrafluoroethylene (ePTFE), polylactic acid (PLA), poly(-caprolactone) (PCL), polyurethane (PU), polyethylene terephthalate (PET), poly(glycolic acid) (PGA), and GORE materials [3-5].

Modern additive manufacturing methods have revolutionized the production of tubular implants by enabling the fabrication of complex geometries that mimic anatomical details [6]. This breakthrough opens up possibilities for the creation of custom-made urethras, esophagi, and blood vessels [6-8]. A notable application is the development of vascular

replacements that can accurately replicate intricate structures such as the aortic arch, which includes the brachiocephalic trunk, the left common carotid artery, and the left subclavian artery [8].

The focus of our research is the advancement of 3D printing techniques for vascular replacements. In this the feasibility study, which follows [9,10], the use of a biodegradable printed material composed of polylactic acid (PLA) and polyhydroxybutyrate (PHB) was investigated.

2 Material and methods

Rectangular strips of PLA-PHB were fabricated using 3D printing technology. Preprocessing of the printing process was carried out in Simplify 3D software (Simplify 3D, USA). The filament used for printing was developed in-house and prepared using the Maker Composer 450 series (3devo, Netherlands). Before the actual filament production, the apparatus was cleaned with HDPE cleaning material at 180 °C. The cleaning was followed by extrusion of PLA/PHB + TAC 25% material. The filament composition consisted of 85% PLA and 15% PHB by weight. To enhance the material's properties, 25% TAC (Tricytyl 2-Acetyl Citrate) was incorporated into the final PLA-PHB blend as a plasticizer. Fig. 1 shows the design and dimensional characteristics of the rectangular samples fabricated using Fused Deposition Modeling (FDM) technology, utilizing the DeltiQ2 printer (Trilab, Czech Republic). The temperature of the extruder was 175°C, the speed of the extrusion was 30 mm/s, and the cooling of the extruded melt was 60% (temperature of the substrate was 90°C). The entire sample preparation process was conducted at the Department of Biomedical Engineering and Measurement, Faculty of Mechanical Engineering, Technical University of Košice.

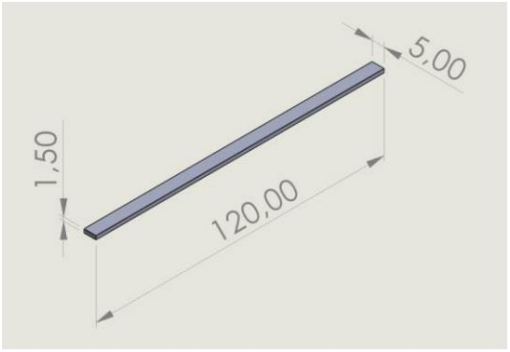

Fig. 1 Design and dimensional characteristics of rectangular samples for mechanical testing.

There is an EN ISO 7198 standard for the marketing of vascular substitutes. This specifies the tests to be carried out on a sample of tubular vascular substitutes. However, our study is at a point where we are still in the process of testing the suitability of PLA-PHB material. For such a stage of development, it is more appropriate to use conventional uniaxial tensile tests to show how the PLA-PHB material actually behaves when compared to a material that has already met EN .ISO 7198.

Cyclic uniaxial tensile tests were conducted at the Department of Mechanics, Biomechanics, and Mechatronics, Faculty of Mechanical Engineering, Czech Technical University in Prague. A Zwick/Roell universal testing machine (Zwick/Roell, Germany), see Fig. 2, specifically designed for testing soft tissues (blood vessels) and polymeric materials, was employed. The testing machine featured electromechanical actuators with a working load

range of -200 to 200 N in compression-tension mode. HBM U9C +/- 25N load cells were used in our experiments. The machine offered a displacement range of 0 to 140 mm, with a position resolution of 1 μm. Deformation of the specimens was measured using a built-in video extensometer equipped with a 5 Mpx uEye 3.0 CMOS camera. The applied loading rate was set at 0.2 mm/s. The specimens underwent preconditioning through 6 loading cycles, reaching up to 7 N and then returning to 0 N (not necessarily back to the initial length). All data were recorded on a control PC at a sampling rate of 20 Hz for subsequent post-processing.

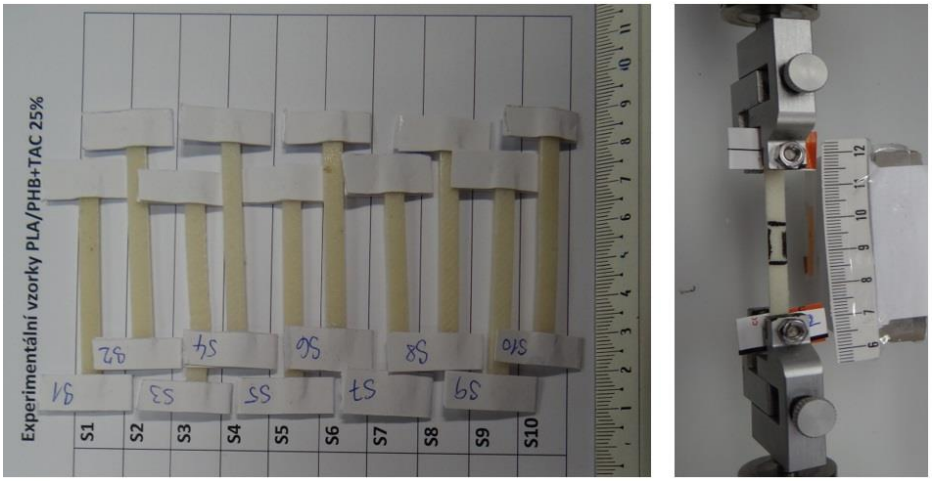

Fig. 2 Rectangular samples of PLA-PHB prior to the tensile testing (left panel) and the sample mounted in the testing machine (right panel).

The mechanical response of the tested specimens was described using the nominal stress $\sigma = F/S_0$, where F represented the recorded loading force, and S_0 denoted the reference cross-sectional area of the specimens. Deformation was quantified as the engineering strain $\varepsilon = l/L - 1$, where L referred to the distance between marks made on the specimen's surface prior to the test, and l represented this distance in the deformed state. The initial Young's modulus E_{ini} was determined by performing linear regression on the recorded responses within the small deformation (linear) regime ($\varepsilon < 0.01$).

In addition to the PLA-PHB strips, mechanical tests were also conducted on commercially available samples of GORE-TEX material. Longitudinal and circumferential strips were prepared from a vascular substitute marketed under the brand name SA1802 (W. L. Gore & Associates, Inc., USA) and subjected to the same uniaxial tensile tests as the PLA-PHB strips.

3 Results and discussion

The stress-strain relationships obtained from the experiments are depicted in Fig. 3 and Fig. 4. Fig. 3 illustrates the responses of PLA-PHB and GORE-TEX materials during the first cycle of loading, while the preconditioned response of the GORE material (6th cycle of loading) is presented in Fig. 4. It was observed that the preconditioned response of PLA-PHB exhibited negligible differences compared to the primary response, hence only the primary response is shown in both figures. However, this was not the case for the GORE material. Its response indicated saturation of hereditary effects, and the response during the 6th cycle was deemed repeatable.

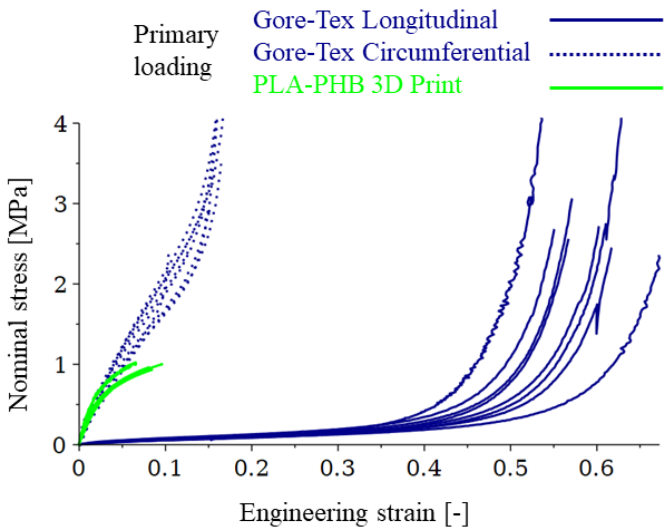

Fig. 3 Stress-strain relationships determined in uniaxial tensile tests for the pristine PLA-PHB and GORE-TEX materials.

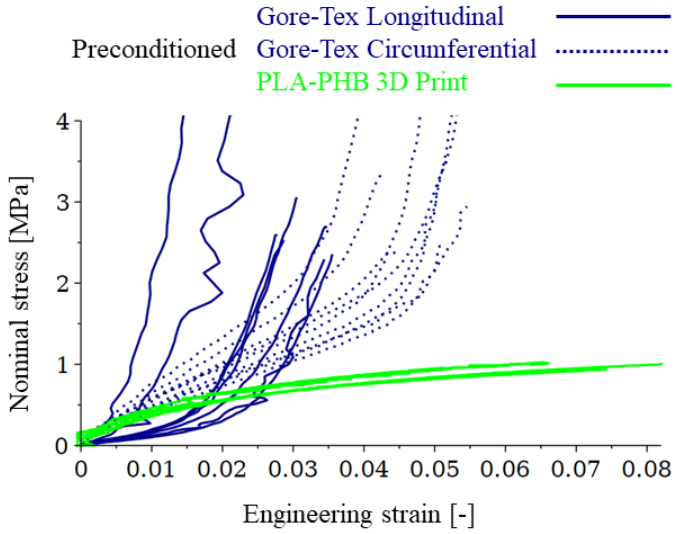

Fig. 4 Stress-strain relationships determined in uniaxial tensile tests for the preconditioned (6th loading cycle) PLA-PHB and GORE-TEX materials.

In contrast to PLA-PHB, where all rectangular samples were obtained from the same printing plane, GORE samples were cut from the tube in two different orientations, leading to anisotropic behaviour. Fig. 3 and Fig. 4 illustrate the stress-strain responses of GORE material in longitudinal and circumferential orientations. It is evident that longitudinal strips of GORE material exhibit significantly higher initial compliance compared to circumferential strips, regardless of the loading history.

The most significant observation from our study is that within the linear regime (small deformations with $\varepsilon < 0.01$), the mechanical response of circumferentially oriented GORE strips closely resembles that of PLA-PHB. The mean initial Young's modulus obtained for PLA-PHB samples was E_{ini} = 39.04 MPa (± 8.27 MPa SD). In comparison, GORE strips

exhibited E_{ini} values of 1.49 MPa (± 0.339 MPa), 30.1 MPa (± 5.84 MPa), 41.7 MPa (± 61.0 MPa), and 54.9 MPa (± 10.4 MPa) for the 1st cycle in the longitudinal and circumferential directions, and for the 6th cycle in the longitudinal and circumferential directions, respectively. These results suggest that although there are noticeable differences in the perceived compliance when handling the materials (GORE appearing more compliant), objective measurements indicate that this difference is not significant in the small deformation range. Fig. 5 provides a detailed comparison of the mechanical properties between the two materials through a box plot representation.

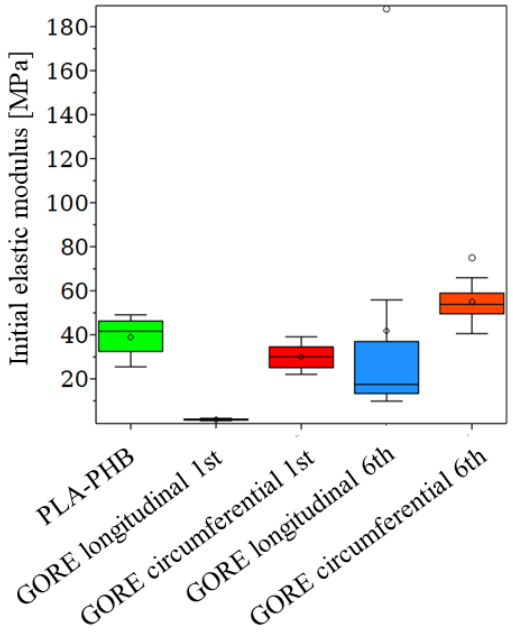

Fig. 5 Box plot comparing the obtained values of the initial Young's modulus of elasticity for PLA-PHB and GORE-TEX materials.

Conclusion

Our study focused on comparing the mechanical properties of PLA-PHB material, which is easily applicable in current 3D-printing methods, and GORE-TEX material used for vascular replacements. Using uniaxial tensile testing, the response of GORE-TEX was found to be significantly non-linear, anisotropic and dependent on the deformation history. This behaviour of GORE-TEX can be attributed to its elastomeric nature, where gradually straightening molecular chains are responsible for its large strain stiffening.

On the other hand, the observed behaviour of PLA-PHB was consistent with the response known for thermoplastics and was not highly dependent on loading history in the small strain regime. Although GORE-TEX is more compliant than PLA-PHB in a certain strain range, in the range of validity of the linear approximation (small strains), the differences between PLA-PHB and GORE were not significant. As GORE-TEX is an established mateiral in the field of vascular replacements, this comparison suggests that a vascular replacement could be developed using PLA-PHB with mechanical properties that match the physiological conditions of blood vessels. However, it is of course clear that further research is needed to

verify the long-term mechanical behaviour, biocompatibility, and other properties of the PLA-PHB material to comprehensively evaluate its suitability.

Acknowledgements

We would like to acknowledge the support provided by the Czech Ministry of Education, Youth and Sport in the project LUASK22174 "Bioresorbable materials for additive manufacturing of vascular replacements and their biomechanical characterization." Additionally, we are grateful for the support received from the Slovak Research and Development Agency in the project SK-CZ-RD-21-0056 "Bioresorbable materials for additive manufacturing of vessel substituents and their biomechanical characterization."

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