#25785 CUSTOMIZED 3D-PRINTED THERMOPLASTIC POLYURETHANE ELASTIC MESHES FOR PELVIC FLOOR RECONSTRUCTION

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Hypothesis / aims of study

In pelvic floor surgery, mostly non-degradable, synthetic materials are used. To date, polypropylene meshes are the most frequently used material, characterized by "monofilament, macropore, and lightweight" mesh properties. The pelvic floor is a dynamic region of the body; therefore, the ideal mesh material should be flexible and elastic enough to allow a range of movements while being strong enough to provide adequate support. Thermoplastic Polyurethane (TPU) for producing vaginal meshes due to its natural elasticity and biocompatibility, and the resulting meshes could be more suitable mechanical properties for pelvic floor applications compared to polypropylene meshes. The main features of TPU include being more flexible and more resistant to mechanical trauma compared to polypropylene. The ideal mesh should be biocompatible, minimally inflammatory, flexible according to tissue needs, and resistant to stretching until connective tissue support develops. Additive manufacturing (AM) or three-dimensional (3D) printing is defined as a process that creates complex 3D structures in almost any shape through the step-by-step addition of layered material, produced from a computer-aided design. Various medical applications of 3D printing have been identified, including orthopedics, tissue engineering, and the production of medical devices. AM has enabled the production of personalized medical products and instruments. Advances in technology and material science allow for the personalization of meshes according to an individual's anatomy and tissue characteristics.

Objective:

This study aims to develop a 3d printed TPU mesh and evaluate adhesion formation, tissue integration, and biomechanical characteristics on a rat model.

Study design, materials and methods

Material: Ultrafuse® TPU 95A, a 3D printing filament from BASF SE (Ludwigshafen, Germany), was used to produce custom mesh. Composed of thermoplastic polyurethane Elastollan®, its 'A' designation indicates Shore hardness. It has a tensile strength of 44.2 MPa and elongation at break of 661%. The filament passed cytotoxicity (ISO 10993-5:2009) and skin irritation (ISO 10993-10:2013) tests, proving biocompatible and non-cytotoxic.

Design and Manufacturing: Meshes were designed using SOLIDWORKS and printed with a Bambu P1P 3D FDM printer (0.4 mm nozzle) using TPU filament. Optimal settings included 220°C print head temperature, 60°C bed temperature, 0.2 mm layer height, 25 mm/s print speed, and 100% infill density.

Animals: Twenty-four female Wistar Hannover rats (10–12 weeks old, 215–247 g) were randomly divided into two groups. The rats were housed at Bezmialem Vakif University under controlled conditions (21–23°C, 50–55% humidity, 12-h light/dark cycle). The study was approved by the Animal Care and Use Committee of Bezmialem Vakif University (Ethics decision: 2022/11).

Surgical Procedure: Anesthetized with ketamine (50 mg/kg) and xylazine (5 mg/kg), rats underwent a 4-cm ventral midline incision. Polypropylene and 3D-printed TPU meshes (2×3 cm each) were placed using the on-lay technique, followed by skin closure with 3/0 polypropylene suture. No antibiotics were administered, and the surgical site and general health were monitored daily.

Histological Evaluation: Twelve weeks post-implantation, rats were euthanized. Implant sites, including surrounding tissue, were excised for morphometric and histological analysis.Histological EvaluationA 0.3 × 0.3-cm specimen was fixed in formalin, sectioned, and stained (H&E, Masson's trichrome). A pathologist, blinded to the specimens, scored cellular infiltration, vascularity, giant cells, fibrous tissue, and new ECM on a 0-3 scale. Immunohistochemical staining for TGF-Beta (Serotec) was graded from 0 to 3.Biomechanical TestsUniaxial tensile strength and elasticity were tested at 20°C and 65% humidity using an Instron 10000e system per ASTM D882-12 standards.

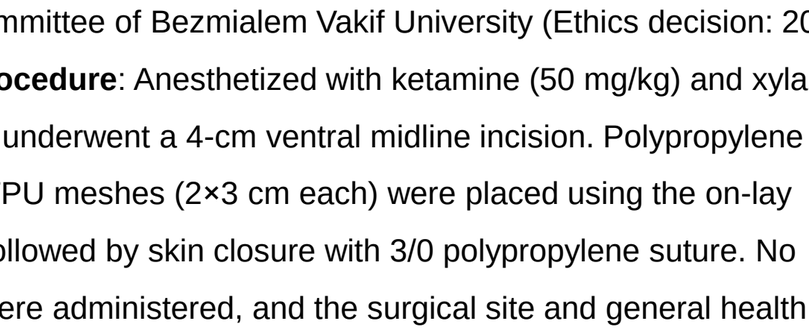

Figure 1: Computer-Aided Design of Mesh, 3D-Printed Thermoplastic Polyurethane Mesh, and Onlay Implanted Customized Thermoplastic Polyurethane Mesh Applied to Rats' Anterior Abdominal Wall

Results and interpretation

Early postoperative complications, including hematoma and surgical site dehiscence, were noted in both the thermoplastic polyurethane (TPU) and polypropylene (PP) groups, occurring in 33.3% (4 cases) of TPU and 25% (3 cases) of PP subjects. Both materials achieved satisfactory tissue integration, with comparable levels of connective tissue development and vascularization observed. The prevalence of multinucleate giant cells ranged from moderate to high in the meshes of both types, with TPU meshes experiencing more pronounced cell infiltration. Immunohistochemical evaluation disclosed significant and intense staining for TGF Beta in the TPU mesh, in contrast to the PP mesh, which exhibited widespread but moderate staining after a 12-week period.

The TPU mesh displayed exceptional elasticity and maintained structural integrity under mechanical stress, evidenced by a breaking elongation of 150% and a tensile strength of 30 N/cm, thereby preserving effective porosity.

	TPU *n* = 12 Number (percentage)	PP *n* = 12 Number (percentage)	*P* value
Surgical Complications			
Death	2 (16.7)	1 (8.3)	0.5
Late complication	-	-	
Early complication	4 (33.3)	3 (25)	0.6
Early dehiscence	2 (16.7)	1 (8.3)	0.5
Hematoma	2 (16.7)	2	1

Table 1: Surgical complication in TPU and PP mesh groups. PP; Polypropylene ,TPU; Thermoplastic Polyurethane

	TPU *n* = 10 Median (range)	PP *n* = 11 Median (range)	*P* value
Histopathological analysis			
Cellular ınfiltration	1 (0-1)	0	0.04
Vascularity	3 (2–3)	3 (2–3)	0.9
Mulitinucleate giant cell	3 (2-3)	3 (3)	0.2
Connective tissue organization	1 (1–2)	1 (1)	0.9
Immunohistochemistry			
TGF-Beta Staining	2 (2–3)	3 (2–3)	0.2

Tables: Surgical complication in TPU and PP mesh groups. PP; Polypropylene ,TPU; Thermoplastic Polyurethane

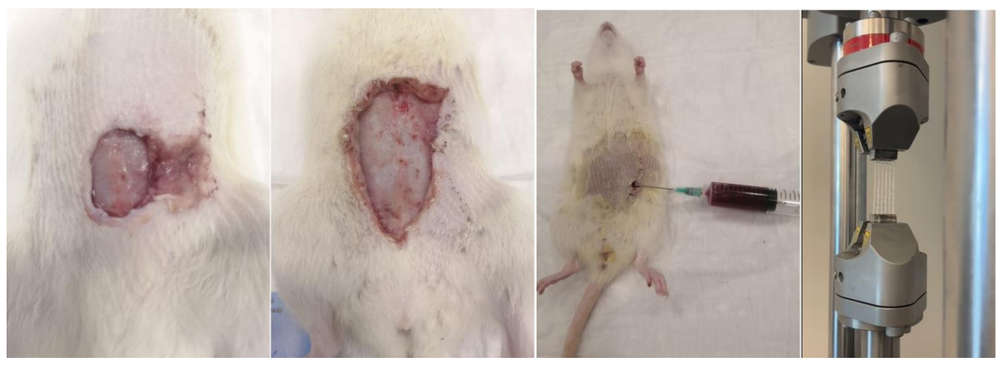

Figure 2: Dehishence and Hematoma on mesh site and biomechanical analysis of mesh implants

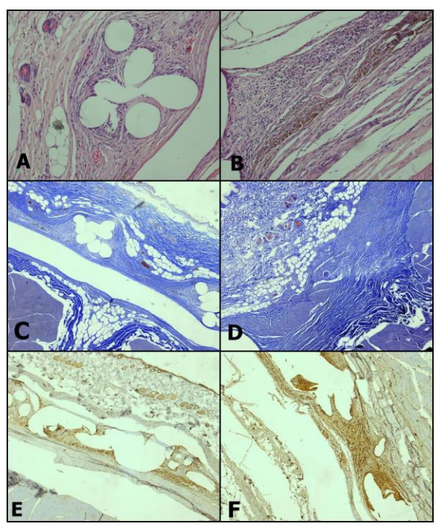

Figure 3:
Multinucleated giant cells and vascularization (A) (H&E x100)Inflammation, vascularization, and multinucleated cells (B)
(H&E x100)Moderate fibrous tissue formation (C)
(Masson's Trichrome x40)Fibrous tissue formation in the TPU group (D)
(Masson's Trichrome x40)Extensive TGF-beta staining in inflammatory cells and vascular endothelial cells (E) (IHC x40)
Extensive and strong TGF-beta staining in inflammatory cells and vascular endothelial cells in the TPU group (F) (IHC x40)

Conclusions

The elasticity, tissue integrity and tensile strength of 3D printed TPU make the mesh ideal for pelvic floor surgery. The encouraging results from our investigation suggest that further exploration into the application of TPU mesh in pelvic floor surgeries. This is particularly relevant for procedures tailored to the unique anatomical and biomechanical requirements of individual patients.

References

1. Lambertz A, Van Den Hil LC, Schöb DS, Binnebösel M, Kroh A, Klinge U, Neumann UP, Klink CD. Analysis of adhesion formation of a new elastic thermoplastic polyurethane (TPU) mesh in comparison to polypropylene (PP) meshes in IPOM position. Journal of the mechanical behavior of biomedical materials. 2016 Jan 1;53:366-72.
2. Yuan M, Hu M, Dai F, Fan Y, Deng Z, Deng H, Cheng Y. Application of synthetic and natural polymers in surgical mesh for pelvic floor reconstruction. Materials & Design. 2021 Nov 1;209:109984.
3. 3. Farmer ZL, Domínguez-Robles J, Mancinelli C, Larrañeta E, Lamprou DA. Urogynecological surgical mesh implants: New trends in materials, manufacturing and therapeutic approaches. International Journal of Pharmaceutics. 2020 Jul 30;585:119512.

Disclosures:
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