3D Printed Polymers for Medical Devices: a Public Health Approach

Polímeros Impressos em 3D para Dispositivos Médicos: Uma Abordagem em Saúde Pública
Polímeros Impresos en 3D para Dispositivos Médicos: Un Enfoque en Salud Pública

RESUMO
Objetivo: Desenvolver protótipos de dispositivos médicos tubulares por impressão 3D de polímeros, avaliando sua viabilidade técnico-científica e potencial aplicação no Sistema Único de Saúde (SUS), com vistas a contribuir para a incorporação desta tecnologia no âmbito da saúde pública brasileira.**Método:** Estudo experimental utilizando polímeros comerciais (TPU Flex, Nylon, Tritan, PLA Flex e ABS) processados por impressão FDM. Os protótipos foram desenvolvidos mediante modelagem CAD e caracterizados por Microscopia Eletrônica de Varredura (MEV), com parâmetros comparativos estabelecidos a partir de dispositivos comerciais da JOTEC. **Resultados:** Os protótipos de TPU flex 98A apresentaram melhor desempenho com destaque para a flexibilidade e homogeneidade superficial. **Conclusão:** A impressão 3D de polímeros comerciais representa uma alternativa tecnologicamente viável para produção de dispositivos médicos personalizados, com potencial impacto na saúde pública brasileira mediante independência tecnológica.
DESCRITORES: Polímeros; Impressão Tridimensional; Saúde Pública; Próteses tubulares; Biocompatibilidade.

ABSTRACT
Objective: To develop prototypes of tubular medical devices using 3D printing of polymers, evaluating their technical-scientific feasibility and potential application in the Brazilian Unified Health System (SUS), with a view to contributing to the incorporation of this technology within the scope of Brazilian public health. **Method:** Experimental study using commercial polymers (TPU Flex, Nylon, Tritan, PLA Flex and ABS) processed by FDM printing. The prototypes were developed using CAD modeling and characterized by Scanning Electron Microscopy (SEM), with comparative parameters established from commercial JOTEC devices. Results: The TPU flex 98A prototypes showed the best performance, especially in terms of flexibility and surface homogeneity. **Conclusion:** 3D printing of commercial polymers represents a technologically viable alternative for the production of personalized medical devices, with potential impact on Brazilian public health through technological independence.
DESCRIPTORS: Polymers; Three-dimensional printing; Public health; Tubular prostheses; Biocompatibility.

RESUMEN
Objetivo: Desarrollar prototipos de dispositivos médicos tubulares mediante impresión 3D de polímeros, evaluando su viabilidad técnico-científica y su potencial aplicación en el Sistema Único de Salud (SUS), con el fin de contribuir a la incorporación de esta tecnología en el ámbito de la salud pública brasileña. **Método:** Estudio experimental utilizando polímeros comerciales (TPU Flex, Nylon, Tritan, PLA Flex y ABS) procesados mediante impresión FDM. Los prototipos se desarrollaron mediante modelado CAD y se caracterizaron mediante microscopía electrónica de barrido (MEV), con parámetros comparativos establecidos a partir de dispositivos comerciales de JOTEC. **Resultados:** Los prototipos de TPU flex 98A presentaron un mejor rendimiento, destacando su flexibilidad y homogeneidad superficial. **Conclusión:** La impresión 3D de polímeros comerciales representa una alternativa tecnológicamente viable para la producción de dispositivos médicos

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INTRODUCTION

Polymers, materials made up of macromolecules, have become pillars of modern society, transcending their everyday use in packaging, household utensils, electronic components, and clothing to become indispensable in the medical field. [1] Their chemical versatility allows the manipulation of properties such as flexibility, resistance, transparency, and biocompatibility – the ability of a material to elicit a biological response that is not adverse in the body. [2] In the medical context, polymers are already widely used in a multitude of devices, such as blood and serum bags (polyvinyl chloride - PVC), disposable syringes (polypropylene - PP), surgical gloves (polyisoprene), absorbable sutures (polycaprolactone - PCL), contact lenses (poly(methyl methacrylate) - PMMA), and conventional vascular prostheses, such as those made of expanded polytetrafluoroethylene (ePTFE) and polyester (Dacron®). [3]

Despite this widespread adoption, traditional medicine often operates with a one-size-fits-all model, where medical devices are mass-produced with standardized dimensions. This approach presents a significant limitation, especially in a country of continental dimensions and population diversity like Brazil, where patient anatomy can vary considerably. [4] It is in this context that three-dimensional (3D) printing of polymers emerges as an innovative technology, enabling the transition from mass production to mass customization. [4] This technology enables the on-demand manufacturing of medical devices with complex and customized geometries, perfectly tailored to the individual anatomy of each patient, based on models generated from X-ray, computed tomography, or magnetic resonance imaging. [5]

The relevance of 3D polymer printing for Brazil, and especially for the Unified Health System (SUS), lies in enabling technological and sanitary sovereignty. Brazil has a significant dependence on imports of highly complex medical devices, which generates vulnerability in supply chains, exchange rate fluctuations, and high costs. Developing internal capacity to produce these devices using polymeric raw materials and digital fabrication equipment reduces this dependence and strengthens the autonomy of the national health system. [6]

Furthermore, this technology presents potential for cost savings, through the ability to produce prototypes and final devices on demand, locally and at a fraction of the cost of imported equivalents, potentially generating substantial savings for public coffers. These resources can be reallocated to other underserved areas of the SUS (Brazilian Public Health System), expanding the population's access to innovative technologies. [7] Additionally, it simplifies the logistics chain, reducing storage and distribution costs.

Finally, this article aims to develop prototypes of tubular medical devices using 3D-printed polymers, with potential application in the Brazilian public health system (SUS). Therefore, it seeks not only to evaluate the technical and scientific feasibility of the devices, but also to contribute to the incorporation of this transformative technology within the scope of Brazilian public health.

METHOD

This is an experimental study for the development of medical devices. The following thermoplastic polymers were chosen: TPU flex (manu-

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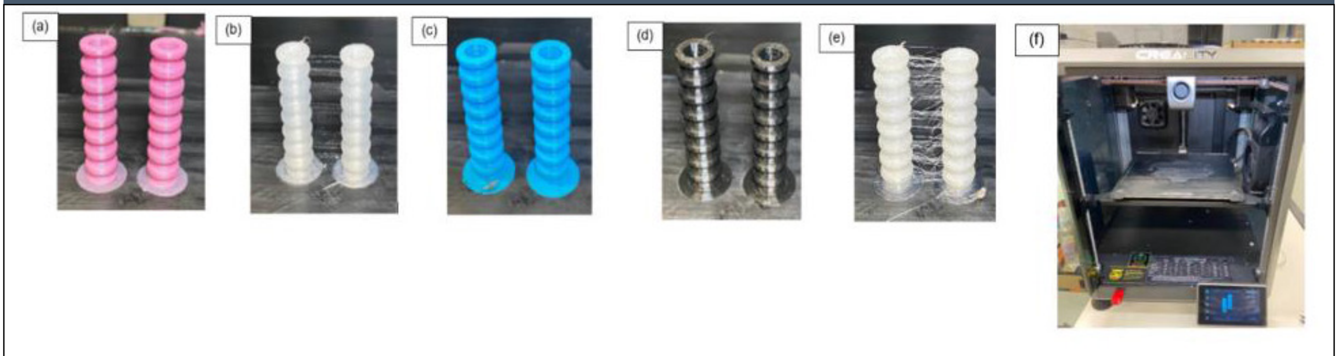
facturer 3D LAB), nylon (manufacturer 3D LAB), Tritan (manufacturer GT Max), PLA Flex (manufacturer 3D LAB), and ABS (manufacturer 3D LAB). For the development of the prototypes, CAD modeling software was used (developer PTC, CREO PARAMETRIC platform, educational license linked to the Polytechnic School of PUCRS), allowing the obtaining of files in STL formats, compatible with 3D printing (CAM) to design the most suitable formats for these devices.

In order to establish reference parameters and adapt the design of the prototypes, commercial medical devices from the manufacturer JOTEC were acquired and characterized, specifically PTFE and Dacron® vascular prostheses. Direct comparison with these commercial standard devices was fundamental to guide the geometric optimization of the printed devices. The prototypes were sectioned longitudinally and transversely to perform structural and surface analysis tests using Scanning Electron Microscopy (SEM) to evaluate the quality of the 3D printing, homogeneity, presence of defects or porosity, and adhesion between layers.

RESULTS

Initially, corrugated tubes were produced using a Creality K1c 3D printer, as described in Figure 1.

Figure 1. Initial prototypes of corrugated tubes obtained by 3D printing (FDM technology) from the following polymers: (a) ABS; (b) Nylon; (c) PLA; (d) Tritan; (e) TPU Flex, (f) 3D printer.



Source: Prepared by the authors.

The parameters used for the corrugated tube printing process are described in Table 1.

Table 1: Printing parameters for corrugated tube prototypes.

Filament	Nozzle temp (°C)	Table temp (°C)	S (mm/s)	Thi (mm)	D (mm)	H (mm)	W (mm)	L (mm)
ABS	260	105	40	1,6	0,4	0,2	0,42	60
Nylon	245	105	40	1,6	0,4	0,2	0,42	60
PLA	220	60	40	1,6	0,4	0,2	0,42	60
Tritan	265	100	40	1,6	0,4	0,2	0,42	60
TPU flex	240	70	40	1,6	0,4	0,2	0,42	60

T: temperature; s: average cylinder head speed; Thi: pipe wall thickness; D: nozzle diameter; H: layer height; L: extrusion width; C: tube length.
Source: Prepared by the authors.

Subsequently, the printing of filaments based on ABS, PLA flex, TPU flex 98A, and TPU flex 65D was tested, as described in Figure 2. The superior flexibility acquired by TPU flex 98A and TPU flex 65D is noteworthy; therefore, for the subsequent stage of surface analysis of the prostheses using SEM (Figure 3), these prototypes were selected due to their better performance.

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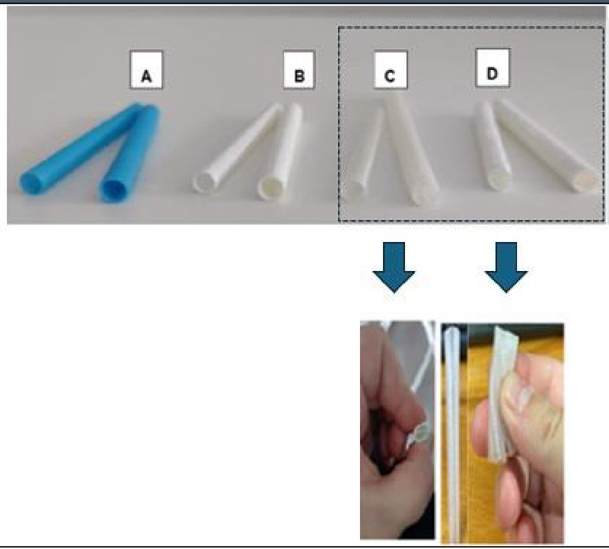
Figure 2. Prototypes of straight tubes obtained by 3D printing (FDM technology) from commercial polymers: (a) ABS, (b) PLA flex, (c) TPU flex 98A and (d) TPU flex 65D.



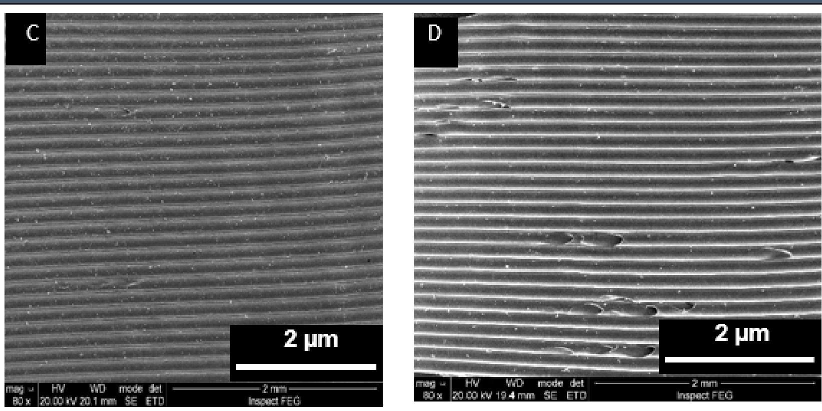
Source: Prepared by the authors.

Tabela 1: Parâmetros de impressão dos protótipos de tubos sanfonados

Filament	Nozzle Temp (°C)	Table Temp (°C)	S (mm/s)	Thi (mm)	D (mm)	H (mm)	W (mm)	L (mm)
ABS	260	60	20	0,8	0,4	0,12	0,42	60
PLA flex	220	60	20	0,8	0,4	0,12	0,42	60
TPU flex 98A	220	60	20	0,8	0,4	0,12	0,42	60
TPU flex 65D	220	60	20	0,8	0,4	0,12	0,42	60
TPU flex	240	70	40	1,6	0,4	0,2	0,42	60

T: temperature; s: average cylinder head speed; Thi: pipe wall thickness; D: nozzle diameter; H: layer height; L: extrusion width; C: tube length.
Source: Prepared by the authors.

Figure 3. Surface result of the 3D Prototypes from commercial polymers: (c) TPU flex 98A and (d) TPU flex 65D.



Source: Prepared by the authors.

DISCUSSION

The development of corrugated tube prototypes allowed for the customization of parameters for different polymeric materials, as detailed in Table 1. The significant variation in nozzle temperatures (220-265°C) between polymers demonstrates the need for specific thermal adjustments for each material, consistent with thermoplastic processing principles. [9] This thermal customization is essential to ensure proper material flow during extrusion, guaranteeing complete layer consolidation and structural integrity of the prototypes. [9]

The standardization of geometric parameters (E=1.6mm, H=0.2mm, L=0.42mm) for all materials, contrasting with the variation in thermal parameters, reveals a methodological approach that seeks to isolate the effect of the material on the final quality of the prototypes. This strategy emphasizes the importance of controlling geometric variables in comparative studies of materials for additive manufacturing. [5]

The transition from accordion-style to straight tube design, illustrated in Figure 2, was featured in the comparative analysis with reference to commercial medical devices. This approach allowed for a focus on the best layout, reducing complex geometric variables that could mask intrinsic properties of the polymers. [10] The selection of flexible TPU filaments (in 98A and 65D hardness versions) for subsequent stages was justified by their superior mechanical performance, particularly in flexibility – a critical property for vascular applications where conformability and resistance to kinking (torsional collapse) are essential. [11]

Scanning Electron Microscopy analysis revealed crucial aspects of print quality (Figure 3). The TPU flex 98A prototype presented a more homogeneous surface with a lower incidence of defects when compared to

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TPU flex 65D, suggesting a better fit for the established printing parameters.

The better surface quality of TPU 98A does not necessarily indicate that it is a superior material, but rather that the printing parameters used were superior for its specific mechanical characteristics, while TPU 65D would require more specific adjustments in speed, temperature, and shrinkage to achieve equivalent quality. [12]

The comparison of printing parameters between the corrugated (Table 1) and straight (Table 2) tubes revealed procedural refinement, with a reduction in printing speed to 20 mm/s and layer height to 0.12 mm in the straight prototypes – adjustments that promoted greater dimensional accuracy and surface quality. [13,14]

CONCLUSION

The results of this study demonstrate that the TPU 98A filament yielded the most promising prototypes for vascular applications. This material presented an ideal balance of flexibility and design compatible with vascular dynamics – and satisfactory surface quality, with homogeneity and absence of critical defects that could compromise performance in clinical use. [11,15]

These findings reinforce the potential of 3D polymer printing for the development of affordable medical devices within the context of the Brazilian Unified Health System (SUS), aligning technological innovation with public health needs. [6] However, it is crucial to emphasize that the clinical validation of these prototypes depends on conducting complementary biocompatibility studies, which should evaluate the tissue response, thrombogenic potential, and long-term physiological stability of these materials. [15]

Continuing this line of research, focusing on biological characterization and regulatory compliance, is essential to transforming these promising prototypes into safe and effective medical devices, contributing to technological autonomy and improved healthcare in Brazil.

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