

Design and 3D printing of flexible products for public health using TPU: social and economic issues

Design e fabricação digital de produtos flexíveis para a saúde pública com uso de TPU: aspectos de sustentabilidade social e econômica



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ABSTRACT

This paper presents, describes, and analyzes, from the perspective of social and economic sustainability, the development and manufacture of two products for use in public hospital with the use of 3d printing, having as main material a thermoplastic polyurethane polymer (TPU) in the form of filament. The applications were for the physiotherapy sector of the hospital, with a focus on urology and gynecology/obstetrics. The research and development method, of the experimental and exploratory type and based on Design, involved four main stages: 1) immersion in the problem through conversation with a specialist, research of similar and search for scientific articles related to the theme; 2) ideation using manual sketches and team discussion; 3) experimentation, through digital 3D modeling and 3D printing of prototypes, and 4) Testing of prototypes with patients by a specialist who requested the products. The need for flexible material was one of the common points between the products, and one of the main results pointed to TPU as a suitable material to produce prototypes through 3D printing, with both economic and social implications, which are analyzed in the end of the article.

KEYWORDS

Public health; 3D printing; social sustainability; economic sustainability

RESUMO

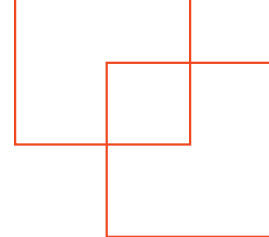
Este artigo apresenta, descreve e analisa, sob a ótica da sustentabilidade social e econômica, o desenvolvimento e fabricação de dois produtos para uso em um hospital público com uso de impressão 3D tendo como material principal um polímero de poliuretano termoplástico (TPU) na forma de filamento. As aplicações foram para o setor de fisioterapia do hospital, com foco em urologia e ginecologia/obstetrícia. O método de pesquisa e desenvolvimento, do tipo experimental e exploratório e com base em Design, envolveu quatro etapas principais: 1) imersão no problema por meio de conversa com uma especialista, pesquisa de similares e busca de artigos científicos relativos ao tema; 2) ideação com uso de esboços



manuais e discussão em equipe; 3) experimentação, por meio de modelagem 3D digital e impressão 3D de protótipos, e 4) Teste dos protótipos com os pacientes pela especialista que solicitou os produtos. A necessidade de um material flexível foi um dos pontos em comum entre os produtos, e um dos principais resultados apontou o TPU como um material adequado para produção dos protótipos por meio de impressão 3D, com implicações tanto econômicas quanto sociais, as quais são analisadas ao final do artigo

PALAVRAS-CHAVE

Saúde pública; produtos flexíveis; impressão 3D; sustentabilidade social; sustentabilidade econômica



1 INTRODUCTION

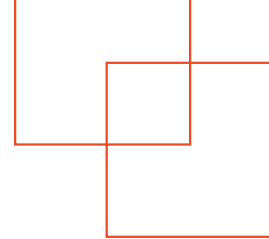
1.1 Context: Public Health, Digital Manufacturing of Hospital Products, and Fab.i HU

The Digital Manufacturing Hub of HU-UEL (Fab.i HU) was established within the University Hospital of the State University of Londrina (HU UEL) as a support structure to provide greater resilience and autonomy to the hospital in future pandemic scenarios. The initiative arose in 2020 when hospital products were scarce in the market during the onset of the SARS-CoV-2 pandemic. Professors from the Design and Physiotherapy departments of the State University of Londrina collaborated to create solutions for the hospital. The production of hospital artifacts aimed to address issues identified during the pandemic, particularly the shortage of supplies and the contamination of frontline healthcare professionals.

Currently, this initiative has expanded to focus on developing artifacts through digital manufacturing to enhance the quality of life and health of the population utilizing public services. Digital manufacturing refers to a range of manufacturing technologies used to produce limited quantities of products, enabling local production based on 3D digital models (Gershenfeld, 2012).

In the healthcare sector, digital manufacturing using 3D digital models has been predominantly applied to the development of new therapeutic approaches, such as individualized prostheses and orthoses (Mallmann, 2018), and in streamlining surgical procedures, improving prognosis and quality of life (Bernardes, 2018). The integration of Design and Healthcare through digital manufacturing saw significant growth during the pandemic due to shortages of personal protective equipment (PPE) (Kumar; Pumera, 2021; Corsini; Moultrie, 2019).

It is worth noting that HU UEL is the second-largest public hospital in Paraná, serving SUS (Brazilian Unified Health System) patients (Paraná, 2021). It has impressive capacity and outreach, catering not only to Londrina but also to a vast macro-region extending beyond state boundaries. The development of these artifacts provided



opportunities for growth and contributions to public health, both in practice and in the generation of theoretical and methodological knowledge regarding the development and implementation of these solutions.

In this context, the aim of this study was to investigate the development, production, and testing of two products - one for Urology (penile clamp) and another for Gynecology/Obstetrics (mesh for fibrosis break) - through Design, Physiotherapy, and digital manufacturing. The results of this process were evaluated considering the social and economic implications of these interventions, as well as some relevant technological aspects.

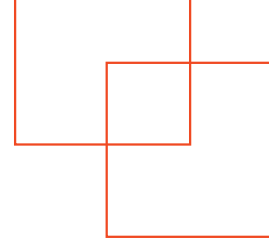
2 THEORETICAL FRAMEWORK

2.1 Problem 1: Male Urinary Incontinence and the Use of Clamps

Urinary incontinence (UI) is defined as any involuntary loss of urine that impacts quality of life. UIs are classified as stress UI (SUI), associated with activities such as physical exercise, coughing, or sneezing; urgency UI (UUI), occurring alongside a strong urge to urinate; mixed UI (MUI), where both SUI and UUI occur simultaneously; and unconscious UI, which occurs without urgency or awareness of leakage. Of these, SUI is the most prevalent, accounting for 86% of cases (Monteiro; Filho, 2018).

Several urine containment and storage devices assist individuals in improving their quality of life while undergoing treatment. Macaulay et al. (2015) compared the performance of four devices used by male patients over three weeks for each device. The study evaluated absorbent pads, penile clamps, and other unnamed devices. Positive and negative aspects were reported for all devices, with the conclusion that there is no single best option. Instead, combining these devices provides a broader range of choices, allowing patients to select the most suitable one for a specific activity or task while benefiting from the strengths of each product.

Moreover, Macaulay et al. (2015) highlighted that penile clamps demonstrated the highest level of reliability in preventing urine



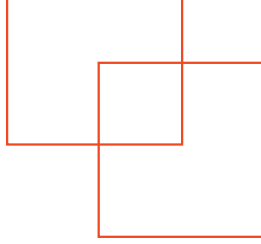
leakage. However, they also caused the greatest discomfort and highest levels of pain. Based on these findings, the development of an alternative clamp through 3D printing aimed to significantly reduce discomfort and pain while maintaining urinary containment effectiveness. This product's demand originated from a urogynecology specialist physiotherapist at HU UEL, who was treating a male patient experiencing UI.

2.2 Problem 2: Female Fibrosis and the Use of a Mesh for Breakdown

The lymphatic system is part of the circulatory and immune systems, playing a crucial role in maintaining fluid balance between tissues. Lymphedema is a pathological manifestation of the lymphatic system characterized by the accumulation of interstitial fluid. If untreated, it leads to extensive fibrotic areas, increased volume, and deformity of the limbs (Monteiro; Resende, 2018).

At HU UEL, there is a population of women suffering from severe chronic lymphedema following mastectomy (complete surgical removal of the breast). The development of a specialized artifact was aimed at these patients with advanced lymphedema, characterized by extensive fibrosis and changes in the size of the upper limb (arm and forearm). The primary treatment for managing lymphedema is Complex Physical Therapy (CPT), which consists of two stages. The first stage combines manual lymphatic drainage, elastic compressive bandaging, lymphomyokinetic exercises, and skin care. The second stage aims to optimize and maintain the results achieved (Monteiro; Resende, 2018).

The goal of the artifact (a mesh for fibrosis breakdown) developed through 3D printing was to enhance outcomes during the first stage of treatment. Its application involves placing it directly on the lymphedema area under the elastic bandage. The prototype required a certain degree of malleability to conform to the targeted body region. Additionally, its surface needed different relief heights, which, under pressure from the elastic bandage, create varying pressure points on the skin to aid in breaking down fibrosis.



As with the penile clamp, this product was also developed in response to a demand from a urogynecology specialist physiotherapist at HU UEL.

3 METHODOLOGICAL PROCEDURES

The research and development method, characterized as experimental and exploratory with a Design-based approach, involved four main stages:

1. Immersion in the Problem: Engaging with a specialist, researching similar products, and reviewing scientific articles related to the topic.

2. Ideation: Utilizing manual sketches and team discussions.

3. Experimentation: Conducting 3D digital modeling and 3D printing of prototypes.

4. Prototype Testing: The requested specialist tested the prototypes with patients.

The activities were carried out at the Fab.i HU, utilizing its physical space, equipment (FFM 3D printers and resin-based LCD printers), and software tools (Rhinoceros 7, Cura, etc.). The testing of the products was performed by the healthcare professional who had initially requested their development.

4 APPLICATIONS AND RESULTS

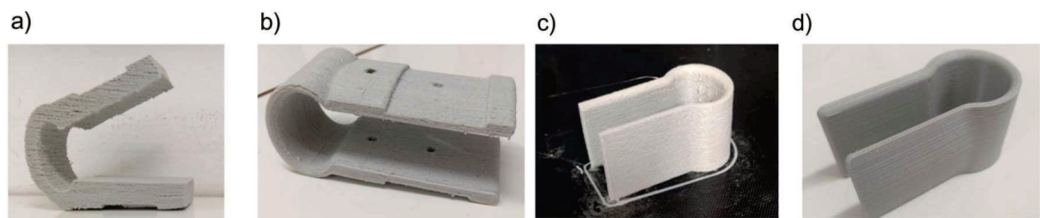
4.1 Product 1: Penile Clamp

The development process began with an analysis of the qualitative parameters of similar products available in the market (Pazmino, 2020). A common feature of the devices analyzed was identified: the penile compression mechanism was always applied horizontally, targeting only a cross-sectional area of the organ. Since force increases as the area decreases, a solution was proposed to change the compression direction to be longitudinal along the penile body. This adjustment increased the compression area and reduced the force, thereby improving comfort and minimizing pain.

Four prototypes were created before finalizing the product (Figure

1). The first prototype served as a preliminary visualization of the concept and to evaluate the behavior of the TPU filament selected for the printing tests. Subsequent prototypes were tested with the patient, with modifications between iterations informed by observations of the product's application and feedback from the patient.

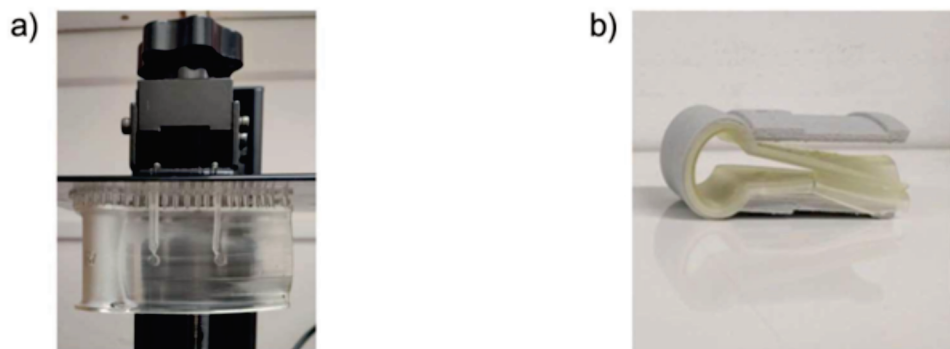
Figure 1: Four versions of penile clamp prototypes: a) 1st version, b) 2nd version, c) 3rd version, d) 4th and last version



Source: Authors

1). The first prototype served as a preliminary visualization of the concept and to evaluate the behavior of the TPU filament selected for the printing tests. Subsequent prototypes were tested with the patient, with modifications between iterations informed by observations of the product's application and feedback from the patient.

Figure 2: Prototypes 2 (b) with internal part printed in flexible resin (a).



Source: Authors

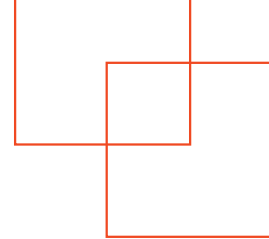


Figure 3: Final prototype with Velcro strap.



Source: Authors

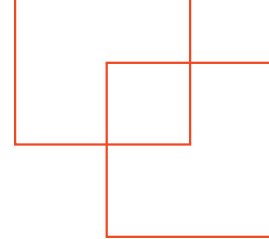
Figure 4: Final prototype being used by the patient.



Source: Authors

Prototypes 2 and 3 included an additional component made of flexible resin, which was intended to act as a cushion between the TPU print and the penile shaft (Figure 5). This component was excluded in the final version due to the quality of the finish obtained with TPU filament printing.

To assess the effectiveness of the product, two outcomes were investigated: urinary containment and some levels of subjective sensations. Levels of pain, confidence, and comfort were collected through a questionnaire created via google forms, which included scales from 1 to 10, where 1 indicated the lowest level of pain and 10 the highest level of confidence and comfort.

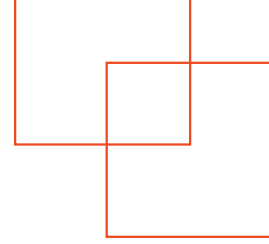


For urinary containment, the pad test was applied, which evaluates urinary continence based on the weight of a male absorbent pad (Abrams; Cardozo; Wagg, 2017). The test was conducted over one hour and followed this sequence: the patient places the previously weighed male absorbent pad close to the external urethral meatus of the penis, already wearing the penile clamp; next, he drinks 500 ml of water and remains at rest for 15 minutes. After the rest period, he performs daily life activities such as climbing up and down stairs for 15 minutes, sitting and standing ten times, coughing ten times, picking objects up from the floor five times, running in place for one minute, and washing his hands under running water for one minute (Krhut et al., 2014). After performing the proposed activities, the absorbent pad is removed and weighed again. Prototypes 2, 3, and 4 were tested (Figure 1). The questionnaire was sent via whatsapp and answered after using all the prototypes, while the pad test was applied only with the final version (4th prototype, Figures 3 and 4).

The pad test classifies urinary loss as follows: up to 1 g – insignificant; between 1.1 and 9.9 g – light loss; between 10 and 49.9 g – moderate loss; and above 50 g – severe loss (Krhut et al., 2014). Before the test began, the penile absorbent pad had an initial weight of 20 g. After completing the test, the used absorbent was weighed again using the same digital scale, model SF-400, with a minimum reading of 1 mg and a maximum capacity of 10 kg, and showed a final weight of 21 g. In other words, the patient had a urinary loss of 1 g, which is classified as insignificant. The final version of the 3D-printed penile device (Figure 4) was able to fulfill its function of urinary containment without causing pain to the patient, who, in the previously mentioned efficacy assessments, reported a significant improvement in comfort, reduced

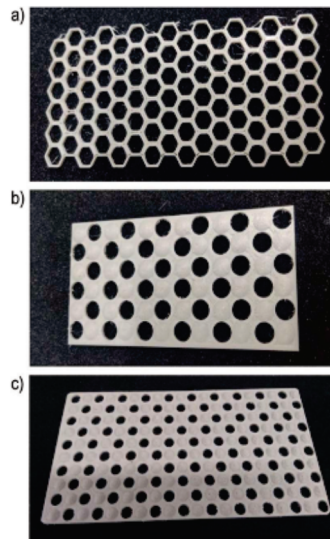
4.2 Product 2: Mesh for Fibrosis Breakdown

The development process for this product also followed a Design-based methodology. It began with a foundational phase that involved researching lymphedema, its treatment processes, and understanding the artifact's required functionality. This phase also included discussions with the healthcare professional who requested the product. The mesh needed to be flexible to adapt to the body region



where it would be applied and available in different sizes to suit various treatment areas. Due to its flexibility, TPU was selected as the initial material for testing. A mesh pattern with alternating positive and negative spaces was used to enhance flexibility. The three stages of development are shown in Figure 5.

Figure 5: Printed prototypes during the development process of the fibrosis-breaking mesh. a) 1st prototype, b) 2nd prototype, c) 3rd prototype.



Source: Authors

The focus of the first prototype was solely on developing the mesh, initially using hexagons. However, it was found that this structure could cause skin injuries to the patient due to excessive pressure. Consequently, the hexagons were replaced with semi-spheres. The module was designed to mimic the manual movements performed in physiotherapy to break down lymphedema.

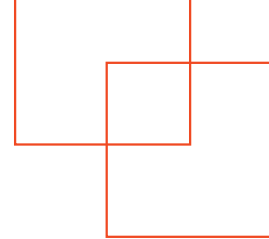


Figure 6: Final Prototype being used by the patient

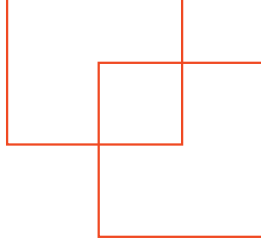


Source: Authors

Evaluation to determine whether there was a reduction in the fibrotic area was carried out through ultrasound examination and perimetry (measurement) of the lymphedema region in the left upper forearm. The ultrasound was performed before the use of the 3D-printed mesh, and after six weeks of its use, the examination will be repeated—however, this second evaluation had not yet been conducted at the time of writing this article. Perimetry was conducted prior to the use of the mesh and subsequently measured at each treatment session during its use, with all measurements taken before the session began. The use of the mesh as a complement to Complex Physical Therapy (CPT) showed a highly beneficial clinical result for the patient, as after just ten days of use, there was a reduction in the patient's forearm volume by approximately 2 cm at each measured point.

5. ANALYSIS AND DISCUSSION OF RESULTS

The sustainability aspects of the two products presented here are discussed mainly in terms of their social and economic implications,



and to a lesser extent, environmental concerns, which will be the focus of another dedicated article. This choice is justified by the fact that, as previously mentioned, these are products aimed at public healthcare, since the HU UEL serves exclusively the Brazilian Unified Health System (SUS).

5.1 Social Sustainability Aspects: Benefits for the Hospital's Public

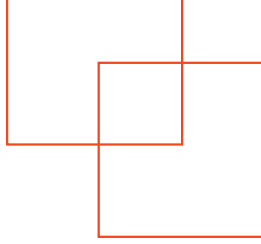
According to Santos et al. (2019), the social dimension of sustainability can be approached in the context of Design through two main concepts—social cohesion and equity—which are reflected in the following principles (or heuristics): improving working and employment conditions; fostering inclusion of all; improving social cohesion; valuing local resources and skills; promoting sustainability education; and encouraging responsible consumption. Among these, we consider that the solutions presented here particularly align with two of them: fostering inclusion of all and valuing local resources and skills.

Promote the inclusion of All

This heuristic involves creating solutions that enhance equity and ethics in society, benefiting those in disadvantaged or vulnerable situations (Santos et al., 2019). In the specific context of public hospitals, this means serving a significant portion of the population that relies directly on public healthcare services and would otherwise be unable to afford products and services like those discussed in this article. Incorporating these digitally manufactured solutions into hospital services therefore enables access for a large group of people who would otherwise be marginalized. This access directly relates to the concept of the Human Development Index (HDI), which includes the right to a long and healthy life (health), along with access to education and income, as one of its key dimensions for enhancing human freedom and well-being.

Valuing Local Resources and Skills

This heuristic relates to promoting and encouraging systems, products, and services that protect, regenerate, and value locally



available resources and skills (Santos et al., 2019), which leads to a distributed economic model in which products and services are locally produced and delivered. This contrasts with traditional centralized systems where producers are far removed from consumers. The development and production process of the solutions presented here aligns with this distributed economy concept, as both the understanding of user needs and the design, prototyping, and testing of solutions were carried out within the hospital itself—without dependence on external producers or long-distance transportation. This provided patients with greater speed and convenience, with faster access to products.

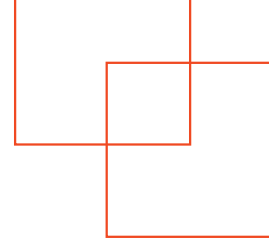
In this case, the local resources and skills valued were mainly the knowledge and expertise available within the university to which the hospital belongs, directly reflected in the operation of the Fab.i HU, which is managed and run by university researchers. The new knowledge generated through this process benefits the hospital and the local/regional community it serves. Furthermore, the innovation hub adopts an open-source approach, utilizing existing community solutions and sharing locally developed ones.

5.2 Economic Sustainability Aspects: Benefits for the Hospital and the SUS

Regarding the economic dimension, Santos et al. (2019) propose the following principles (or heuristics) to be assessed through a Design lens: strengthening and valuing local resources; respecting and valuing local culture; promoting the local economy; supporting networked organizations; encouraging waste reintegration; and promoting education for a sustainable economy. Among these, we identify three as directly related to the solutions in this study: strengthening and valuing local resources, promoting the local economy, and supporting networked organizations.

Strengthening and Valuing Local Resources

This principle implies prioritizing local resources (material, technical, financial, human) over external ones to gain a competitive advantage. In the case of the products discussed in this article, we refer



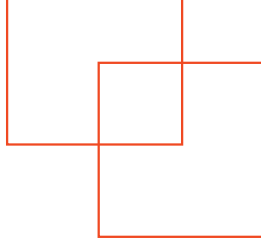
primarily to the acquisition of equipment and supplies from local suppliers. Although the equipment manufacturers are mostly foreign (mainly from China), there are already national and local suppliers of materials such as plastic filaments. Another important aspect concerns cost savings for the hospital, as the 3D-printed products made in-house have proven to be more affordable than industrially manufactured ones, which are also harder to source.

Promoting the Local Economy

Using these solutions helps strengthen local production arrangements and value chains, promoting a local economy based on small, local businesses and the development of local skills, now enhanced by digital manufacturing technologies. Increasing the autonomy of these local actors is one of the main objectives of this heuristic, along with fostering entrepreneurship and creating a social environment based on trust and reciprocity, often referred to as a social economy (Lévesque, 2007 apud Santos et al., 2019). In the case of Fab.i HU, one of its goals is to foster new businesses based on technologies developed within the hub, with potential benefits to the hospital through technology transfer. The university to which the hospital is affiliated has an innovation agency that offers such services (business incubation and technology transfer).

Supporting Networked Organizations

This economic principle involves creating and expanding interaction structures to strengthen social, economic, and environmental resilience for the involved parties. The solutions discussed here were developed in the context of an innovation and digital manufacturing hub within a public hospital, designed to operate in network with other healthcare system actors—especially other hospitals (public or private), universities, government agencies, companies, as well as researchers, professionals, and individuals interested in collaborating with HU UEL. This networked collaboration is enhanced by the current technological information resources, allowing HU UEL to develop a resilient structure that increases the hospital's technological and innovation autonomy. This structure could prove vital in future pandemics.



5.3 Technological Aspects: Process Challenges and Benefits

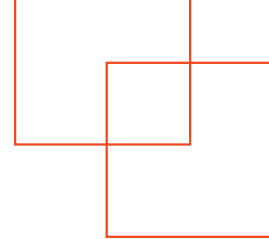
Beyond social and economic issues, the most significant technological challenges observed in the solutions presented include:

- Constant need for technological updates, in both equipment and materials/processes, with the risk of rapid obsolescence
- Maintenance of infrastructure, especially 3D printing and related equipment.
- Ongoing search for funding sources for both infrastructure and maintaining qualified technical personnel.
- Growing demand from the hospital for products and services, requiring expanded hub capacity.
- Dependence on university-provided labor, especially researchers and short-term research fellows whose contracts must be renewed annually. New fellows also require training in using the infrastructure and following internal procedures.

Addressing each of these issues requires the design and implementation of an appropriate innovation policy and strategy for Fab.i HU. This strategy should encompass dimensions such as technological, economic-financial, informational, intellectual capital, social, and environmental aspects, among others.

5.4 Environmental Aspects: To Be Explored in Future Studies

Finally, environmental aspects may be addressed primarily through a product life cycle approach, from two perspectives: Environmental efficiency (eco-efficiency) – aiming to optimize resource use, employ low-impact resources, extend product and material life, and enable easy disassembly. Dematerialization in production and consumption – striving for solution sufficiency and effectiveness, supported by strategies such as using services as complements or substitutes for products. These two approaches will be addressed in detail in a future article focused specifically on the environmental dimension of 3D-printed hospital products.



6. CONCLUSION

This study has demonstrated the importance of having a research, development, and digital manufacturing structure within a public hospital, enabling the rapid development and production of solutions for public healthcare. In this case, these solutions were directed toward two important hospital areas: urology and gynecology/obstetrics.

Beyond the technical and functional viability, effectiveness, and efficiency of the products printed with flexible polymer (TPU), we have also highlighted their social and economic implications. Based on the social and economic principles or heuristics proposed by Santos et al. (2019), we were able to better understand these solutions from the perspective of social and economic sustainability, as well as the mutual influence between the guiding principles of these analysis dimensions.

The use of TPU-based 3D printing for creating flexible medical products has proven to be an important method within hospital environments provided by a design-led process of problem understanding, development, prototyping, and testing, characterized by interdisciplinary interaction between design and healthcare areas. The results indicate a promising path for research and development, which should be further explored in the coming years by Fab.i HU. A key area for future investigation is the environmental impact of these processes—an acknowledged limitations of this current article, but one that will be addressed in further studies.

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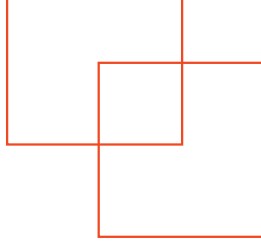
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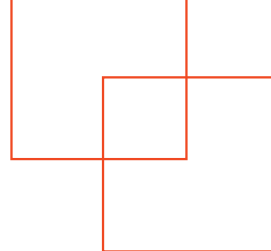
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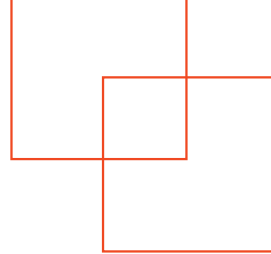
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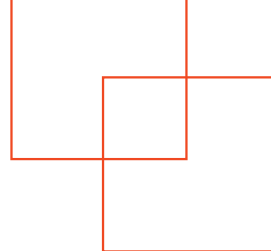
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