MATERIALS AND PROCESSES SELECTION FOR MEDICAL DEVICE PROTOTYPING FOR CLINICAL TRIALS

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Abstract: In developing countries like Brazil, technological innovation is crucial for advancing healthcare systems, but it faces challenges due to socio-economic and cultural specificities influenced by inequality. The local manufacturing of medical devices is impacted by regional technological capabilities and limitations, placing regions with restricted access to necessary resources at a disadvantage. Therefore, adaptations to processes, materials, and workforce are often necessary for successful local production. This article aims to explore approaches that aid in adapting healthcare technological innovation projects, considering materials and processes available in pre-industrial stages. The methodology involves bibliographic research on material and process selection, followed by an analysis of the life cycle of technological medical products, taking into account the incidence of regulation in this process. As a result, the study proposes a flowchart of stages for research and selection of materials and processes that enable small-scale production of medical device prototypes intended for clinical trials conducted in low complexity healthcare settings.

Keywords: Technological Innovation; Healthcare Systems; Developing Countries;

SELEÇÃO DE MATERIAIS E PROCESSOS PARA PROTOTIPAGEM DE DISPOSITIVOS MÉDICOS PARA ENSAIOS CLÍNICOS

Resumo: Em países em desenvolvimento, como o Brasil, a inovação tecnológica é crucial para avançar nos sistemas de saúde, mas enfrenta desafios devido às especificidades socioeconômicas e culturais influenciadas pela desigualdade. A fabricação local de dispositivos médicos é impactada pelas capacidades e limitações tecnológicas regionais, colocando regiões com acesso restrito aos recursos necessários em desvantagem. Assim, adaptações nos processos, materiais e força de trabalho são frequentemente necessárias para uma produção local bem-sucedida. Este artigo tem como objetivo explorar abordagens que auxiliem na adaptação de projetos de inovação tecnológica em saúde, considerando materiais e processos disponíveis em etapas pré-industriais. A metodologia envolve pesquisa bibliográfica sobre seleção de materiais e processos, seguida de uma análise do ciclo de vida de produtos médicos tecnológicos, considerando a incidência da regulamentação nesse processo. Como resultado, o estudo propõe um fluxograma de etapas para pesquisa e seleção de materiais e processos que permitam a produção em pequena escala de protótipos de dispositivos médicos destinados a ensaios clínicos executados na baixa complexidade hospitalar.

Palavras-chave: Inovação tecnológica; Sistemas de saúde; Países em desenvolvimento;

1. INTRODUCTION

In developing or emerging countries, such as Brazil, technological innovation plays a fundamental role in advancing and improving healthcare systems. However, the path to implementing such innovation in these systems faces several obstacles, given the socio-economic and cultural specificities influenced by inequality. The local manufacturing of these products is influenced by the technological capabilities and limitations of the region [1], meaning that regions with limited access to any of the necessary agents in the process are logically at a disadvantage [2]. Therefore, for innovation production to thrive in these areas, adaptations to the process, materials, and available workforce are sometimes necessary. Demanding that products meet the standards of large industries can hinder the growth and development of these locations [3]. When it comes to the development of medical devices (MDs), the pursuit of regulatory harmonization should prioritize ensuring the safety and efficacy of these devices, facilitating their circulation while respecting the specific context in which they are produced.

This article aims to explore approaches that assist in adapting technological innovation projects in healthcare, considering the available materials and production processes below industry standards. The next section presents the methodology in the form of a bibliographic research on the role of materials and processes in product realization, as well as processes suggested by established authors in the field for conducting their selection. Subsequently, the study explains the life cycle of technological products developed in the healthcare sector and the impact of regulation on this process. As a result, the intention is to propose a flowchart of stages for research and selection of materials and processes that enable the small-scale production of high-fidelity medical device prototypes intended for clinical trials in low-complexity healthcare settings.

2. METHODOLOGY

This study is classified as an exploratory research based on bibliographic about materials and processes selection in product development for data collection [4]. Consequently, the aim was to guide the New Product Development (NPD) life cycle for healthcare, clarifying the need for aligning the project with regulatory requirements established by the National Health Surveillance Agency (ANVISA).

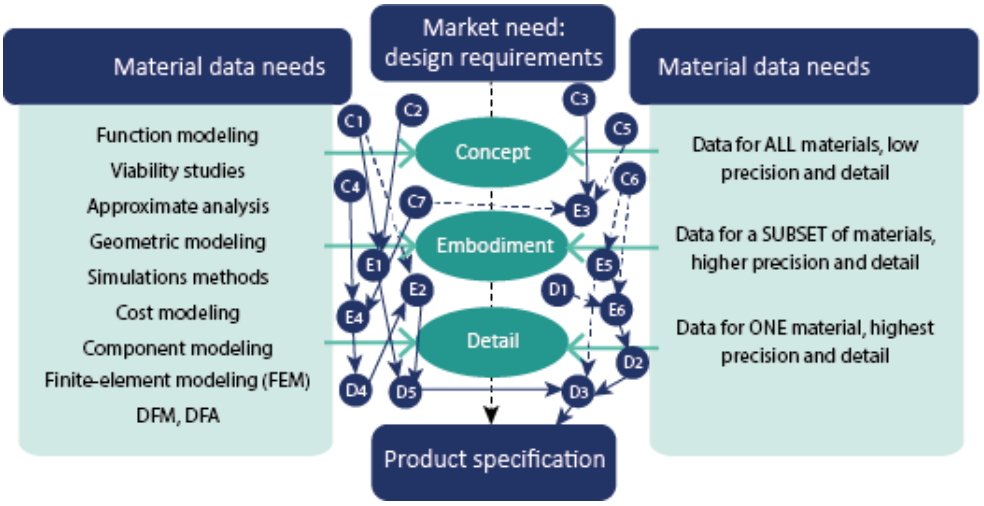
2.1 Material and process selection for Product Development

Establishing the shape of a product encompasses the selection of the material and process combined to build it [1]. The product's function leads to the definition of its form and the material used to materialize it. The nature and primary structures of each material dictate their capabilities. The processes, in turn, determine the shapes that certain materials can attain, as well as their size, precision, and cost [5]. In a bilateral relationship, the processes are influenced by the characteristics of each material, such as its formability, machinability, heat treatment, among others [1]. Therefore, these four factors - form, function, material and process - work in an integrated manner, affecting one another, and it is through the analysis of this interaction that the central point of the materials and processes selection lies [1].

Design for Manufacturing (DFM) proposes a systematic analysis of the necessary attributes in a part, followed by the selection of the materials and proces-

ses required to build it [6]. There are several methods and software tools available for technical designers and materials engineers, but how can we make this process accessible to other contexts with limitations in interpreting highly technical data? Figure 1 explains the process from project requirements to product specification.

Figure 1. Process from design requirements to product specifications, adapted from the book "Materials Selection in Mechanical Design"



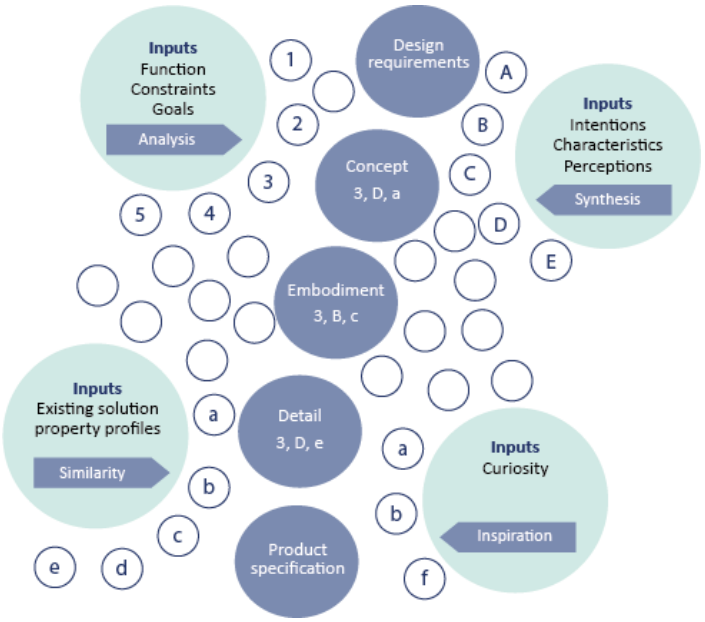
[1]

The image links the design tools applied at each stage of the process, along with the necessary material information, which evolves into the product specification. The process should connect the proposed concepts, illustrated by bubbles labeled “C+number” of the concept, to a preliminary design, expressed by “E+number”, and to its detailing, symbolized by “D+number”. The journey is iterative: conceptual and design choices may sometimes prove unfeasible when detailed, requiring reconfiguration or adaptation of the proposals.

Selecting materials and processes involves converting design requirements into a list of feasible options, which often deals with requirements conflicts. Ashby & Johnson [5] explain that problem-solving reasoning processes involve either deductive or inductive associations. Deductive reasoning relies on logic and analysis distributed in steps that use technical and mathematical data for decision-making. It forms the basis for the analytical selection process, relying on well-established rules for selection, which starts with an analysis of the product's functions and requirements compared to the technical characteristics of materials. Inductive reasoning, on the other hand, is based on accumulated data resulting from our observation and interpretation of facts, guiding choices based on the subject's experiences. This approach supports selection methods through synthesis, similarity, and inspiration. Selection by synthesis relies on examples of previous projects, "solved problems" with similarities to the current project. Selection by similarity analyzes similar materials, seeking a substitute for the material usually used if it does not meet specific design requirements. Selection by inspiration, on the other hand, occurs more casually, triggered by an "inspiring" experience that sparks creative thinking. In line with this, Boothroyd *et al*. [6] suggests conducting an economic evaluation of competing processes and materials during the conceptual phase of the product. This way, by reaching the detailed design phase, knowledge about economically viable options is available, increasing the chances of selecting those that offer the best cost-benefit ratio.

Each of the aforementioned methods, therefore, relies on a specific data source, making their use dependent on the quantity and content of information available to the designer. At times, design requirements may lack well-defined specifications, which hinders the use of the analytical method. In such cases, the synthesis method can facilitate the selection process by generating potential solutions through the analysis of other similar products, summarizing material and process information about them. However, if there are no specified products as data sources, the similarity method can guide the search for materials with profiles similar to what is being sought. Ultimately, the solution may come through the analysis of randomly chosen products, gathering data and using the findings as a source of inspiration. Analyzing the functioning of each method, their complementarity becomes evident, which inspired Ashby & Johnson [5] to propose their integration in the materials selection process (figure 2).

Figure 2. Models operating from project specification to product detailing



[5; 1]

By combining the four methods, the selection is carried out according to the data accessible to the project. As illustrated in figure 2, each method generates a series of possibilities, represented by the "bubbles" on the sides of each method, which must meet the requirements and be gradually evaluated for technical feasibility as the concept is built and evolves into detailed design. As said, the process is iterative and concludes when the connection between need, concept, and each material and process involved in the established proposals is viable. The central, colored bubbles indicate the concept, preliminary design, and detailed design formed from the combination of data provided by the methods. The suitability of this procedure for application in small organizations developing new healthcare products is addressed in the following section.

2.1 Material and process selection for Product Development

The life cycle of a medical product should follow a sequence of fundamental phases to ensure the quality, safety, and effectiveness of the medical device. However, the prototype production stage, in particular, is significantly influenced by

the available infrastructure, equipment, workforce, and materials [8]. As a result, small organizations with deficiencies in these aspects operate at a disadvantage. Boothroyd *et al.* [6] explains that the selection of materials and processes in the early stages of a project should consider requirements such as: the required production volume; the possible categories of part shapes and their levels of complexity; appearance and accuracy factors; allowed levels of tooling costs, and the requirements of the service or environment to which the product is intended. In this sense, selecting the appropriate processes for manufacturing a specific part should take into account the combination of the part's necessary attributes, the material characteristics and the capabilities of the process [6; 5; 1].

To ensure the safety and effectiveness of medical devices (MDs), ANVISA uses a set of action instruments, such as legislation and technological devices, to regulate and control the risks associated with these devices [3]. From the product development phase, risks related to the use of materials, their characteristics and compatibility with the intended function must be considered and controlled. Among the measures to ensure safety, MDs developed in Brazil must pass through Clinical trials. There are hundreds of technical standards within the scope of ABNT/ISO applicable to different stages of the MD production process. The specifications about materials vary primarily based on the sterilizing agent used, the type of product to be sterilized, the required controls for monitoring and validating the sterilization process. Therefore, the construction of MDs intended for clinical trials, even in the form of prototypes, must comply with the current regulations to meet evaluation criteria.

Once the requirements of the MD are defined, and the safety, biocompatibility, sterilization, and other relevant regulations it must meet are acknowledged, potential materials for its construction must be identified. Consideration is given to characteristics such as mechanical and chemical properties, commercial availability and cost, which can be found in technical literature, supplier catalogs, and expert advice in the field. This search can be aligned with Ashby & Johnson [5] proposal for integrating selection by analysis, synthesis, similarity or inspiration (figure 2). The concept is incorporated into a preliminary design and analyzed, where viable materials are chosen to meet the requirements. In the detailing phase, each component must be analyzed, along with each material and process used to enable them, prioritizing those with the best cost-benefit ratio for the project. The feasibility of each process must be assessed based on the complexity of the design, accuracy, intended production batch, "necessary x available" time and the characteristics of the chosen materials [6; 5; 1].

The following step involves testing and iterations with the selected proposal to execute the conceptual solutions of the project. As stated by Thompson [8], the technological structure, human resources and materials in the context where a product is built determine its quality, aesthetic aspects, manufacturing speed, costs and environmental impacts involved. Therefore, prototyping requires the analysis of possible ways to materialize the model, guiding the alignment of the concept with a development strategy that meets the local limitations and possibilities for its production [9]. When dealing with low-volume production, without industrial equipment for mass production, the possibilities for high-fidelity product manufacturing are more restricted. The processes tend to be more manual, which can hinder process accuracy. Thompson [8] indicates four main categories of forming technologies that can be used in these contexts: molding and casting - used to transform materials such as metals and plastics into complex shapes, using

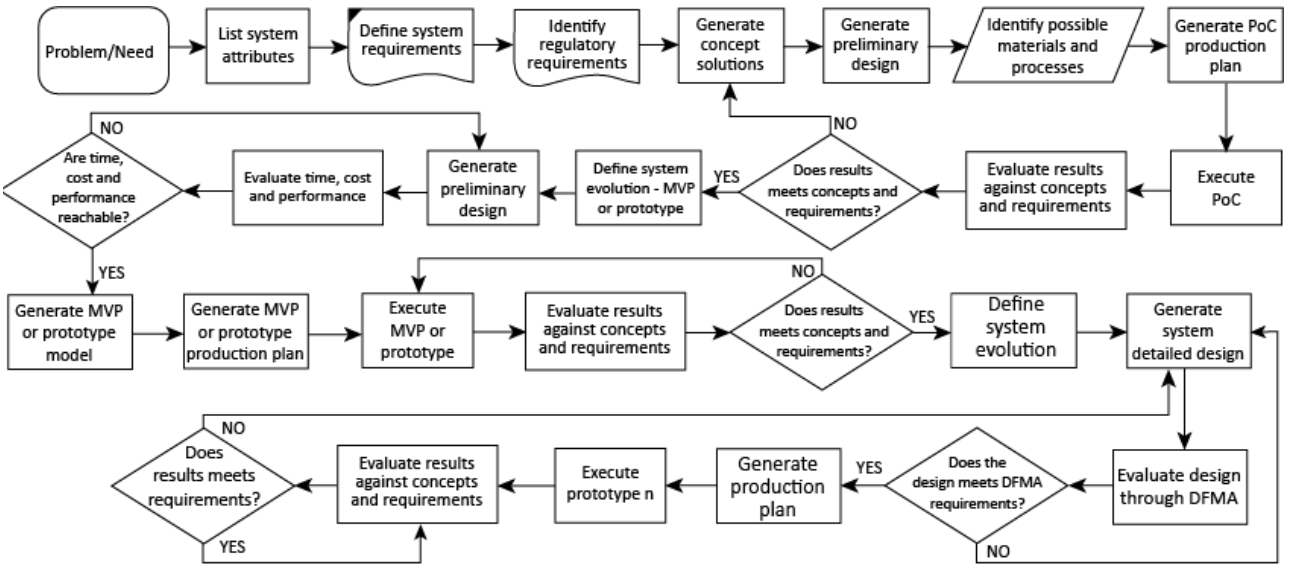
techniques like vacuum forming and reactive injection molding (RIM); machining and cutting - applying reduction processes like CNC, EDM, laser cutting, photochemical machining, water jet cutting, grinding, sanding, and polishing; bending and pressing - utilizing the ductility and elasticity of materials to mold them using various techniques, depending on the material; rapid prototyping - layer-by-layer construction processes based on a digital model using different materials.

Different forming processes can be applied based on design intention, considering the aforementioned requirements necessary for their selection. In the case of prototypes, it is essential to establish the functions that will be evaluated with the materialization of the solution. For MDs developed for clinical trials, prototypes play a crucial role in enabling the testing of various aspects of the proposal, such as form and function evaluated in real situations, compliance of the proposal with sanitary restrictions, mechanical strength of materials, production and assembly time, among others. They allow the analysis of the solution from different sources and angles, so that feedback from healthcare professionals and patients can be incorporated into the process to improve the design. The next item illustrates the knowledge gathered in this study in a step-by-step flow, considering the requirements and general activities of each one.

3. RESULTS AND DISCUSSION

Given the above, the organization and integration of activities required for the selection of materials and processes for the production of medical device prototypes, destined for clinical trials, is crucial for the success and efficiency of this complex procedure. Each step plays a fundamental role in ensuring scope compliance and project suitability to make it viable in a specific context. To meet the inherent requirements of quality, safety, and efficacy in the production of medical devices, the choice must be systematized, considering factors such as material properties, technical and regulatory requirements, and possible processes. The flowchart illustrated in Figure 3 aims to provide a brief guide to the procedure, outlining the basic stages for the development of medical devices in the pre-industrial stage.

Figure 3. Flowchart for Selection of Materials and Processes for Medical Device Prototyping



Each step illustrated above assumes a set of activities for data collection and analysis that guide decision-making and the continuation of the process. Each analysis allows for revisiting previous steps to make necessary adjustments as needed. Prolonging any inadequacy can lead to delays and increased rework. Compliance with regulations is a critical aspect in the construction of these devices, so organizing the steps of material and process selection to ensure compliance facilitates confident decision-making. This, in turn, facilitates the process of obtaining necessary certifications, ensuring that the device meets all safety and quality requirements.

The lack of accessible methods to guide the development process of medical devices in limited contexts represents a significant barrier to innovation. In regions with less advanced industrial development, the lack of infrastructure, technical resources, and specialized workforce can limit the innovation process. Prototyping tools, simulation software, and advanced technologies often come with prohibitive costs for small companies or institutions working on innovations in these locations. The lack of access to these resources can restrict the ability to conduct tests and iterations and affect creative potential, delaying the development of essential medical solutions for these regions.

The absence of specific studies addressing the needs and particular challenges of these regions hinders a complete understanding of these scenarios and their specific demands. The lack of data and research on this subject hampers a targeted and efficient approach in creating medical devices adapted to territorial specificities. In this sense, it is crucial to encourage and promote research and studies that explore the feasibility and effectiveness of medical device prototyping in these environments. This will allow for a deeper understanding of local needs and, consequently, the direction of actions to mitigate the adverse effects that the deficiencies of the scenario bring to the innovation process. The study presented here, along with the proposed organization of activities illustrated in figure 3, aims to assist in this process. As the designer conducts the construction of the project in accordance with local particularities, there is an increase in the feasibility of its production in the region.

4. CONCLUSION

The development of medical devices is a field of utmost importance for the evolution and accessibility of healthcare treatments, where technological innovation becomes a powerful ally. Traditionally, developing these devices requires infrastructure and technology facilitated by a high degree of industrial development in a region. The lack of comprehensive studies and the scarcity of accessible methods to conduct this process in late-stage industrial development economies represent a significant challenge for professionals and residents in the area. Through structured planning, possible obstacles can be identified, along with anticipating solutions to avoid delays and rework. Moreover, an organized approach enables a more comprehensive analysis of the implications of each decision, allowing for the selection of the best alternatives for each component of the medical device. The organization and integration of selection stages also contribute to cost reduction and resource optimization. By avoiding inadequate choices and rework, prototype development can be more economical and efficient, enabling the medical device to reach healthcare systems more quickly.

The lack of studies related to technological innovation development in limited contexts, along with the scarcity of accessible methods to conduct this process, must be addressed by promoting research and collaboration among different stakeholders in the search for innovative solutions. Cooperation between educational institutions, research centers, and private companies is fundamental to foster this discussion and drive healthcare innovation in late-stage industrialization economies. By sharing knowledge, resources, and experiences, it is possible to find creative and efficient solutions to overcome challenges and advance in creating quality healthcare solutions, regardless of their geographical and socioeconomic circumstances. The search for methods that make the development process of medical devices more accessible, considering local demands and the context of their manufacturing, can favor the democratization of technology access and promote healthcare innovation in these regions. In conclusion, medical device prototyping is a complex and critical journey that requires robust planning and organization. The seamless integration of material and process selection stages is essential for the successful development of innovative medical products that meet the needs of the healthcare field and drive significant advancements in medicine. Through a careful approach, we can promote continuous improvement in patients' quality of life and the advancement of medical technology as a whole.

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