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3D DESIGN AND PRINTING OF MEDICAL PROSTHETIC - TECHNICAL AND ECONOMIC ASPECTS

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Abstract: *The present research is based on the need to create synergy among three essential elements for building a sustainable and healthy society: entrepreneurship, medical engineering, and the healthcare sector. By 2027, Romania will receive substantial funding through operational programs and the National Recovery and Resilience Plan (PNRR) for the development of businesses in urban and rural areas. Furthermore, research and development of new biocompatible products that can be 3D printed, are essential for societal advancement. The utilization of products created by entrepreneurs with the support of researchers will contribute to solving medical challenges more quickly and cost-effectively.*
Key words: *medical engineering, 3D printing, european grants, entrepreneurship, management, start-up.*

1. INTRODUCTION

In the last decades, medical engineering has undergone a remarkable evolution, bringing significant innovations to the field of healthcare. One of the key technologies that has facilitated this evolution is 3D printing. With the help of non-repayable funding, this technology has found its place in medical research and development, contributing to the improvement of medical care, customization of treatments, and cost reduction.

Analyzing the strategic documents, existing scientific works, and a series of companies operating in technical fields (metal processing, construction, electrical installations, 3D design and printing of medical devices) funded through these non-repayable grants, we have identified a significant potential for the development of the medical engineering sector. This becomes even more crucial when we delve deeper into the situation of entities funded through non-repayable funds and observe that there is still no established connection with the academic sector and the research, development, and innovation sector. [1]

In a research study conducted in the year 2021, among entrepreneurs funded through non-repayable funds (both through the National Rural Development Program [2] and the Human Capital Operational Program [3]) and the research infrastructures they have accessed, we found that the connection is almost non-existent. Despite the fact that the academic environment and research infrastructures are developing new technologies and concepts, these companies have not integrated them [1].

Taking Romania as a case study, we conducted an in-depth research on the types of non-repayable funding allocated to startups in Romania. Non-repayable funding is particularly important as Romanian entrepreneurs choose these grants to put their business ideas into practice, taking advantage of the non-repayable funding received [4]. As mentioned on the official website of the Ministry of Investments and European Projects, during the period from 2018 to 2020, over 290 million euros were allocated (through the Human Capital Operational Program) [5] for the establishment and development of startups, leading to the creation of over 9,000 companies. Researching this funding sector is crucial to assess the sustainability of funded firms involved in the field of medical engineering, prosthetic design, and production, as the volume of non-repayable

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funding to be granted between 2021 and 2027 exceeds 330 billion euros [6]. Additionally, ING Bank has compiled a "dashboard" [7] for non-repayable funding, mentioning that Romanian entrepreneurs will have access to over 8 funding programs in various fields starting from 2023.

Analyzing the existing scientific studies and specialized materials regarding non-repayable funding for such companies, we can identify scientific articles presenting applied research of engineering companies funded as early as 2014. In 2014-2015, through the Sectoral Operational Program for Human Resources Development 2007-2014, Social Economy Structures (SES) were funded, with amounts ranging from 100,000 to 200,000 euros to develop businesses. One of the businesses funded through POSDRU was the entity "Atelierele KOTYS" [8]. The non-repayable funding was 98%, allowing the business to grow by acquiring new high-performance equipment for metal and glass processing. The analysis of this organization reveals annual revenue growth over a period of 3 years (2015, 2016, 2017). During this period, the entity increased its revenue from metal and glass processing from 26,000 euros in 2015 (Average exchange rate for 2015 according to BNR: 1 Euro = 4.4450 RON) to over 188,000 euros in 2017 (Average exchange rate for 2017 according to BNR: 1 Euro = 4.5681 RON).

Furthermore, a research study was conducted among 20 companies in the South-Muntenia region [1], funded between 2018 and 2020 through the European Social Fund, the Operational Program Human Capital 2014-2020, Priority Axis 3 "Jobs for All," state aid scheme Romania Start-Up Plus - POCU/82/3/7/105905 [9], [10]. The aim was to identify performance indicators at the operational, financial, and profitability levels. Financial sustainability was identified in four firms operating in sectors such as "Manufacture of other fabricated metal products, Repair and maintenance of motor vehicles, Electrical installation work, Floor and wall covering work." All these firms recorded a current funding rate between 44% and 60% in the years 2019-2020, and a global indebtedness rate between 39% and 55%. The rest of the companies operating in different fields, especially those in services such as tourism, restaurants, consulting, did not register financial performance indicators in the two years analyzed.

Analyzing these opportunities for development in the field of medical engineering and management, in conjunction with the sources of funding that will be allocated for business development in this domain, we consider it necessary to approach this subject from a scientific perspective. In the field of medical engineering, businesses are beginning to see significant growth in the 3D design and printing segment. Biomaterials are becoming increasingly important in medicine due to their properties (osteogenic, osteoconductive, mechanical support and stability, etc.), making them ideal substitutes for bones [11].

On a large scale, the most widely used biomaterial is Polylactic Acid (PLA), which is also used by the company analyzed in this article. PLA can be produced from resources such as corn starch, and when combined with other compounds (typically compounds with better mechanical and antiseptic properties), it can be layered to create various prosthetics using 3D printing technology [12], [13].

Medical engineering represents a continuously developing field, where technical expertise meets the specific needs of modern medicine. 3D printing or additive manufacturing has revolutionized the production of medical devices and replacements for tissues or organs affected by conditions or injuries. From personalized prosthetics to organ models for planning complex surgical interventions, this technology has had a positive impact on patient treatment.

Non-repayable funding provided by various governmental organizations, foundations, or private companies has been essential for promoting research and projects related to medical engineering utilizing 3D printing. These fundings have enabled:

a) Personalization and more efficient treatments: With the aid of 3D printing, medical devices can be tailored to individual patient needs, thereby increasing the success of medical interventions.

For instance, customized implants and prosthetics created through 3D technology can perfectly match the patient's anatomy, reducing the risk of rejection or other complications.
b) Cost reduction: The use of 3D printing in medical engineering can lead to a significant decrease in costs, especially concerning prototypes and personalized devices. Moreover, this technology enables local and rapid production of devices or spare parts, eliminating the need for costly imports and transportation.
The main applications of 3D printing in medical engineering are:
a) Production of personalized prosthetics and implants: 3D printing allows the creation of personalized prosthetics and implants, uniquely tailored to each patient. These can be manufactured from biocompatible materials, such as titanium or bioabsorbable polymers.
b) Organ and tissue models: 3D printing can create accurate models of organs and tissues, which assist doctors in planning complex surgical interventions and understanding the anatomy of challenging cases.
c) Innovative medical devices: 3D technology enables the design and manufacturing of innovative medical devices, such as microdevices for controlled drug release or personalized devices for health monitoring.
One of the most impressive advances is represented by 3D-printed hip prostheses, offering an innovative solution for patients with severe joint issues. This technology, combined with advanced materials, allows for the creation of personalized, durable, and functional prostheses that significantly improve the quality of patients' lives.

2. 3D PRINTING AND THE MEDICAL REVOLUTION

3D printing, also known as additive manufacturing, is a process for creating numerous objects and parts, including medical prosthetics, using a 3D printer and specialized software. The production process is not difficult, as the machine has the ability to deposit layer upon layer of material in accordance with the information input into the software until the object/prosthesis is completed. Implants and prosthetics can be printed in almost any geometry by decoding X-ray, MRI, or CT scans into 3D printing files. One significant benefit offered by 3D printing technology is a substantial reduction in production costs.

Manufacturing prosthetics using traditional methods is viable only for mass production. The cost of designing and 3D printing an object remains the same regardless of the volume of objects produced. This is advantageous, especially for companies with low production volumes or those producing complex parts or products that require frequent modifications, as is the case with the organization under analysis [14].

2.1. Materials used in 3D printing of hip prostheses

In addition to metallic materials used for creating prosthetics and implants, biomaterial polymers have the highest potential for 3D printing and can be categorized into synthetic and biologically derived polymers. Another important aspect is not only the printing potential but also the use of these polymers for other purposes. According to a study conducted by Kim [15], 3D printed implants can efficiently serve as a means of drug delivery into the body by incorporating antibiotics directly into the polymer and transporting it to the desired area. Natural polymers cannot be used as standalone implants due to their lack of favorable mechanical properties. Polymers such as poly(lactic-co-glycolic acid) (PLGA) and poly(ε-caprolactone) (PCL) have been produced using 3D printing technology [16]. Although they undergo biodegradation due to wear and tear, the fact that they can be used to deliver various nutrients absorbed by the body from the prosthetic area, have a very low toxicity threshold, and can be manufactured more easily and cost-effectively is a significant economic advantage for companies engaged in the design and 3D printing of prosthetics and implants.

3. THE BENEFITS OF 3D-PRINTED HIP PROSTHESES

This technology offers more flexibility in both design and production, which is a significant advantage for medical engineering. Taking these factors into account, we have investigated the financial situation of the company "All 3D Works," which designs and prints prosthetics and orthotics for both commercial purposes and research projects in collaboration with the University of Medicine, Pharmacy, Sciences, and Technology of Târgu Mureș and the Emergency Institute for Cardiovascular Diseases and Heart Transplant of Târgu Mureș [17].

Personalization and Customization: One of the most significant advantages of 3D printing in hip prosthesis manufacturing is the ability to create personalized implants. Each patient's anatomy is unique, and 3D printing enables the fabrication of implants tailored to match the patient's specific requirements. This level of customization enhances the fit and functionality of the implant, ultimately leading to improved patient outcomes.

Complex Geometries: Hip joints are intricate structures, and traditional manufacturing techniques often struggle to produce implants with complex geometries. 3D printing excels in creating intricate shapes and structures that would be challenging or even impossible to achieve using conventional methods. This capability allows for the optimization of implant design for better biomechanical performance.

Reduced Lead Times: Traditional manufacturing processes for hip prostheses can be time-consuming, involving multiple steps and manual labor. 3D printing streamlines the production process, significantly reducing lead times. This efficiency is particularly crucial for patients requiring urgent surgical interventions.

Material Flexibility: 3D printing offers a wide range of compatible materials, including biocompatible metals and polymers. This allows surgeons to select materials that closely match a patient's physiological characteristics, enhancing the longevity of the implant and reducing the risk of adverse reactions.

Enhanced Surgical Planning: 3D printing facilitates the creation of patient-specific models based on medical imaging data. Surgeons can use these models to practice and refine their surgical approach before the actual procedure. This preoperative planning improves the accuracy of surgery and reduces potential complications.

As seen in Fig. 1, the hip of the patient was scanned with the help of the CT image acquisition machine GE Revolution HD and after that with the help of Slicer3D software the scanned slices were cleaned and processed to obtain a 3D model of the hip following as after that the 3D model generated by the Slicer3D software to be post-processed in Meshmixer software created by Autodesk in order to close all the holes in the model and to be exported as a manifold 3D model.

The next step is to slice the digital 3D model in the 3D printer slicer and input all the necessary parameters in order to 3D print the model, for this it was used by All3Dworks the Prusa Slicer software (Fig. 2)

The result is the hip printed in polylactic acid (PLA) (Fig. 3) with the internal structure as close as it can to the natural hip, thus helping, as described previously, that surgeons to use these model to practice and refine their surgical approach before the actual procedure.

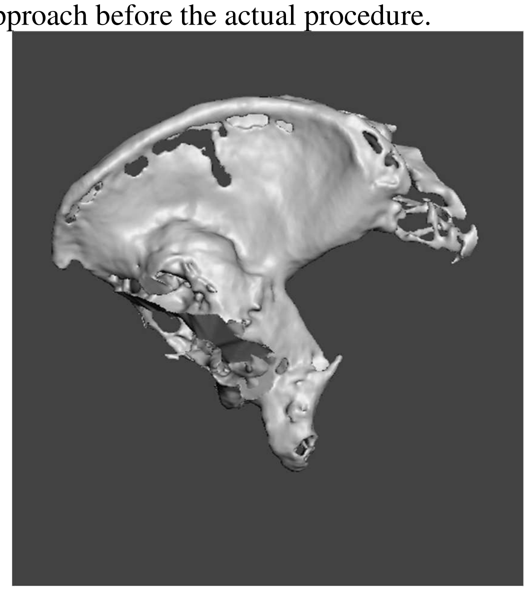

Figure 1. Image from the programme before printing

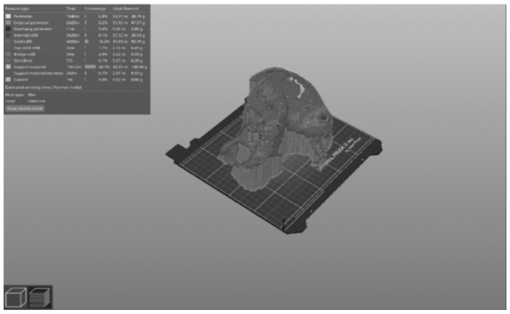

Figure 2. Image from the programme before printing

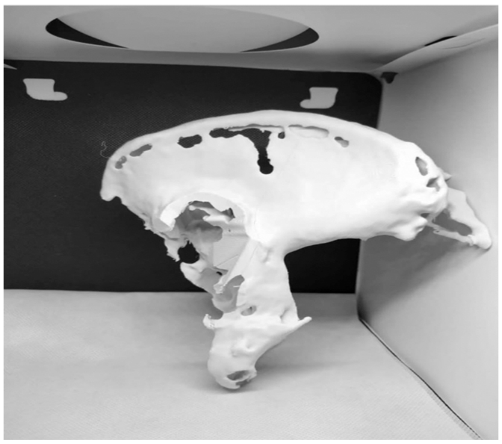

Figure 3. Printed Hip Prostheses

During the development of this article, we had a valuable collaboration with ALL3DWORKS, a company engaged in rapid prototyping. This company provides its clients with three comprehensive services essential for project development: 3D Printing, 3D Design, and 3D Scanning.

4. ALL 3D WORKS IN NUMBERS

This is a company that operates in 3D design and printing and was funded through the Human Capital Operational Program 2014-2020, Priority Axis 3 "Jobs for All," state aid scheme Romania Start-Up Plus - POCU/82/3/7/105904, with a 100% non-repayable grant worth approximately 40,000 EURO (177,060.00 RON). Financial value represents a crucial element in the quantitative assessment of a company's activity. By examining this aspect, we can evaluate the enterprise's capacity to generate revenue from its operations.

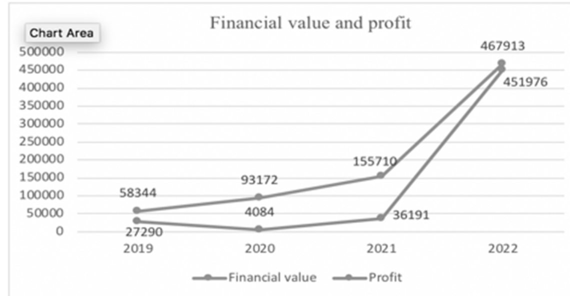

Figure 4. Financial value and profit recorded during the period 2019-2022

According to financial results, the company experienced a decrease in profit in the year 2020 compared to 2019, with a value of (-23,206), representing an 85 percentage point reduction in profit. This decline was attributed to increased labor-related expenses. After the pandemic period, the company began to show upward trends, and in the year 2021, the profit reached a level of 36,191 lei, marking a significant expansion of 786% compared to 2020. Between 2020 and 2021, the firm developed a website to streamline customer access to its services. The positive impact of this platform became evident in 2022 when the majority of orders were placed online, resulting in a profit of 451,976 lei, signifying an exponential growth of 1149%. At the end of the four-year period, the company records an EBITDA of 479,741. The team of employees within a company constitutes the engine that drives its operations, and evaluating their productivity becomes crucial. By analyzing relevant information, informed decisions can be made to optimize the efficiency of the workers and, consequently, the entire activity.

All 3D Works is a microenterprise where the personnel composition consists of the single associate and one current employee. Throughout the 4-years period of activity, the company had a maximum of 2 employees in the years 2019 and 2020, while in the years 2021-2022, the number of employees reduced to a single individual. Given the small size of the company, the personnel productivity in the years 2021-2022 corresponds to the total financial value, with the note that approximately 80% of the work performed comes from the single associate. For the organization "All 3D Works," resource consumption parameters represent a crucial aspect. The company has 5 3D printers, requiring both raw materials and projects developed by the employees. The production process is primarily managed by the team of specialists, who monitor and conduct checks for prints that require more time (4-6 hours). Analyzing data related to resource consumption provides significant opportunities for improving efficiency.

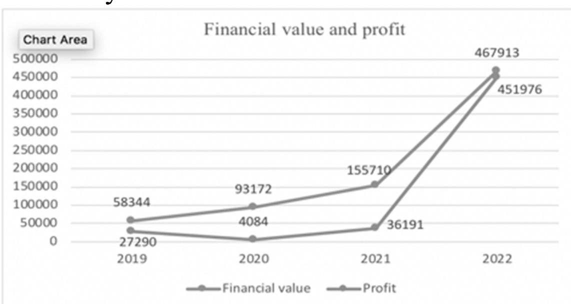

Figure 5. Graph of expenses

The organization "All 3D Works" pays special attention to resource consumption indicators. With a fleet of 5 3D printers, the production flow requires a constant supply of raw materials, along with internally developed projects. The production process is primarily guided and supervised by experts, with a focus on ensuring quality, especially for extended-duration prints (4-6 hours). By analyzing consumption indicators, the company finds a valuable opportunity to enhance efficiency and performance. As shown in Figure 5 and Table 1, operating expenses (from own resources, not from the non-repayable grant received) experienced an increase in the first 3 years, followed by a decrease in 2022 to the level recorded in 2019 when the company was established, at approximately 12,000 RON. In the first 3 years, these costs saw a constant increase because the business plan mainly included equipment expenses and very few expenses related to the company's operation. For this reason, these expenses were covered by the company (the largest budgets were allocated to marketing, promotion, and customer identification). This aspect reveals that the company begins to achieve financial stability after establishing itself in the relevant market and forming partnerships with healthcare entities in Târgu Mureș, where it is most active.

In practice, this collaboration with the healthcare system, as well as with the academic environment supporting the development of new 3D printing products and techniques, brings in higher revenues for the company (467,943 RON in 2022 compared to 29,172 RON in 2019) and lower operating expenses (marketing and promotion budgets and customer identification expenses disappear, with operating expenses decreasing from 12,298 RON in 2019 to 12,656 RON in 2022). Paradoxically (from 2 employees in 2019 to 1 employee in 2022, and from 53,461 RON in 2020 to 1,687 RON in 2022), the startup's revenue has increased significantly (from 12,298 RON in 2019 with 2 employees to 46,586 RON in 2020 with 2 employees, and further to 155,710 RON in 2021 with 1 employee and 467,913 RON in 2022 with 1 employee). Once again, this aspect highlights that the labor efficiency and the 3D printing technologies used are becoming increasingly efficient, eliminating the need to hire a large number of designers or medical engineers to produce the parts required by medical entities.

5. SWOT ANALYSIS OF THE BUSINESS

The entity operates as a business founded by an associate with expertise in technical design and deep knowledge in the field of 3D printing, eliminating the need to hire a designer or a specialized technician in 3D printing. By utilizing state-of-the-art printers, the company achieves rapid and highly precise results. This represents a cost-effective solution, avoiding additional costs associated with external hiring.

A significant strength of the company lies in the limited competition. In the central and north-western regions of Romania, the notable companies in the 3D printing field include Renegades 3D, Control 3D, 3DMinime, Prototype Studio, and Cluj Makers. Simultaneously, in Târgu-Mureș, there is only one company operating in this field, but it applies excessively high rates for its services, which can be discouraging for regular consumers.

With the advantage of its cutting-edge technology, the company will not only compete with these enterprises but can even surpass them due to its comprehensive service package, more affordable prices catering to all types of clients, and the well-established experience in the field of 3D modeling.

Another distinctive advantage of the company lies in the extensive variety of raw materials used and the diverse technologies applied. This allows the company to precisely adapt to the requirements of each client, eliminating the need for compromises in terms of the quality of the printed products.

Tabel 1 . S.W.O.T. Analysis

Strengths	**Weakness**
1.CAD and technical drawing skills; 2.3D printer operation knowledge; 3.CAD consultation prior to part production; 4.State-of-the-art technology.	1.Limited Equipment 2.Limited Capital 3.High Specialized Equipment Costs
Opportunities	**Threatens**
1. The possibility of creating a unique, personalized, innovative product. 2. Changes in consumer preferences. 3. A new market. 4.Increasing market demand. 5.Prostheses and medical implants.	1. Existing companies in the field on the market.

Performing a SWOT analysis, based on Table 2, for the company under study, we observe that among its strengths, we identify CAD technology, which the entrepreneur is highly proficient in, along with the necessary knowledge for 3D printing through specialized printers. The need to acquire increasingly advanced equipment and technologies is seen as a weakness, especially since the entrepreneur hasn't pursued additional grants for expansion after receiving initial funding to start the business. However, new opportunities for business expansion in various sectors have been identified, without excluding the medical sector, even though competition in this sector is on the rise.

6. CHALLENGES AND FUTURE DIRECTIONS

In order to achieve synergy among the three components (the business environment, research institutes/researchers, and the healthcare system) for the period 2021 - 2027, the European Commission has allocated grants and loans through the NextGenerationEU program to support reforms and investments in EU member states, totaling 723.8 billion euros. Out of this total, 338 billion euros will be provided to member states in the form of grants. The allocation of these funds will be distributed across various sectors. Pillar 2, Economic Recovery and Support for Private Investments, will receive an allocation of approximately 56.3 billion euros, while Pillar 3, Smart, Sustainable, and Inclusive Growth, from the National Recovery and Resilience Program (PNRR), will have an allocation of up to 2.359 billion euros for the development of the private sector and the strengthening of Research and Innovation. Pillar 5 of the PNRR, primarily dedicated to the Healthcare sector, as well as economic, social, and institutional resilience, will have a total budget of 2.455 billion euros.

While 3D printing holds immense promise in hip prosthesis manufacturing, there are still challenges that need to be addressed. Quality control, regulatory approvals, and standardization of processes are critical aspects that must be refined to ensure patient safety and the efficacy of 3D-printed implants. Ongoing research and collaboration between engineers, surgeons, and regulatory bodies will play a crucial role in overcoming these challenges.

By offering patient-specific customization, intricate designs, reduced lead times, and enhanced surgical planning, 3D-printed hip prostheses are paving the way for improved patient outcomes and higher quality of life. As technology continues to evolve and healthcare embraces innovation, the marriage of 3D printing and hip prostheses showcases the immense potential to reshape the landscape of medical interventions.

In Figure 6, we have created an illustrative diagram to clearly and concretely highlight the essential connection that should exist between entrepreneurs, the academic environment, and medical institutions. Additionally, the necessary flow of this collaboration is depicted, along with the potential non-repayable funds that can be accessed to establish and finance a startup.

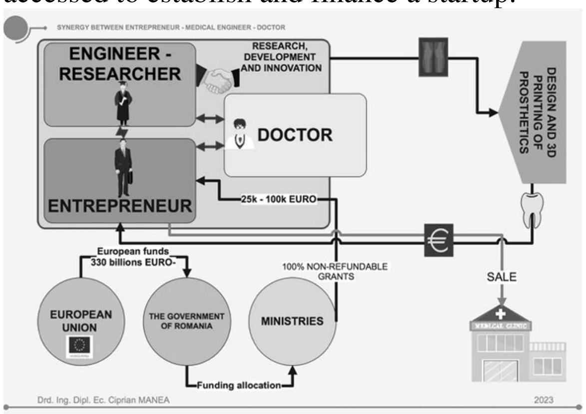

Figure 6. Diagram: Entrepreneur - Engineer - Researcher - Doctor (Source: the authors)

7. CONCLUSIONS

The conducted research presents the relevant aspects of the economic and financial analysis carried out within the organization All 3D Works, an organization engaged in 3D design and printing activities. The research results, conducted over a four-year period from 2019 to 2022, using information from balance sheets and profit and loss accounts, lead to the following conclusions:

From a financial performance perspective, All 3D Works consistently records profits throughout the analyzed period, with a significant increase starting in 2021 when collaboration with researchers in the field of medical engineering and doctors within the Târgu Mureș healthcare system commenced. Additionally, these profits are complemented by 3D printing activities for private clients conducted through the company's online platform, designed for service promotion and online order processing. However, in 2022, there was a substantial 89% reduction in these expenses compared to 2021, despite a considerable increase in revenue. This decline was attributed to the entrepreneur's accumulated expertise in the field of 3D design and printing, the identification of new suppliers to ensure the necessary raw materials for prosthetic creation and other objects using 3D printing technology.

Moreover, the reduction in personnel, based on the entrepreneur's experience, also contributed to the expense reduction. Regarding the progress in expenses, the rate of total expenditure efficiency saw an increase until 2021. However, in the year 2022, it dropped to 27 lei expenditure per 1,000 lei of income, compared to the previous year when a rate of 638 lei expenditure per 1,000 lei of income was recorded. These changes indicate the company's efforts to optimize resource utilization and enhance overall operational efficiency.

Additionally, from an economic perspective, the success of this company is primarily attributed to the fact that in 2019, for its establishment and acquisition financing, it accessed a non-repayable grant, relieving the entrepreneur of the burden of these costs. During the programming period of 2021 - 2027, non-repayable funding for start-ups could be an opportunity for graduates in medical engineering with entrepreneurial skills to independently implement the scientific knowledge they have acquired about medical engineering and its implications in current medicine.

The success of 3D printing in manufacturing hip prostheses results from collaboration across multiple disciplines. Engineers, researchers, orthopedic surgeons, radiologists, and regulatory agencies all play a crucial role in ensuring the safety and efficacy of 3D printed implants.

As technology advances, partnerships between research institutions, medical centers, and industry entrepreneurs are likely to grow, and European guidelines for non-repayable funding encourage these practices, which can be accessed by certain categories of individuals.

This collaboration will accelerate the development of standardized processes, regulatory guidelines, and quality assurance protocols. Ultimately, the goal is to make 3D printed hip prostheses a general option accessible to a broader population of patients in need. This approach also has psychological benefits, as patients are more likely to have confidence in improved recovery and mobility.

Furthermore, the use of 3D printed models for surgical planning improves precision. Surgeons can simulate the procedure, analyze potential challenges, and develop strategies to address them before entering the operating room. This level of preparation translates into reduced surgical intervention time, fewer complications, and faster patient recovery. All of these elements compel us to continue researching this subject and put into practice the theoretical studies conducted by researchers. The business environment will benefit from substantial sums in the upcoming period for the acquisition of state-of-the-art technologies and equipment. Furthermore, the tripartite research approach involving medical engineering, 3D printing, entrepreneurship funded through non-repayable grants, and the current requirements of the healthcare system will contribute to synergy. This synergy will lead to significant progress in transitioning from the traditional economy to the circular economy, as mandated by European regulations. For instance, certain components or parts discarded by the healthcare system can be repurposed by entrepreneurs and medical engineers to create end-of-life treatment solutions, necessary for the transition to a Circular Economy.

8. ACKNOWLEDGMENTS

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Proiectare și printarea 3D a protezelor medicale - aspecte tehnice și economice

Rezumat: *Prezenta cercetare se bazează pe nevoia de a crea sinergie între trei elemente esențiale pentru construirea unei societăți durabile și sănătoase: antreprenoriat, inginerie medicală și sectorul sănătății. Până în 2027, România va primi finanțare substanțială prin programe operaționale și Planul Național de Redresare și Reziliență (PNRR) pentru dezvoltarea afacerilor în zonele urbane și rurale. În plus, cercetarea și dezvoltarea de noi produse biocompatibile care pot fi imprimate 3D sunt esențiale pentru progresul societății. Utilizarea produselor create de antreprenori cu sprijinul cercetătorilor va contribui la rezolvarea provocărilor medicale mai rapid și mai eficient din punct de vedere al costurilor.*

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