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Specificity of 3D Printing and AI-Based Optimization of Medical Devices Using the Example of a Group of Exoskeletons

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Featured Application: The application of this work concerns the use of 3D printing and AI as systems supporting the design and manufacture of medical devices, especially powered exoskeletons and passive orthoses.

Abstract: Three-dimensional-printed medical devices are a separate group of medical devices necessary for the development of personalized medicine. The present article discusses a modern and specific group of medical devices and exoskeletons, which aims to present our own experiences in the selection of materials, design, artificial-intelligence optimization, production, and testing of several generations of various upper limb exoskeletons when considering the Medical Devices Regulation (MDR) and the ISO 13485 and ISO 10993 standards. Work is underway to maintain the methodological rigor inherent in medical devices and to develop new business models to achieve cost-effectiveness so that inadequate legislation does not stop the development of this group of technologies (3D scanning, 3D printing, and reverse engineering) in the healthcare system. The gap between research and engineering practice and clinical 3D printing should be bridged as quickly and as carefully as possible. This measure will ensure the transfer of proven solutions into clinical practice. The growing maturity of 3D printing technology will increasingly impact everyday clinical practice, so it is necessary to prepare medical specialists and strategic and organizational changes to realize the correct implementation based on the needs of patients and clinicians.

Keywords: information technology; manufacturing; artificial intelligence; industry; process analysis; process optimization; medical devices; exoskeleton

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1. Introduction

In this study, the current state of the research field was carefully reviewed. The 3D printing of medical devices is becoming increasingly popular, but despite this, a review of the five major bibliometric databases found only 23 publications addressing this topic in both a scientific and practical way (industrial and clinical), allowing us to benefit from the experience of our predecessors.

Three-dimensional printing enables the rapid production of patient-specific personalized anatomical models (e.g., for assessing surgical access and practicing the procedure), surgical instruments, rehabilitation supplies (orthoses and exoskeletons), and implants [1–4]. These advantages make 3D-printed medical devices increasingly necessary. The availability of such devices in the US has recently been improved by the establishment of point-of-care (PoC) 3D printing centers, which has translated into a shorter pathway between the healthcare provider, the medical center, and the device manufacturer but has also blurred the regulatory differences and responsibilities between these entities [1,5]. Due to the need to update the regulations, the Food and Drug Administration (FDA) is working on guidelines for 3D printing PoCs to best prepare all of the stakeholders for the safe and effective use of 3D printing for medical devices [1,5]. The advantages of 3D printing when compared

to traditional preparation methods include flexible design, the printing of more complex designs, rapid prototyping, the mass printing on demand of personalized products, the creation of strong and lightweight components (including spare parts), faster design and production in line with the Industry 4.0 paradigm, waste minimization and environmental friendliness, profitability (even in short series), and ease of access (including from home). The disadvantages of 3D printing include the still limited (but increasingly wide) number of materials available for 3D printing, limited print size, the need for post-processing, the price of a single product not decreasing with the number of prints, the internal structure of the product depending on the technology, print inaccuracies, and problems with intellectual property rights for the designs [1,5].

Not only clinical but also logistic and regulatory aspects of the development of the above-mentioned technologies are necessary to ensure the safety and legality of personalized therapy [6–8]. Today, personalized treatment methods using 3D-printed medical devices can be employed in select complex cases, especially when conventional therapeutic methods are not effective. This reality needs to change so that 3D-printed solutions become a normal alternative to other ways of proceeding, rather than burdened with higher risks. Regulatory, economic, ethical, and organizational challenges were identified, but home and industrial applications have posed the highest number of challenges, while hospital applications have presented the fewest challenges [9]. The lower price of polymers may change the market situation for solutions made of titanium mesh plates, as 3D-printed parts are reliable and much cheaper than their traditional counterparts [10].

The situation of medical 3D printing is complicated by the fact that no internationally recognized general exception to intellectual properties rights enforcement (or health emergencies) has been observed. However, there are possible tools, such as compulsory licensing, voluntary licensing agreements, and the potential World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) exemptions [11].

Most controversial and diverging hypotheses concern research being conducted on the variance introduced during the digital conversion of images into models, which affects the resulting accuracy of the 3D print relative to the design intent and clinical requirements. This variance led to the introduction of metrics to measure the differences and degrees of variability between the models and the printouts to achieve their validation and technical control under the Industry 4.0 paradigm [12]. Regulations should, therefore, balance safety and effectiveness with innovation and autonomy in order to optimize the positive impacts on the efficiency of healthcare system procedures [13–16].

The present study discusses a modern and specific group of medical devices, exoskeletons, i.e., wearable robots that actively support human functions. This article aims to present our own experience in the selection of materials, design, artificial-intelligence optimization, production, and testing of several generations of various upper limb exoskeletons when considering the Medical Devices Regulation (MDR) [17] based on the ISO 13485 [18] and ISO 10993 [19] standards.

The scientific, technological, and clinical issues described in this paper are prototypical, and may be addressed in different ways with different medical solutions and for different markets, often for the first time. The examples presented herein could inspire independent research by scientists and clinicians. We know that such assemblages are not often encountered. However, in the case of exoskeleton technology, they are a necessity, as they allow us to analyze a medical device from different perspectives. The novelty of our approach involves directly sharing practical knowledge and experiences from the previous research on four different exoskeletons and presenting that knowledge against the background of state-of-the-art research. This approach will allow other researchers to better approach the subject of exoskeletons and replicate or improve the results of our research, bypassing our mistakes and the literature reviews. This factor constitutes the primary contribution of our article, as such works are rare but remain necessary for the development of science, technology, economy (including Industry 4.0 and eHealth), and clinical practice using exoskeletons.

2. Exoskeletons as 3D-Printed Medical Devices

A search of the five leading bibliometric databases using specific keywords (3D-printing, additive manufacturing, exoskeleton, etc.) returned only 20 publications (2015–2022). For comparison, the same search for the keywords 3D printing, additive manufacturing, and orthoses yielded 94 publications (2013–2022). We can, therefore, conclude that there are relatively few publications on exoskeletons. This factor highlights the need to intensify research and increase the number of scientific publications, especially since the above-mentioned 20 publications included three reviews [20–22] and two clinical trials [23,24] but no meta-analyses. In the case of 3D-printed orthoses, only four reviews and nine clinical trials were identified, with no meta-analyses.

The first review covered 3D-printed exoskeletons used in bone repair and regeneration, including biomaterials for their manufacture [20]. The second review underscored the role of exoskeletons in the rehabilitation of gait and posture among paraplegic patients and near hip and knee fractures and, in the case of 3D printing, highlighted the more effective role of personalized exoskeletons. With the development of artificial intelligence, breakthroughs and wider applications of exoskeletons in the rehabilitation of trauma patients are expected [21]. The third review demonstrated that the combined potential of cutting-edge developments, such as connected care, artificial intelligence, 3D printing, and reality-mimicking prosthetics could result in a breakthrough in the treatment of patients with musculoskeletal conditions. Cost-effective and precise interventions could, in the future, be based on realistic biomarkers and algorithms used to assess patients and generate alerts about deterioration [22]. A study by Yoo et al. proposed a novel 3D-printed hand exoskeleton controlled by electromyography (EMG) signals for spinal cord injury (SCI) patients to support the grasping functions among those with cervical SCI with tetraplegia. Not only was this device found to be effective, but most participants were also satisfied with the device, with no side effects [23]. A study by Ou et al. proposed an anterior–posterior exoskeleton for stroke patients as a robotic assistive device to support upper limb rehabilitation and thereby restore motor function related to the maintenance of activities of daily living [24].

3. Own Studies

A 3D-printed exoskeleton has a certain specificity that distinguishes it from other 3D-printed medical devices:

1. An exoskeleton is a robot for people with deficit(s) that actively supports the user's movement and must:
    - Be adapted to the dimensions of the supported body parts, as well as the kind and level of deficit(s), therapy goals, and functional assessment of the user;
    - Read the user's intent;
    - Include built-in appropriate sensors and effectors;
    - Have a control system;
    - Have a power source;
    - Incorporate a fail-safe shutdown system.
2. An exoskeleton is not implanted and does not affect the user's skin, so the requirements in this area are mild;
3. An exoskeleton contains moving parts that wear out during operation, necessitating replacement;
4. Except for some temporary use by debilitated patients during their recovery, an exoskeleton is intended for permanent use. Therefore, an exoskeleton must:
    - Grow with the user;
    - Be modified in accordance with changes in the user's health (improvement or deterioration);
    - Support an aging user with neurodegenerative changes, as such changes affect the exoskeleton control system.

These features mean that the concept of a 3D-printed exoskeleton must be very refined; hence, few printed industrial and clinical prototypes of such a device have been developed to date. We had the opportunity to work on many generations of four such solutions: an exoskeleton for children with weaknesses in the upper limbs (e.g., arthrogryposis), two different hand exoskeletons, and an exoskeleton for the elbow joint. The selected 3D-printed exoskeletons mentioned in the article are shown in Figure 1.

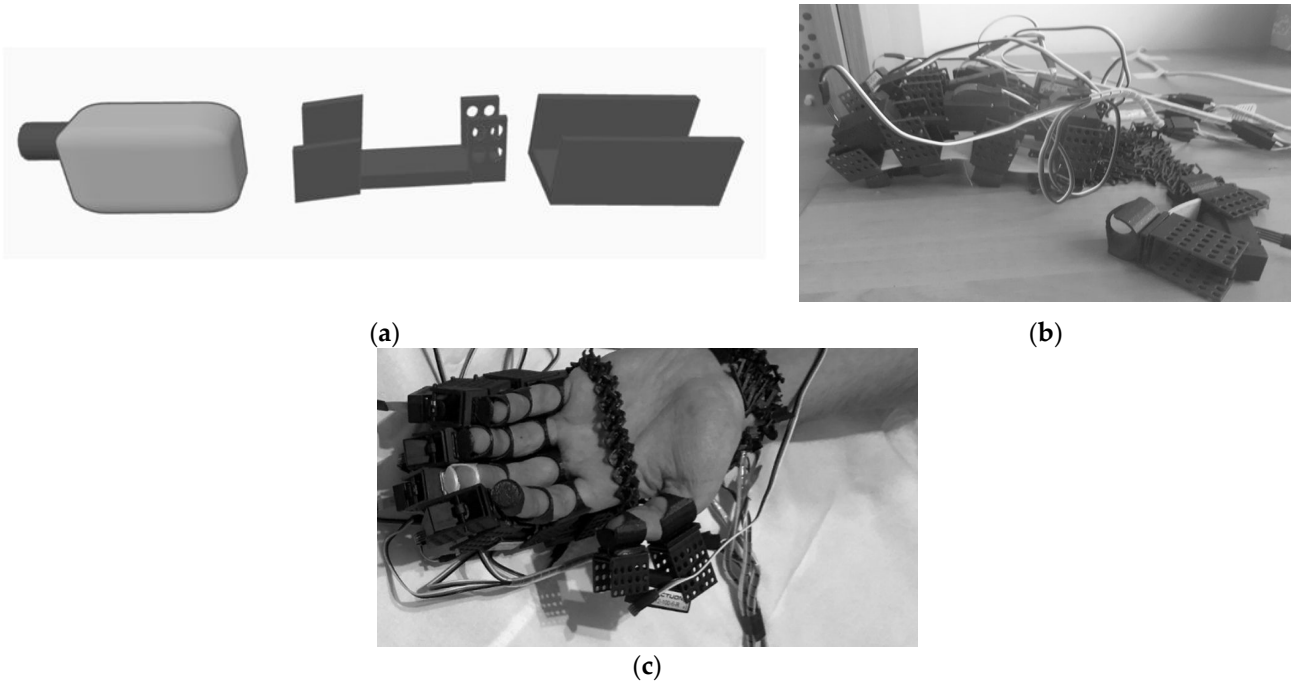


Figure 1. Selected 3D-printed exoskeletons mentioned in the article: (**a**) elbow exoskeleton, (**b**) hand exoskeleton, and (**c**) hand in hand exoskeleton.

3.1. Planning and Production Cycle

The planning and production cycle and life cycle of the 3D-printed hand exoskeleton (our own version) are shown in Figure 2.

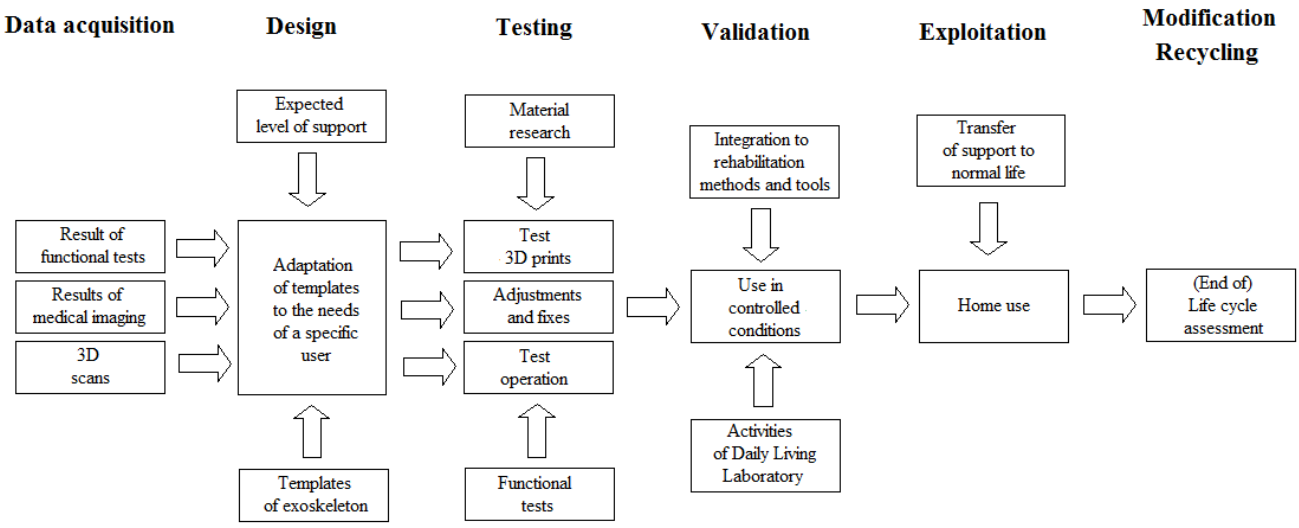


Figure 2. Planning and production cycle of the 3D-printed hand exoskeleton (own version).

The cycle includes the following stages:

- Stage 1: Data collection based on combined indications for exoskeleton use, functional diagnosis, the results of diagnostic imaging, and 3D scans of the part of the patient's body on which the exoskeleton is to be fitted. Digitization of this stage eliminates the need for additional, often manual measurements of the user and the impact of the associated inaccuracy/uncertainty;
- Stage 2: Design based on pre-programmed exoskeleton templates in Computer Assisted Design (CAD) software, taking into account the results of the analyses from Stage 1 and the therapy goals derived from the rehabilitation plan and the patient's priorities (patient-centered therapy);
- Stage 3: Testing, using the results of materials research and optimization (including artificial intelligence-based optimization) of the selected materials and their characteristics (lightness, strength, direction of action, and chemical properties) to produce 3D test prints, followed by operational testing and functional testing of the patient in the exoskeleton to check the optimum fit of the exoskeleton to the user;
- Stage 4: Validation, involving testing the use of the exoskeleton by the user under the controlled conditions of the Activities of Daily Living Laboratory. Here, under the supervision of specialists, the user performs all the activities envisaged for later use at home, including those resulting from the rehabilitation plan, hence the need to integrate the exoskeleton with rehabilitation methods and tools. At this stage, the final adjustments of the exoskeleton are made before it is issued to the user;
- Stage 5: Exploitation, covering the normal use of the exoskeleton at home (if necessary, adjustments are also made for hospital or outpatient settings), monitoring its wear, and providing technical support and modernization as needed—e.g., due to wear or damage to the exoskeleton, changes in the user's health, launching a new version on the market, or better supporting the user;
- Stage 6: Modification and recycling, including significant changes to the mechanical parts and software of the exoskeleton. This process goes beyond servicing to replacement and recycling of the unit as part of the Life Cycle Assessment, as well as monitoring and the implementation of conclusions from the above analyses for the planning and production cycle of the exoskeleton (e.g., considering the fastest wearing elements or necessary structural changes).

The LCA assessment can be carried out in accordance with the methodology already tested by us [25]. Technical control of the exoskeleton is carried out at all stages of production in accordance with the Industry 4.0 paradigm.

3.2. Support of the User Movement

The exoskeleton should support the natural position of the limb (e.g., the hand in free-hanging position). Notably, in this position, the joints are not straight but slightly bent. However, the exoskeleton for the upper limb is required to support all grips, with four in one-handed work and two in two-handed work. These grips are necessary to maintain the user's independence in the activities of daily living.

In some cases, the support force expected from exoskeletons may be too high. Thus, it is worth starting with lower values, which translates into a lower weight for the actuators and, thus, for the exoskeleton as a whole. In addition, the support force can reduce the power requirements and thus extend the autonomous operation of the exoskeleton from the battery. For these reasons, it is worth considering the possibility of using actuators with different characteristics as early as the design stage of the exoskeleton, which will enable the replacement of such parts as the user's health changes.

3.3. Selection of Materials for the Exoskeleton

The number of 3D printing technologies and dedicated materials is growing. These developments include materials with antibacterial activity, slower aging, inactivity when coming into contact with bodily fluids, and resistance to environmental factors (sun, water,

and temperature). These factors put great demands on designers, as does the efficiency of material use, the amount of waste, and the potential recycling of used exoskeleton elements.

The selection of materials for clinical 3D printing depends not only on the properties of the materials themselves (i.e., materials with specific physical and chemical properties and the characteristics of their changes over time, including materials with shape memory or programmable properties similar to the replaced tissue) but also on the following factors:

- Three-dimensional printing technology using stereolithography (SLA), selective laser sintering (SLS), and fused-deposition modeling (FDM) has the greatest potential for printing medical devices);
- The possibility of optimizing the material's parameters and consumption;
- Planned clinical use, including in exoskeletons, orthoses, prostheses, implants, other devices facilitating rehabilitation and care, anatomical models for learning and pre-operative planning, dressings, drugs, tissues and organs, and future personalized electronic systems for neuroprostheses and brain–computer interfaces.

AI-based optimization improved the speed of calculations and print quality and allowed researchers to identify a set of print parameters not previously considered [26,27]. It is possible to reduce filament consumption by up to 13.04% by reducing the amount of waste and thus reducing the environmental impact [28].

3.4. Design of the Exoskeleton

Another element of the exoskeleton can also be personalized: the 3D-printed fabric (i.e., chainmail). The stiffness and bending angles of the fabric can be adjusted to the patient in different directions (with an adjustable one- or two-way bending module) [29,30]. The use of the above solutions in an exoskeleton allow one to shape the skeleton's mechanical properties, including limiting the direction and angle of movement if required by the rehabilitation plan. A simple exchange of chainmail, which can be fully recycled, allows for greater patient safety (Figures 3 and 4).

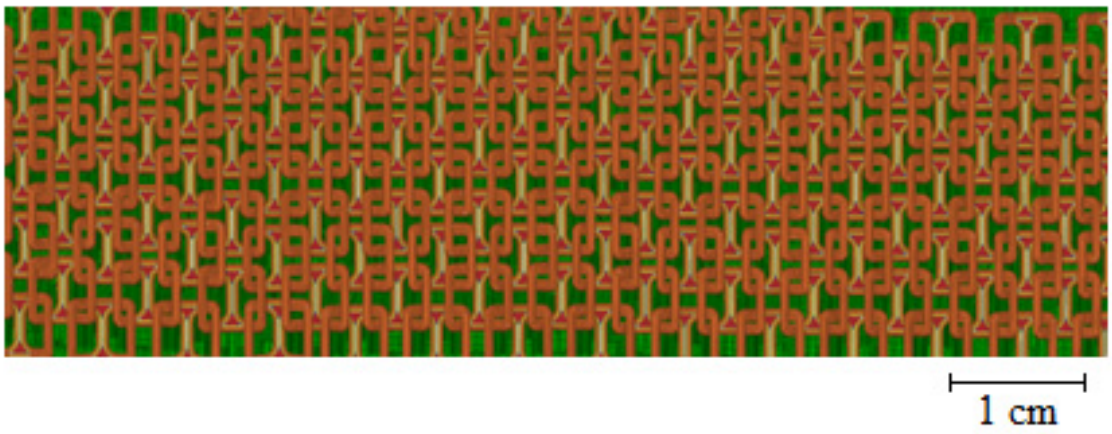


Figure 3. Chainmail (project in CAD).

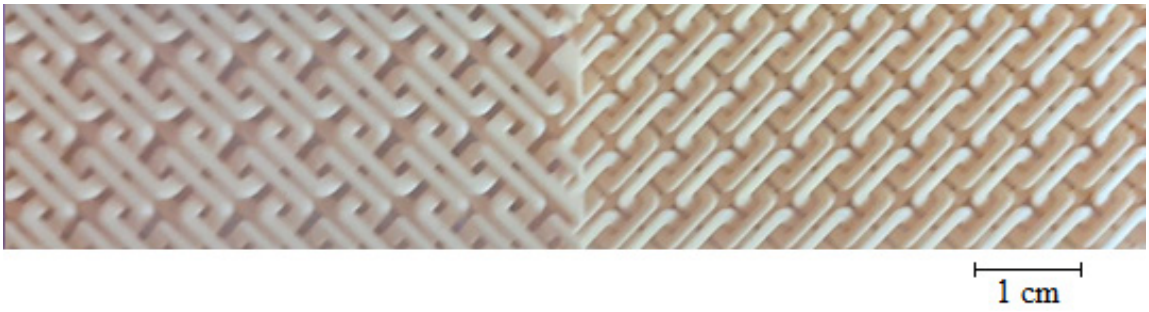


Figure 4. Printed chainmail.

In addition, the use of artificial neural networks allows for easier automatic adjustment of the chainmail structure to the desired properties, which greatly reduces the time needed for its design and production [29,30], including through the use of recyclate, which is a pro-environmental approach. Reducing the computation time also translates into lower energy consumption.

As part of the chainmail work, both the geometry and the features of these materials can be printed. Hence, this technology is often called 4D printing. Basic chainmail features that can be programmed include the following:

- Chainmail dimensions;
- Separate maximum bending angles in both directions;
- Maximum tensile force;
- Materials;
- Number of layers;
- Shape of the chainmail elements.

The aforementioned parameters can be shaped depending on one's needs, but it is also possible to impose limiting parameters (e.g., physiological bending angles in individual planes), as selected by an AI-based program (Figure 5) [29,30].

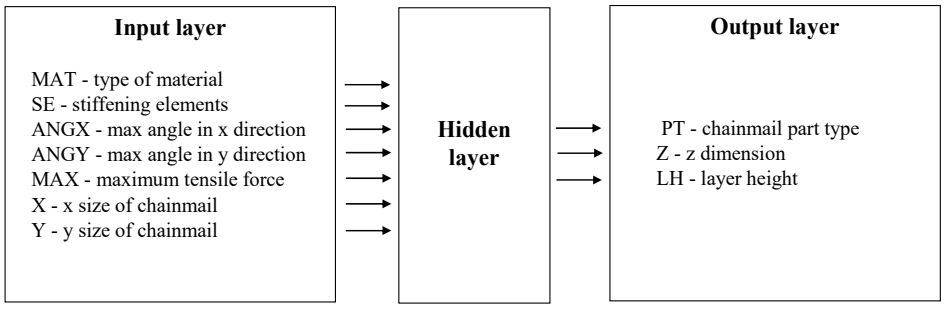


Figure 5. Traditional artificial neural network structure for chainmail's parameters selection [29,30]. Where: MAT—type of 3D printing material (e.g., filament), SE—presence of stiffening elements in the 3D-printed chainmail (yes/no), ANGX—max angle of chainmail bending in x direction, ANGY—max angle of chainmail bending in y direction, MAX—maximum tensile force, X—size of chainmail in x direction, Y—size of chainmail in y direction, PT—chainmail part type, Z—chainmail part height, LH—3D printing layer height.

The stages of designing and printing the 3D chainmail are as follows:

- Determining the required parameters of the chainmail (as part of a personalized therapy for an individually designed exoskeleton);
- The creation of a computational model for chainmail through the use of proprietary software based on artificial intelligence allowing for an optimal description of the chainmail parameters. This software automatically takes into account the inaccuracy resulting from the imbalance between the shape and dimensions of individual chainmail elements and the same parameters for the entire chainmail consisting of many such elements;
- Selecting the values of the parameters for the printing process, selected on the basis of the recommendations from manufacturers of materials and printers, previous research and scientific publications, and the experience of team members;
- Three-dimensional printing and cleaning;
- Testing and adjustment, as well as possible corrections [29,30].

A similar role is played by the analysis of the life-cycle of the exoskeleton. Thanks to the printing of various plastics and metals, almost all elements of a 3D-printed exoskeleton are recyclable. This makes it possible to achieve unprecedented environmental friendliness among medical devices [25], regardless of the need to ensure the possibility of decontamination. This approach is not only quantifiable and objective but also enables a comparison

between multiple solutions, which may not only be important in the future (for assessing the material or energy consumption of products and services) but could also become a standard for similar products.

General trends aimed at reducing the carbon footprint of 3D-printed products are in line with EU policy and support the dissemination of the proposed approach.

3.5. MDR Directive and ISO 13485, ISO 10993 Standards

The MDR directive [17] as it relates to the ISO 13485 [18] and ISO 10993 [19] standards describes the current European requirements for medical devices, including exoskeletons. The MDR directive regulates the manufacture and distribution of medical devices in Europe. Compliance with the MDR is mandatory for medical device companies wishing to sell their products on the European market and ensures that the medical device is safe, of good quality, meets the essential requirements for EU medical devices, and is CE-marked [28]. ISO 13485:2016 specifies the quality management system requirements for organizations providing medical devices and related services. Adherence to this standard certifies that throughout the product's life cycle (planning, research and development, production, storage and distribution, installation/implementation, servicing and related services, and recall and recycling), customer and relevant regulatory requirements will be consistently met. This standard also applies to suppliers or other external parties providing product-related services [29]. The ISO 10993-1:2018 standard applies to the biological assessment of all types of medical devices, including active, inactive, implantable, and non-implantable devices. This standard allows the assessment of biohazards based on risk (e.g., changes in the medical device over time), as well as the rupture of a medical device (or its components) exposing the user to new materials [30].

3.6. Intellectual Property Rules

Mechanical 3D-printed medical products, such as exoskeletons, are strictly covered by intellectual property protection (patents, utility models, and industrial designs), database and software protection (depending on the country), and know-how protection (e.g., under agreements with employees).

Protecting the topography of dedicated integrated circuits can help protect software. Due to the large scope when adapting solutions to a patient's needs and the interchangeability of parts within the product families, it is important to select the method and scope of protection in such a way that a wide range of possible modifications does not result in decreasing protection. Hence, it seems more beneficial to patent/protect smaller parts of the exoskeleton with a clear functional purpose and technological novelty, rather than the entire exoskeleton.

3.7. Product or Service Dilemma

A 3D-printed exoskeleton can be considered a custom-made medical device and is thus subject to different regulations than those governing mass-produced items. For the above reasons, healthcare facilities undertaking in-house bespoke manufacturing operate such that the diagnosis, treatment, rehabilitation, and care by means of bespoke 3D-printed products in a healthcare facility are carried out without fully complying with the European Parliament and Council regulations, provided that the materials used are ISO 10993 certified and agree with Article 4.4a of the MDR [16].

The manufacture of a 3D-printed medical device, particularly one as complex as an exoskeleton, raises a number of questions about the scope of the activity, as the manufacture of the product itself involves a number of other activities both prior to the manufacture of the exoskeleton (diagnostic imaging, 3D scanning, and functional testing on the user) and afterwards (periodic evaluation, servicing, upgrading and replacement of mechanical parts and software, technical support, and advice in the area of rehabilitation). The scoping guidelines for the aforementioned activities have not yet emerged. Three-dimensionally-printed robotics, particularly exoskeletons, are a new development with no funding from healthcare

institutions. However, in time, our solutions will be integrated into the system. To this end, we proposed a Poland-specific method for circulating patients, devices, and documentation based on our earlier study on brain–computer interfaces and neuroprostheses. However, this method is still in the preliminary stages of agreement. For a technology as complex as a 3D-printed exoskeleton, it is important to perform due diligence and remove any uncertainties early in the efforts to bring a new product to market. Notably, national regulations can also determine whether and to what extent a university may carry out manufacturing activities and whether it needs a business partner (consortium) or a spin-off company to do so. These are factors independent of the method by which the exoskeleton is designed and produced but are crucial to the product's appearance on the market.

4. Discussion

4.1. Findings and Their Implications

Previous publications indicate that 3D-printed technologies, including exoskeletons, should be treated as a technologically separate group of medical devices. The development of exoskeleton technology is a consequence of advancements in 3D printing technology and materials, and it is essential to maintain the current pace of development in personalized medicine. Results interpreted from the perspectives of previous studies and the working hypotheses show that exoskeletons are a good rehabilitation tool for the rapid recovery of motor function, e.g., in stroke patients, with the potential to also reduce the number and severity of complications, thus lowering mortality. At the same time, current exoskeletons offer insufficient human–machine coupling and interfere with the user's movement, damaging joints and muscles in the process [31]. It is crucial that the human–exoskeleton system be properly aligned through 3D printing with an increase in degrees of freedom and an optimized control system. It is currently unknown how important the exoskeleton's high strength support (current products offer 58% strength support) and full joint range of motion are (a sufficient joint range of motion was achieved for the activities of daily living). It should be noted that, in the case of the upper limbs, five-finger exoskeletons are rare, and there are currently no solutions that meet all the requirements. These findings and their implications also show that the process of designing, manufacturing, and fitting the exoskeleton should be as short as possible [32].

4.2. Limitations of the Own Studies

There are still too few, albeit diverse, cases to elucidate a single procedure for the use of 3D-printed medical devices. However, due to strong personalization, obtaining a homogeneous group of patients may simply not be possible. An important factor limiting the number of studies on 3D-printed exoskeletons is the need to gather knowledge and experience, create an interdisciplinary research team, construct prototype research stations, and overcome the high cost of such research—mainly due to the number of prototypes that must be developed, tested (including destructive strength tests), and improved as part of subsequent iterations.

Before 3D printing becomes a commonly used therapeutic tool, it is necessary to understand and refine the specific aspects of production challenges, quality control (including those related to different materials, formulations, and processing methods), requirements for excipients, production processes, and related technical and regulatory challenges. Three-dimensional printing is also ideal for, e.g., the production of personalized drugs, with advantages, including dose, dosage form, and drug release kinetics tailored to a specific patient [9]. The largest challenge is the home use of 3D-printed medical devices, which must be implemented in a cyclical control system by specialists to avoid potential side effects.

New mechanisms to manage intellectual property rights for 3D printing designs are becoming necessary and would provide flexibility to support digital technologies more quickly and effectively under global health emergencies [11].

4.3. Future Research Directions

Three-dimensional printing allows for greater accuracy in reconstruction and offers less invasive and more customizable operating procedures. These factors have the potential to improve outcomes in terms of function and morbidity, streamlining treatment, rehabilitation and care procedures, and improve prognoses. Thus, 3D printing may become the standard of healthcare in the future.

The time needed for designing, manufacturing, and using a 3D-printed personalized medical device (including an implant) continue to decrease as both engineers and medical specialists gain experience. For the aforementioned reasons, it is crucial to establish efficient interactions and trust between the corresponding members of an interdisciplinary team [6].

The next frontier of personalized 3D-printed medicine is implantable devices tailored to the needs of patients. Ramaraju et al. [7] proposed a strategy for the selective laser sintering (SLS) of medical devices adapted to patients for the production of an airway support device (tracheal and bronchial implants restoring airway patency to pediatric patients diagnosed with tracheal and bronchial softening). This procedure is in line with the FDA's 2018 recommended additive manufacturing guidelines for medical devices and includes medical image-based modeling, input analysis, design verification, material verification, device verification, and device validation, including validation as a template for the quality control of personalized 3D-printed implants [7].

Further development opportunities for the described group of exoskeletons include the implementation of principles in accordance with the Pre-Industry 4.0 paradigm, including technical control at every stage of production and the analysis of the product life cycle until its recycling or disposal [33–36]. These developments will be facilitated not only by the more widespread use of artificial intelligence and the industrial Internet of Things but also by new methods for signal acquisition, including directly from the central nervous system [37,38].

Robotic rehabilitation with the use of exoskeletons undoubtedly offers greater therapeutic possibilities than current treatment options, including increased and more precise control of the dose of therapy [39–41]. Personalized 3D-printed exoskeletons extend these possibilities even further. However, the development of this technology must be controlled, including relevant research, indications, and contraindications, as well as clinical guidelines.

In exoskeleton research, effectiveness counts. A review by Shahid et al. (2018) indicated as many as 45 prototypes of soft exoskeletons for the hand, while to the best of our knowledge, in 2022, none of these exoskeletons are yet on the commercial market [42].

5. Conclusions

Three-dimensional-printed exoskeletons could represent another breakthrough in the diagnosis, treatment, rehabilitation, and care of patients with deficits, including neurodegenerative ones, among the elderly.

Three-dimensional printing, particularly in the area of exoskeletons, is slowly becoming the leading manufacturing technology in healthcare, including personalized therapy. The use of artificial intelligence allows the planning and design process to be reduced from days to hours, in addition to material optimization and waste reduction, reducing costs by at least one-sixth. The progressive alignment of 3D-printed exoskeletons with the maintenance of methodological and logical rigor for medical devices and new business models to improve cost-effectiveness could increase the clinical implementation of this group of technologies.

The gap between research and engineering practice and clinical 3D printing should be bridged as quickly and as carefully as possible. This development will allow the rapid and efficient transfer of proven solutions into clinical practice. Such a technological shift will entail strategic and organizational changes to ensure correct implementation and adaptation to the needs of patients and clinicians.

As the growing maturity of 3D printing technology will gradually increase this technology's impact on everyday clinical practice, it is necessary to prepare medical professionals in advance for the optimal use of this group of technologies.

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