Advances in Science and Technology
Research Journal

Advances in Science and Technology Research Journal, 18(6), 145–158
https://doi.org/10.12913/22998624/191548
ISSN 2299-8624, License CC-BY 4.0

Received: 2024.07.08
Accepted: 2024.08.15
Published: 2024.09.08

Individualized 3D Printed Orthopaedic and Prosthetic Devices Using AutoMedPrint Technology – Methodologies and Examples

Filip Górski[1], Yuliia Denysenko[1,2], Wiesław Kuczko[1], Magdalena Żukowska[1], Radosław Wichniarek[1], Przemysław Zawadzki[1], Justyna Rybarczyk[1]

[1] Faculty of Mechanical Engineering, Poznan University of Technology, Poznań, Poland
[2] Faculty of Technical Systems and Energy Efficient Technologies, Sumy State University, Sumy, Ukraine
* Corresponding author's e-mail: filip.gorski@put.poznan.pl

ABSTRACT

The article provides readers with a detailed overview of the AutoMedPrint technology, its advantages and opportunities, based on a number of studies and case examples. The AutoMedPrint system represents a significant advancement in the field of orthopedics, offering a comprehensive solution for the automated design and rapid production of personalized orthopedic and prosthetic devices through 3D printing technology. This paper details the system's capabilities and methodologies behind it, which include the design and manufacturing of various devices such as wrist hand orthoses (WHO) and ankle foot orthoses (AFO), among others. These devices are crafted using data obtained from precise anthropometric measurements, allowing for high customization to meet individual patient needs. The AutoMedPrint system enhances the quality of life for patients by providing devices that are not only functional and cost-effective but also rapidly produced, ensuring timely intervention. Case studies demonstrate the system's effectiveness in practical scenarios, highlighting its potential to revolutionize orthopedic care by integrating new materials and technologies that adapt to changing medical and patient requirements. The discussion extends to the lifecycle of the produced devices, emphasizing sustainability and continuous improvement, ensuring the system's relevance and efficacy in modern medical practice.

Keywords: orthosis, prosthesis, 3D printing, 3D scanning, design automation.

INTRODUCTION

3D printing, or additive manufacturing, has significantly evolved since its inception in the early 1980s. Initially used for industrial applications, its potential in the medical field was quickly recognized [1]. By the early 2000s, medical applications ranged from the production of customized prosthetics to bioprinting of tissues and organs [2]. Technologies like stereolithography (SLA), fused deposition modeling (FDM), and selective laser sintering (SLS) have been adapted to create devices tailored to individual patient anatomy, significantly enhancing the personalization of care [3]. 3D printing, or additive manufacturing, has become an important innovative technological solution in the modern world [4, 5], especially for the manufacture of orthoses and prostheses [6]. Its importance lies in the advantages provided by this technology in comparison with traditional production methods:

- personalization of an individual approach [7],
- fast production and availability,
- ease and accuracy of modeling,
- ease of making changes,
- ease of integration of new technologies and materials,
- mass availability and accessibility.

The emergence of 3D printing technology in the medical field represents a transformative development in the production of medical devices, prosthetics, and orthotics. A prominent example of this innovation is the AutoMedPrint system, specializing in the automated design and rapid production of personalized orthopedic and prosthetic devices [8]. The AutoMedPrint system integrates advanced 3D scanning and design technology to produce orthopedic devices such as wrist [9] and ankle foot orthoses [10]. Unlike traditional manufacturing methods, which often involve lengthy and labor-intensive processes, AutoMedPrint uses data from non-contact anthropometric measurements to quickly generate designs that are then manufactured using 3D printing. This approach not only reduces production time but also improves the customization and fit of the devices [10].

Comparatively, systems like AutoMedPrint offer significant advantages over conventional methods by enabling rapid prototyping, iterative testing, and the incorporation of patient-specific geometries. The use of durable, lightweight materials further enhances patient comfort and device functionality [11].

In contrast to broader applications such as bioprinting, where the focus is on replicating biological tissues, AutoMedPrint emphasizes the mechanical production of non-biological components. For instance, while researchers like Kang [12] explore 3D-printed scaffolds for bone regeneration, AutoMedPrint targets the external support systems necessary for patient mobility and rehabilitation. However, both approaches underscore the overarching benefits of 3D printing in medicine: customization, speed, and the potential reduction in healthcare costs.

The clinical outcomes associated with the use of 3D-printed orthopedic devices have been positive, with numerous studies highlighting improved patient satisfaction due to the bespoke nature of the devices. A study by M. Ho [13] demonstrated that 3D-printed orthotics could achieve superior comfort and functionality compared to traditionally manufactured devices. AutoMedPrint's ability to rapidly iterate designs based on patient feedback further enhances this, aligning with trends toward patient-centered care in medicine.

Despite its advantages, the integration of 3D printing technologies into clinical practice faces several challenges. Regulatory hurdles are significant, as each new device must meet stringent standards set by bodies such as the FDA in the United States or the EMA in Europe. Furthermore, the lack of standardized protocols for design and production can impede broader adoption and consistency in clinical outcomes [14].

This article is devoted to a detailed description of activities aimed at continuing the development of cooperation based on the advancement of the capabilities of the AutoMedPrint system. The paper shows the main concepts behind the system and possible to obtain products, highlights basic stages and specificities of lifecycle of these products and presents some case studies – products made and tested for selected patients.

AUTOMEDPRINT SYSTEM – STRUCTURE AND OPERATION

AutoMedPrint system – main concept

The AutoMed Print system was created as a result of a project entitled «Automation of design and rapid production of individualized orthopedic and prosthetic devices based on data from anthropometric measurements». The system allows a comprehensive design and manufacturing process for specific orthopedic products falling under the category of limb orthoses, encompassing two types, namely WHO orthosis and AFO, as well as upper limb prostheses, including both cosmetic and mechanical prostheses, with several subtypes. The automated procedure involves the creation and preparation of production plans, utilizing additive manufacturing techniques, particularly 3D printing, which is guided by 3D scanning of the patient's limb [15]. Throughout the design phase, the patient assumes a pivotal role, being actively engaged in making decisions pertaining to the aesthetic aspects of the product, such as material selection, color preferences, and finishing details. The process is time-efficient, requiring several to several dozen minutes for completion, excluding the production time, which may extend to several hours per single part. Importantly, the involvement of a qualified engineer is not necessary in a typical, repetitive scenario, underscoring the system's user-friendly and accessible nature.

The AutoMedPrint system encompasses a total of four interconnected modules, as illustrated in Figure 1. These modules are not designed to function in isolation but rather operate within a unified IT infrastructure, facilitating data exchange between them. On a hardware level, the system necessitates three computer stations to facilitate its functionalities: 3D scanning and design station - contains an operator panel and a

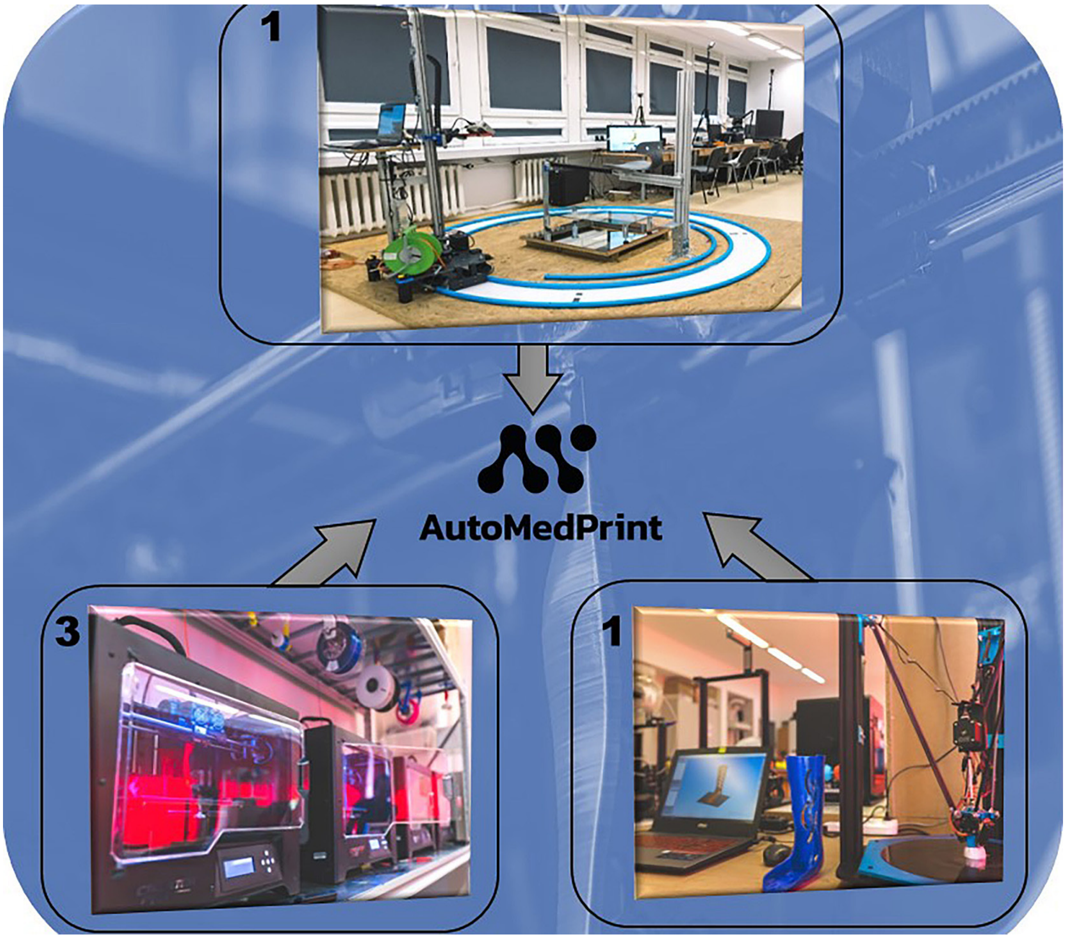

Figure 1. Component modules of the AutoMedPrint system: (1) 3D scanning and design station; (2) user interface station and (3) rapid production station

3D scanner, enabling the data collection process and providing the operator with control over other system components. The user (or patient) does not have access to this station and cannot see messages and the operator panel.

User interface station – distinct from the 3D scanning and design station, this separate computer station is integrated with the operator panel through a network interface. It comprises a touch screen and a motion tracking system, along with specialized programs to support the scanning process and facilitate product configuration. It is a stand that is controlled by the user (or patient), although he is not required to do so, and all necessary actions can be minimized or performed by the operator. User can configure their own product here, in some cases using immersive Virtual Reality, as shown in previous papers [16]. Rapid Production station. This segment of the system comprises two stations, each equipped with a control computer and additive manufacturing machines, alongside essential accessories to facilitate the rapid production process. The key, unique highlight of the system is its potential for automation, as it is entirely within the realm of practicality to obtain a product ready for manufacturing several minutes after first contact of a patient with the system, what has been proven in previous case studies. As an appreciation of these capabilities, the AutoMedPrint system received several awards. Among them, the award in the Polish competition «Product of the Future», as well as the first place in the Polish national competition "Eureka", which was won by the team's invention - a children's prosthetic arm for riding a bicycle.

Orthopedic and prosthetic devices

The AutoMedPrint system allows to carry out a complete design and manufacturing process of selected orthopedic products belonging to the category of upper and lower limb orthoses and upper limb prostheses. The system concept includes the following products:

- wrist orthosis (here and after WHO) for the treatment of injuries and therapeutic purposes.
- ankle foot orthosis (here and after AFO) for universal use.
- modular hand prosthesis, for plenty of various uses (bicycle ride, cosmetic, all-purpose),
- mechanical hand prosthesis, based on open source concepts of RoboHand [17] and Un-Limbited Arm [18].

The diagram of the classification of products is shown in Figure 2. The portfolio of various products available in the system is a result of continuous, extended work with the patients and doctors. Certain products, such as the universal modular prostheses, are a result of gradual evolution from a single-use type of product into a more flexible one, to meet needs of individual patient, with whom the team is cooperating since the very beginning of development of the system. However, the main idea behind the products in the system is their structural simplicity and ease of production and maintenance, which translates to low price, high scalability and availability, proving very useful to the patients. Examples of use cases and work with the system are described in numerous previous papers, pertaining to hand orthoses [9, 19], foot orthoses [10] and hand prosthetics [20, 21].

General principles of work with the AutoMedPrint system

The AutoMedPrint system consists of modules, which in the hardware are represented by autonomous yet interconnected workstations: the 3D scanning and design station; the user interface station; and the rapid manufacturing station. The limb 3D scanning station is automatic and comprises a circular track, a cart with a computer and a 3D scanner, as well as mechanical setups for scanning upper and lower limbs. Access to the station's system and data management is restricted to the operator only.

The user interface station includes a computer with the necessary software (e.g., Slic3r, MeshLab). The patient may access the station's controls, guided by the provided VR technology prompts to assist during scanning, but this is not necessary as all stages are performed by the operator.

The rapid manufacturing module includes a computer, an additive manufacturing device (e.g., FlashForge CreatorPro), cameras for monitoring, and tools for manual finishing of parts. Data is transmitted remotely to create NC code, which is then uploaded to the device via an SD card. The operator manually starts the manufacturing process and performs the finishing of the products.

The work with the system usually is realized in the following procedure:

1. Gathering basic information about the patient and needed product (on the basis of medical diagnosis, performed prior to the use of the system) – Figure 3a.
2. Acquiring anthropometric measurements by 3d scanning – using automated limb scanning station (default approach, software shown in Figure 3b) or manual scanning (when patient's ability to keep their limbs still is low and/or anatomy is not typical).
3. Automated processing of obtained 3d scans: cleaning, transforming coordinate systems,

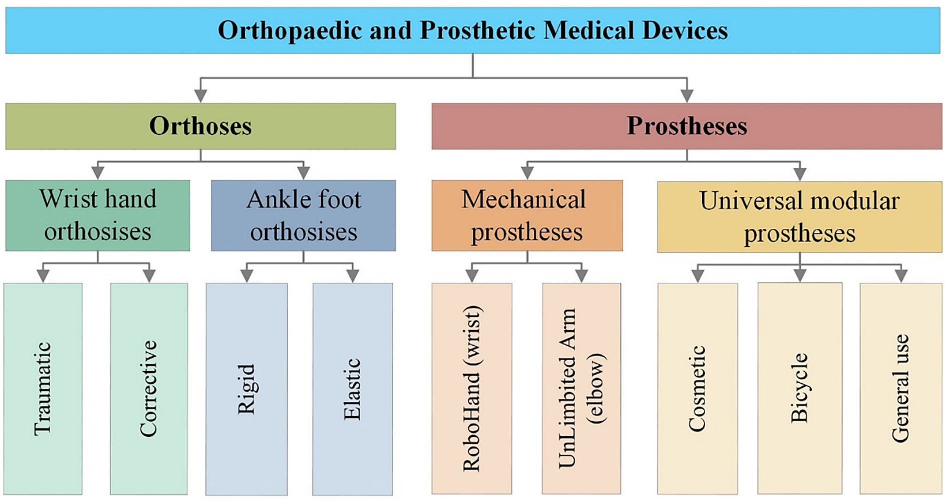

Figure 2. Classification of medical devices available in the AutoMedPrint system

repairing and polishing surfaces, extracting geometrical data (point coordinates, sections, distances) for automated design (as shown in Figure 3c).
4. Configuring the product by the patient (optional stage), selecting materials, colors and features, for some products – mixed or virtual reality is available [16].
5. Creating a design table, aggregating measurements and configuration data (Figure 3d).
6. Automated generation of 3D model (Autodesk Inventor) using the design table, exporting STL files for 3D printing.
7. Rapid manufacturing by 3D printing techniques, post processing, assembly and testing by the user.

SELECTED CASE STUDIES OF THE AUTOMEDPRINT SYSTEM

Studies of AutoMedPrint system

To validate the work, representatives from target groups, including patients, doctors, hospitals, and orthopedic equipment companies, were involved. The goal was to create individualized prostheses and orthoses for a wide range of patients and test their effectiveness and reception.

The experiments with the patients were realized using a consistent, similar scenario, with various approaches for different products. It began with consultations where patients provided medical history, underwent physiotherapist examinations, and were interviewed to decide on product features. Both limbs were scanned using mechanized and manual methods. The scans were processed to create 3D models, using AutoMedPrint system's capabilities (own software algorithms [8, 15]). Various machines and materials were used to produce the prostheses and orthoses, using parameters of production resulting from earlier studies [9]. The products were finished, assembled with standard components, and made skin-friendly by proper lining [21].

Each product was fitted with patients, typically requiring one iteration to meet fit requirements and a second for minor adjustments. At the moment of publication of this paper, the AutoMedPrint system allowed to prepare orthopaedic or prosthetic devices for more than 60 patients, in many cases offering a single patient more than 4 devices. The system was evaluated

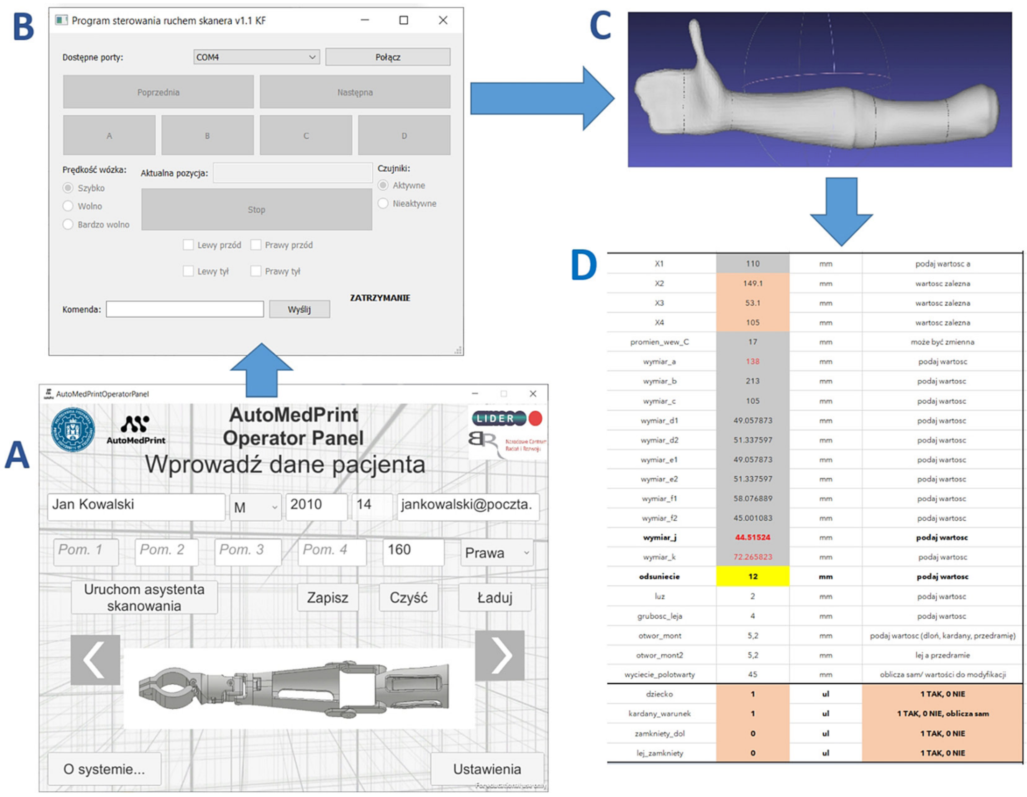

Figure 3. The scheme of data processing: (a) AutoMedPrint Operator Panel Software; (b) control the movement of the scanner software; (c) scan processing software (MeshLab); (d) an automated Excel spreadsheet

and updated with insights from testing, making it adaptable for other customized medical devices.

Hand orthoses prodused for more than 30 patients in the age 3–69 years (more of them 20–30 years). AFO orthoses manufactured for 5 patients in the age 4–26 years. Hand prostheses used by 20 patients (the age 1.5–40 years). Modular prostheses were manufactured for patients in the age 1.5–70 years, with very different amputation levels and needs. The next sections of the paper present details of selected products – orthoses for upper and lower limb – and their use for specific patients.

Wrist hand orthoses

The wrist hand orthosis (WHOs) are used to stiffen the limb in order to support the treatment of injuries to which this limb has been subjected. The term «injury» should be understood very broadly, similarly to «healing support» - many of the patients needed orthoses long after the injury had healed, in order to minimize the effects associated with, for example, muscle and joint pain.

WHO trauma orthosis consists of two shape-fitted halves and is openwork, allowing air supply and free access to the skin of the hand. An additional possibility of stabilizing the elbow joint has been introduced, for the needs of fractures of the forearm bones (the full product is shown in Figure 4). Elbow stabilization consists of two additional halves, also openwork, connected to the base WHO orthosis with the use of a threaded connection, which can be removed after the base fusion of the bones. Trauma orthoses, in the case of a recent injury, are designed on the mirror principle - the unaffected hand is scanned, and the visual assessment of post-traumatic swelling allows the appropriate offset to be applied so that the orthosis is not too tight. In the case of injuries that are already partially healed or do not involve much pain when moving the hand, the correct limb is scanned. The decision in this matter belongs to the orthopedic doctor or physiotherapist.

The orthosis is customized on the basis of a non-contact measurement of geometry of patient's hand and forearm (or mirror image of the other limb, when the actual limb is damaged and e.g. wrapped in plaster cast). The measurement is done by optical 3D scanning, usually at the workplace developed as a part of the AutoMedPrint system, developed at Poznan University of Technology. After measurement, data is processed from raw scans to reconstructed, smooth limb model (Figure 5). Out of this model, sets of points are extracted to feed the intelligent CAD model.

The product was originally designed in the Autodesk Inventor CAD system (Figure 6), as an intelligent model – its design can be changed freely by supplying it with various data from 3D scanning, leading to automated re-design.

The orthosis consists of basic parts (as visible in the Figure 6):

- bottom part (in contact with palm),
- top part (in contact with back of the hand),
- optionally – the bottom and top part could be transversally divided if orthosis.

The second type of WHO orthosis produced in the AutoMedPrint system are corrective and corrective-support orthoses – aimed at correcting

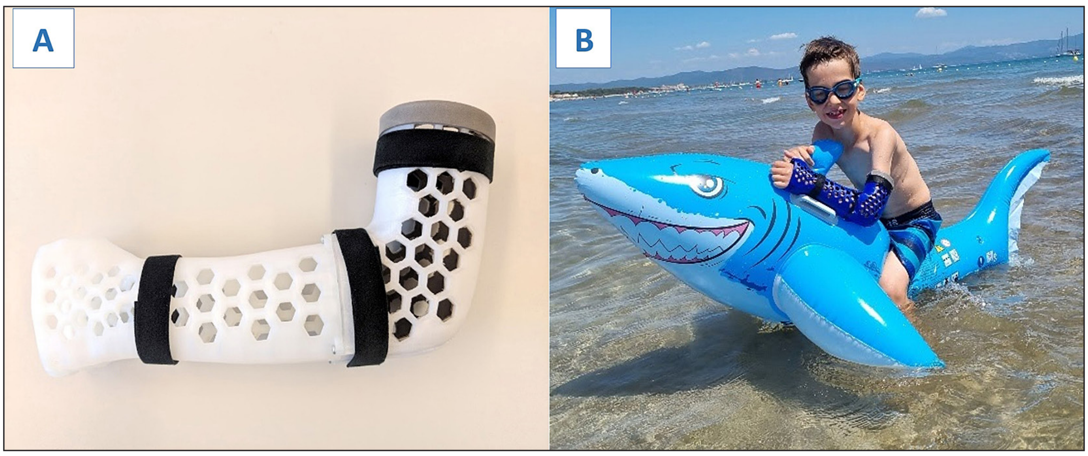

Figure 4. WHO orthosis to support the treatment of injuries: a) full version with support of wrist and elbow joint; b) example of use with the patient (photo courtesy of patient's parents, available at social media of Poznan University of Technology)

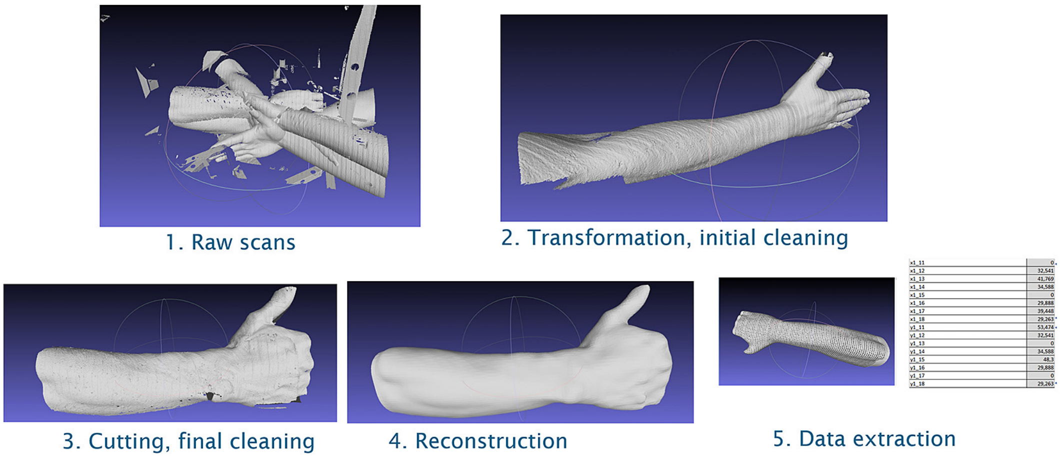

Figure 5. Data processing of 3D scans for the wrist hand orthosis model (AutoMedPrint system materials)

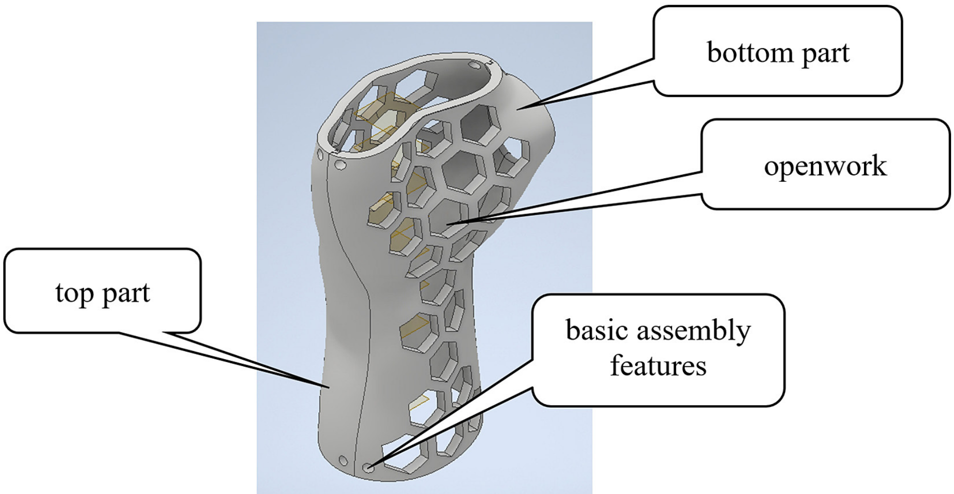

Figure 6. Wrist hand orthosis – intelligent model created in Autodesk Inventor, as part of the AutoMedPrint system

hand posture defects and/or supporting rehabilitation exercises performed by the hand with impaired mobility. Orthoses of this type are intended mainly for pediatric patients with diseases such as childhood cerebral palsy, spinal muscular atrophy or cerebral palsy, or also for the correction of defects or congenital deformities. Compared to the basic version of the WHO orthosis, the main difference is the cutouts in the area of mobility of the thumb and fingers, enabling gripping of objects, as well as lining the entire interior of the orthosis with a soft material (foam) to increase the comfort of use (the orthosis corrects the position of the hand, so it could lead to abrasions and corns). Corrective orthoses also differ in the way they are designed – both limbs of the patient are scanned, and the algorithm (currently only partially automatic, requires manual work with the 3D scans) combines both scans into one image of the corrected limb. A case study of this type of orthosis is presented in previous papers [19]. Examples of corrective orthoses are shown in Figure 7.

Ankle foot orthosis

The ankle orthosis (AFO) is the only product implemented in the AutoMedPrint project that concerns the lower limb, not the upper one. Due to the complexity of gait biomechanics and anatomy of the foot, ankle and calf, as well as the specificity of applications, it is by far the most difficult product in terms of applying automated design and manufacturing by low-cost 3D printing, by author's experience proven in numerous case studies. As part of the tests carried out with

Figure 7. Patients with corrective hand orthosis (photographs by the researchers, with consent of patients' parents)

patients, two basic types of ankle orthoses were proposed in the course of development of the system. The first are monolithic orthoses with a rigid ankle, presented in Figure 8. In these orthoses, the protection of the upper part of the foot and the front part of the calf can be implemented in various ways (tapes, foam – elements added at the post-processing stage), the basic principle is to make the entire orthosis in the form of one block (possibly divided into 2 blocks for larger orthoses and glued later). Orthoses of this type can have several different uses:

- correction of defects resulting from various diseases (e. g. childhood cerebral palsy, spinal muscular atrophy) - active use, while walking,
- correction of deeper defects or in the case of more serious diseases - passive use, during sleep or rest or for verticalization,
- stiffening of the joint after injury or as a result of acquired joint instability or chronic diseases.

The second type of orthoses are semi-flexible, intended for use while walking as an active walking aid. They consist of two separate blocks - one for the calf, the other for the foot - connected by a beam made of a strong, flexible material (nylon or composite with carbon fibers). They are intended for patients who cannot move independently other than with the use of orthoses. Of course, in the case of posture defects, the task of orthoses is also their correction.

Additively manufactured orthoses are also waterproof, if made from an appropriate material (PET-G or PA12) so they can be used, for example, for swimming. Examples of orthoses used by patients are shown in Figure 9.

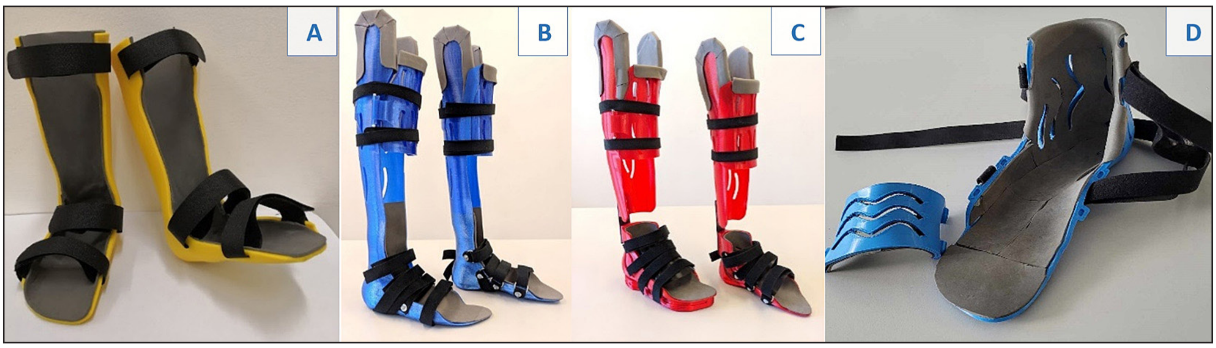

Figure 8. AFO orthoses for various patients: (a) cerebral palsy, 4-year old, rigid; (b) spina bifida, 13-year old, rigid; (c) spina bifida, elastic; (d) foot bone injury, 12-year old, rigid, shortened

Universal modular prostheses

The universal modular prosthesis evolved from a simple, single-purpose mechanical prosthesis into an advanced, modular, fully personalized device. It is a mechanical device, anatomically adjusted to a given patient, based on dimensions taken from a 3D scan of both limbs of the patient (healthy one and a stump, assuming one-sided amputation or defect). The prosthesis can be used by patients of both transhumeral and transradial amputations (below and above the elbow), and has been tested in many of various cases, as presented in previous publications [20–22]. The prosthesis consists of basic parts (as visible in the Figure 10):

- socket (stump part),
- elbow coupling,
- forearm part,
- wrist coupling,
- end effector.

The modules of the prosthesis are, in most cases, interchangeable. It means that all the basic parts (socket, end effector, forearm) can be easily replaced with a part of a different variant, tailored to the same patient (e.g. open end effector can be switched to a closed one, open socket can be replaced with a compressive one etc., as visible in Figure 10). Wrist coupling can also be altered or removed easily. For specific patients or needs, certain degrees of freedom can be also removed, for greater rigidity, at the cost of flexibility. The prosthesis is printable of any filament material – PLA and PET-G are recommended, as they have been tested for proper behavior in contact with user's skin, as well as having suitable strength [9, 21]. PLA is suitable for children version, while more durable materials, such as PET-G, are recommended for adult users [22]. Total 3D printing time of the whole prosthesis in children version can take several hours, depending on the material and the printed, as well as a number of printers (simultaneous production is faster, as the prosthesis has many parts). Standard nuts and bolts are used for assembly, as well as Velcro straps and EVA foam for lining of parts in contact with patient's stump (usually selected areas of socket and forearm part). As the prosthesis is often used for sports activities, risk analysis was realized – its results are shown in one of previous publications [21].

The complete model of a customizable prosthesis was made in Autodesk Inventor software. The parameters (dimensions) are entered through an Excel spreadsheet. The prosthesis preparation is based on anatomical data. The prosthesis can be made on the basis of healthy limb – unless there is significant disproportion in the size of the amputated limb remains. Workflow with the model is the same as in the case of wrist hand orthosis (see Figure 3 and 5 for reference). After automated generation, improving the model, both functionally and visually, can be realized as an optional operation, if special needs arise. After introducing a set of parameters, the model redesigns itself, results of which are presented in Figure 11.

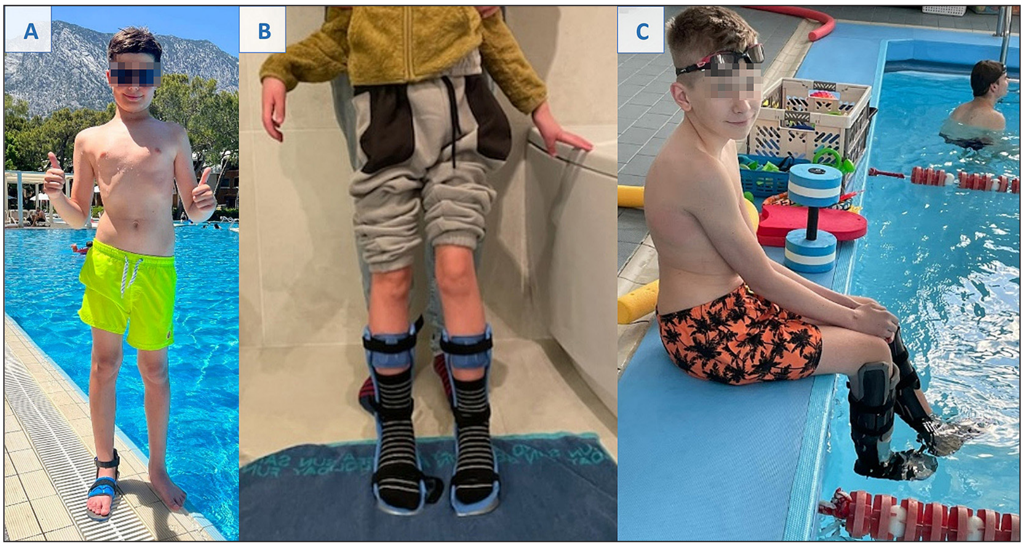

Figure 9. Patient used AFO orthoses: (a) bone injury, lightweight swimming orthosis; (b) ankle joint instability, stiffening orthosis; (c) spina bifida, swimming orthoses (photos courtesy of patients' parents, available at social media of Poznan University of Technology)

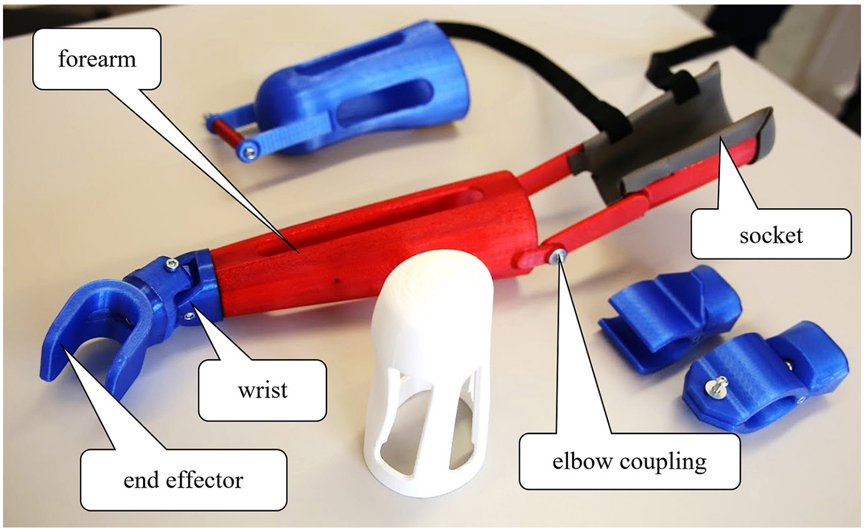

Figure 10. Universal hand prosthesis – modules and some of their variants

After updating, check for errors and possible improvements, the model must be saved to external file for further use, usually all the parts are exported, either as a single OBJ file (in the case of using a 3D printer slicer software that has capabilities of separating the meshes from a single file) or separately as STL files. Printed prosthesis is tried on by the patient and some modifications can be made before a final version is created and put to practical use. There are also frequent examples, of authors' experience, of gradual change of requirements by long-term patients, usually resulting in strong customization and high specialization of use of the prosthesis (as demonstrated in previous case studies [23]).

Examples of various prostheses used by children are shown in Figure 12, while use by adult patients is shown in Figure 13.

LIFECYCLE OF PRODUCED ORTHOPEDIC DEVICES

The importance of the life cycle of medical devices is to ensure the quality, safety, efficiency

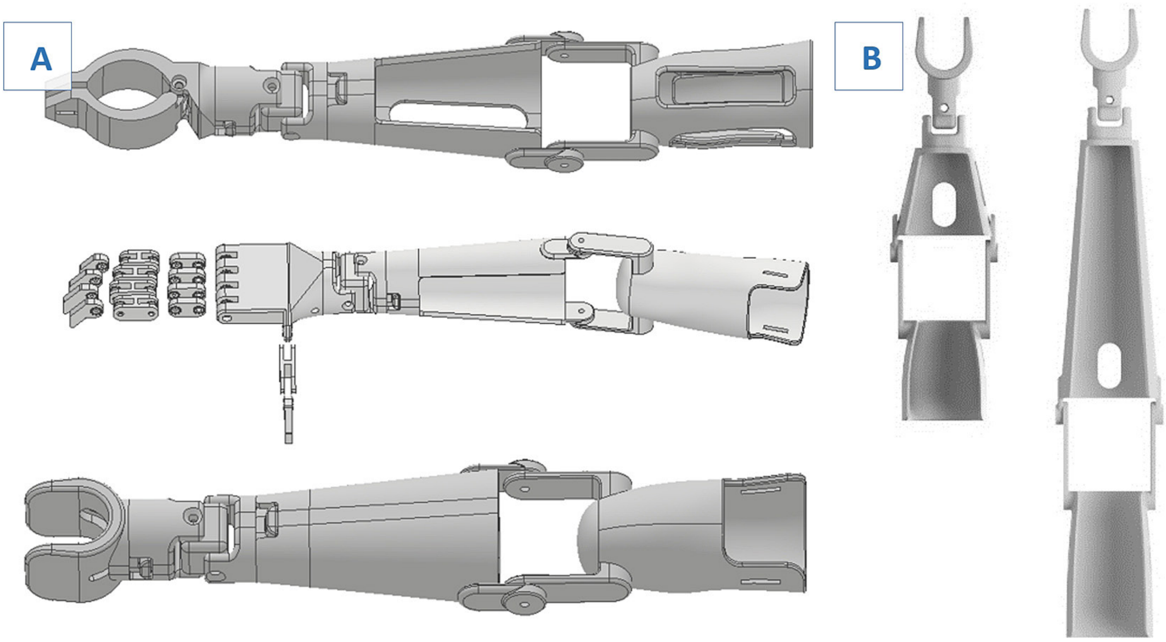

Figure 11. Automated re-creation of prosthesis model, (a) different configurations, the same patient; (b) various patients, the same configuration

Figure 12. The universal prosthesis used by children (different variants), aged 2–10 (photos courtesy of patients' parents, partially available at social media of Poznan University of Technology)

Figure 13. The universal prosthesis used by adults and a teenage patient, different variants (photographs by the researchers, with consent of patients)

and sustainability of the devices throughout their existence – from the initial concept to removal from use. Considering all aspects of the life cycle, manufacturers and suppliers of medical devices can ensure the high quality, efficacy and safety of their products, which contributes to improving the health and quality of life of patients. Life cycle assessment of medical devices can help ensuring [24]:

- patient safety,
- quality and reliability,
- regulation and compliance with standards,
- innovation and improvement (allowing to make medical devices more effective, convenient for patients, and also help to reduce the cost and ensure availability to more people),
- service support,
- environmental responsibility (green technologies and ecological approaches help reduce the negative impact of medical products on the environment).

It is noteworthy that the lifecycle of products that come to life through use of AutoMedPrint system is a unique one, so considerations found in available literature can be used only scarcely and very selectively (just some of available lifecycles are barely similar [24, 25]) when creating and evaluating it. That is why, analysing all the aspects in the process and considering the methodologies and examples of work, a new lifecycle was conceived, taking into account the most critical points of the manufactured devices, that is:

- three-way nature of communication of process participants – patients, doctors and manufacturers of devices,
- automated design, without participation of engineer in day-to-day work with the patients,
- additive manufacturing of modular, ever-changing devices by 3D printing, with flexible capabilities of 3D printing machines and lack of standardized sizes, volumes and shapes, possible to realize outside factories (possibly in hospitals, schools etc.)
- frequent cases of multiple iterations of one product – try-ons resulting in improvement of

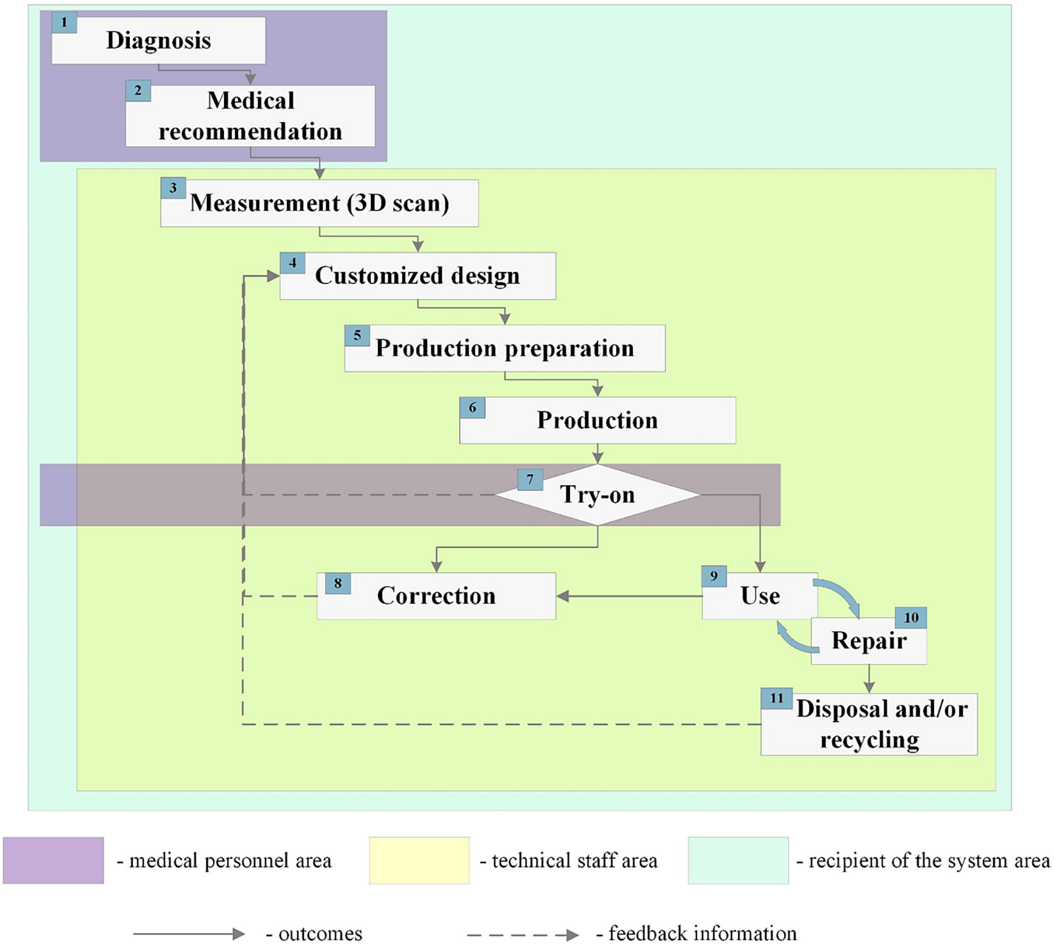

Figure 14. Lifecycle of anatomically individualized medical devices in the AutoMedPrint system

geometry, not treated as a faulty product, but as an imminent part of the process.

A short, entry proposal of the product lifecycle in the AutoMedPrint system is shown in Figure 14. It underscores various participants in the process at various stages, takes into account the automated nature of the process (lack of engineers at the most part of the lifecycle) and shows various ways of information flow. The proposal also takes into account various regulations related to medical devices, such as Medical Device Regulations [25] and various ISO standards focused on quality management of medical devices [26].

The lifecycle is currently at the phase of assessment and further development. One of the stages of its development were various studies, focused on strength, accuracy and surface quality of hand orthoses [9], elements of prosthetic devices and leg orthoses [10], as well as the previously mentioned risk assessment [21]. Once completed and assessed, it will help with implementing AutoMedPrint and other similar solutions in commercial, medical practice, especially concerning meeting of formal requirements towards safety for the patients and quality standards. Quality management system (QMS) for these devices is currently also under development – various requirements of the ISO standard are placed against the current, prototype state of AutoMedPrint technology and various recommendations are being given. This process will last until the technology is considered as ready for clinical implementation.

CONCLUSIONS

AutoMedPrint system use great potential of 3D-printing for the production of orthoses and prostheses for improving the quality of life of people with various disabilities and increasing their opportunities for active participation in society. This technology continues to develop, and its impact on medicine and society may be even greater in the future.

Considering the level of maturity of technologies used as building blocks of the AutoMedPrint (3D printing, CAD, 3D scanning), it should be stated that completion of transitioning from traditional orthopedic product manufacturing to modern methodologies is nearly done, leveraging automated systems like AutoMedPrint for designing and creating orthopedic products. This shift has been facilitated by the use of both commercial and open-source software, alongside algorithms that simplify working with anatomical data.

On the basis of numerous case studies of various devices, successfully delivered to many patients (as shown in this paper and many previous ones), the authors believe it is feasible to develop a fully automated system, where patients, assisted by medical personnel, can complete the entire process of anthropometric data acquisition and device design in a very short time 15 minutes. Considering the number of interventions of an engineer needed during the development of the presented products, such a system could potentially serve over 90% of patients with injuries, amputations and congenital defects and diseases effectively, with the remaining 10% requiring more individualized approach, greatly increasing accessibility of simple, yet effective orthopedic devices, especially for children. This could have big impact in countries with lower level of advanced healthcare, or in difficult conditions (e.g. at war).

Over more than five years of research, the AutoMedPrint team has worked with dozens of patients, creating hundreds of affordable, personalized devices. This prototype system has been crucial in demonstrating that rapid and cost-effective production of prosthetics and orthoses is achievable. On the basis of available cases, a lifecycle of automatically designed, 3D printed personalized devices has been conceived and is currently being evaluated. As one of the main limitations of this study, a number of patients should be indicated – it is still low and insufficient to introduce a complete, robust automation. The authors are working on further case studies, clinical studies are also planned in cooperation with healthcare facilities.

Future research should focus on integrating automated modeling frameworks for orthosis to reduce economic and time costs further. Advances in material science and manufacturing technologies would also help enhancing the robustness and functionality of these devices.

While even basic prosthetic or orthotic devices have significantly improved patients' lives, challenges remain in developing customizable, strong, and aesthetically pleasing prosthetics that are also economical and widely available. In authors' opinion, the need for innovation in prosthetic and orthotic development is now desired more than ever, considering ageing society and increase in biological disability by various causes. Challenges remain in developing a robust quality management system (QMS) and product lifecycle management (PLM), staying compliant with medical regulations (EU's MDR and others). It would also be important to gain interest of big companies and enforcing the change, to fully transition from long & expensive production processes of customized orthopedic devices to short, cheap and mass available automated production.

REFERENCES

1. Ventola C.L. Medical applications for 3D printing: current and projected uses. Pharmacy and Therapeutics. 2014, 39(10), 704–711.
2. Murphy S., Atala A. 3D bioprinting of tissues and organs. Nat. Biotechnol. 2014, 32, 773–785. doi:10.1038/nbt.2958.
3. Tack P., Victor A., Gemmel P., Annemans L. 3D-printing techniques in a medical setting: a systematic literature review. Biomed. Eng. Online 2016, 15, 1–21.
4. Zubrzycki J., Estrada Q., Staniszewski M., Marchewka M. Influence of 3D Printing Parameters by FDM Method on the Mechanical Properties of Manufactured Parts. Adv. Sci. Technol. Res. J. 2022, 16, 52–63. doi:10.12913/22998624/154024.
5. Gade S., Vagge S., Rathod M. A review on additive manufacturing – Methods, materials, and its associated failures. Adv. Sci. Technol. Res. J. 2023, 17, 40–63. doi:10.12913/22998624/163001.
6. Barrios-Muriel J., Romero-Sánchez F., Alonso-Sánchez F.J., Salgado D.R. Advances in orthotic and prosthetic manufacturing: a technology review. Mater. 2020, 13, 295.
7. de Oliveira R.S., Fantaus S.S., Guillot A.J., Melero A., Beck R.C.R. 3D-printed products for topical skin applications: from personalized dressings to drug delivery. Pharmaceutics 2021, 13, 1946.
8. Górski F., Wichniarek R., Kuczko W., Żukowska M., Rybarczyk J., Lulkiewicz M. Evaluation of a prototype system of automated design and rapid manufacturing of orthopaedic supplies. In: Proceedings of the International Scientific-Technical

Conference MANUFACTURING, Cham: Springer International Publishing, April 2022, 1–15.

9. Górski F., Wichniarek R., Kuczko W., Żukowska M., Lulkiewicz M., Zawadzki P. Experimental studies on 3D printing of automatically designed customized wrist-hand orthoses. Mater. 2020, 13, 4091.
10. Górski F., Rybarczyk J., Zawadzki P., Kuczko W., Wierzbicka N., Żukowska M., Siwiec S. Design and additive manufacturing of an individualized specialized leg orthosis. In: Proceedings of the International Scientific-Technical Conference MANUFACTURING, Cham: Springer International Publishing, April 2022, 31–44.
11. Chepelev L., Giannopoulos A., Tang A., Mitsouras D., Rybicki F.J. Medical 3D printing: methods to standardize terminology and report trends. 3D Print. Med. 2017, 3, 4. doi:10.1186/s41205-017-0012-5.
12. Kang H., Peng J., Lu S., Zhu Z., Cao F., Cai Q. Biodegradable 3D printed scaffolds of modified poly(Trimethylene carbonate) composite materials with poly(L-lactic acid) and hydroxyapatite for bone regeneration. Nanomater. 2021, 11, 3215.
13. Ho M., Fontanarosa D., Chua K.H., Pather N. Immediate comfort perception of 3D-printed foot orthoses in individuals with unilateral heel pain. Prosthet. Orthot. Int. 2022, 46, 31–36.
14. Di Prima M., Coburn J., Hwang D., Kelly J., Khairuzzaman A., Ricles L. Additively manufactured medical products–the FDA perspective. 3D Print. Med. 2016, 2, 1–6.
15. Wichniarek R., Górski F., Kuczko W., Żukowska M. Accuracy and repeatability of limb scans obtained on the semi-automatic measuring station. Adv. Sci. Technol. Res. J. 2020, 14, 46–55.
16. Górski F., Gapsa J., Kupaj A., Kuczko W., Żukowska M., Zawadzki P. Virtual Design Process of Customized 3D Printed Modular Upper Limb Prostheses. In: Proceedings of the International Scientific-Technical Conference MANUFACTURING, Cham: Springer Nature Switzerland, March 2024, 206–218.
17. Ten Kate J., Smit G., Breedveld P. 3D-printed upper limb prostheses: a review. Disabil. Rehabil.: Assist. Technol. 2017, 12, 300–314.
18. Bina T.S., Kunkel M.E., dos Anjos E.G.R., Ribeiro R.C., Ribeiro T.V., Silveira H.D. Creation of a 3D printing protocol for the unlimbited arm prosthesis. In: Advances and Current Trends in Biomechanics, Florence: CRC Press, 2021, 327–330.
19. Górski F., Żukowska M., Kuczko W., Wichniarek R., Siwiec S. Automated Design and 3D Printing of Therapeutic Wrist Hand Orthosis. In: Innovations in Biomedical Engineering 2023, Cham: Springer Nature Switzerland, 2024, 24–32.
20. Górski F., Wichniarek R., Kuczko W., Żukowska M. Study on properties of automatically designed 3D-printed customized prosthetic sockets. Mater. 2021, 14, 5240.
21. Górski F., Sahaj N., Kuczko W., Żukowska M., Hamrol A. Risk assessment of individualized 3D printed prostheses using failure mode and effect analysis. Adv. Sci. Technol. Res. J. 2022, 16, 31–43.
22. Hsueh, M.H., Lai, C.J., Wang, S.H., Zeng, Y.S., Hsieh, C.H., Pan, C.Y., Huang, W.C. 2021. Effect of printing parameters on the thermal and mechanical properties of 3d-printed pla and petg, using fused deposition modeling. Polymers, 13(11), 1758.
23. Górski F., Rybarczyk D., Wichniarek R., Wierzbicka N., Kuczko W., Żukowska M., Sanfilippo F. Development and testing of an individualized sensorised 3D printed upper limb bicycle prosthesis for adult patients. Appl. Sci. 2023, 13, 12918.
24. Seo G., Park S., Lee M. How to calculate the life cycle of high-risk medical devices for patient safety. Front. Public Health 2022, 10, 989320.
25. Badnjević A., Pokvić L.G. Medical devices maintenance. In: Clinical Engineering Handbook. Florence: Elsevier, 2020, 520–526. doi:10.1016/B978-0-12-813467-2.00080-8.
26. European Union. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. 2017.
27. International Standardization Organization. ISO 13485: 2016. Medical Devices. Quality Management Systems. Requirements for Regulatory Purposes. 2016.