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Original scientific paper

AUTOMATION OF DESIGN OF MODULAR UPPER LIMB PROSTHESES

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Abstract. *This paper presents the results of automation of the design of a modular upper limb prosthesis. The process of modernization of the existing, standard CAD model in the Autodesk Inventor program was described, introducing structural changes and enriching the geometric form with the knowledge of the design process using the tools of the iLogic module. In addition, the CAD model was combined with special design tables, thus obtaining a KBE class solution. The result is a special, intelligent generative CAD model that allows for the automation of the process of designing various variants of prostheses, tailored to the patient's anthropometric characteristics. The results of the work were then integrated with the AutoMedPrint system developed at the Poznan University of Technology, thanks to which it was possible to test the operation of the developed solution on real data. Based on the measurement results from the 3D scanning process, various variants of the modular prosthesis were automatically prepared for three patients. The final task described in the work is the process of manufacturing the selected variant of the prosthesis in the additive technique. The results of fitting the prosthesis and the opinion of the patient were also presented.*

Key words: *Modular design, Limb prosthesis, Design automation, KBE system, Generative CAD model*

1. INTRODUCTION

Upper limb prosthetics are crucial in restoring function after limb loss due to injury, disease, or congenital issues [1]. Amputation can occur at various levels, influencing treatment, rehabilitation, and prosthesis design [2-4]. The upper limb's complexity, with its

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many degrees of freedom and ability to perform intricate movements, requires prostheses to address basic daily, professional, and social tasks [5]. Depending on whether full or partial functionality is needed, prostheses can be passive (cosmetic, functional) or active (body-powered, externally powered, hybrid) [6,7]. However, a single prosthesis often cannot meet all patient needs, leading to the use of multiple types. The most effective in this area seems to be special modular passive prostheses examples are shown in Fig. 1.

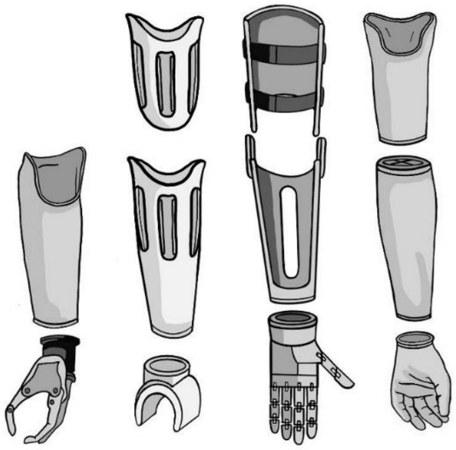


Fig. 1 Examples of modular passive upper limb prosthetics

Modular prostheses are known worldwide but are still not widely used, and research on their design and production is limited. Production of such products is still very complex, time-consuming, and expensive. It is usually done manually [8], although the use of methods and techniques known from other fields of engineering, such as intelligent CAD models, reverse engineering, or additive manufacturing, is becoming more common.

The effectiveness of the traditional approach to design can be increased by using the generative CAD models which are enriched with a description of knowledge in the form of structured rules, relations, parameters, algorithms, and conditional instructions [10]. Therefore, generative models are very often the basic element of KBE (Knowledge Based Engineering) systems, which provide support in making design decisions, allow you to shorten the design time, and minimize construction [10-12]. Issues related to the construction of generative CAD models and KBE systems, both in theory and in practice, are widely described in the literature. Most of these works, however, focus on the area of mechanics, which is of course justified. Examples can be found in the works of [13-15]. Nevertheless, works in this field have been the subject of research in the field of prosthetics and orthotics for some time [16-20]. Generative CAD models are also used in other sectors of medicine, such as implantology, dealing with the production of fitted cranial and craniofacial implants [21-24].

Reverse engineering has become an important aspect of innovative prosthetics. These techniques enable the digitization of real objects, based on data obtained using selected imaging techniques [25, 26]. The most popular are: 3D Scanning, Computed Tomography (e.g. when a morphological record of a body part is desired), or Optical Motion Capture

Systems. They make it possible to visualize the surface of the stump along with its volume, omitting the complicated operations related to making casts [27-30].

The use of additive manufacturing is more and more often used in the biomedical sector, offering printouts in the field of prosthetics and orthotics, preoperative planning, or implantology. Currently, prosthetic supplies are manufactured using technologies such as FDM (Fused Deposition Modeling), SLS (Selective Laser Sintering), SLA (Stereolithography), and PolyJet (Photopolymer Jetting) [31]. Based on the analysis of the literature and various projects related to additively manufactured prosthetics, the tendency of FDM technology to dominate was identified. Despite the relatively large thickness of cross-section layers and difficulties in the production of geometrically complex products, it is characterized by the use of low-cost equipment, simplicity, a wide range of materials, and usually no need for complicated post-processing [32-33].

This work proposes a method that integrates the above technologies to popularize modular prostheses manufacturing, addressing individual patient needs. The goal was to develop a generative CAD model to automate and streamline the production of specialized prostheses. Though prostheses share general geometric features, they must be tailored to individual anthropometric characteristics. Key steps included developing a KBE system, parametric CAD models, and integrating 3D scanning data. The innovation lies in automating design, enabling rapid production of anatomically individualized devices. This process minimizes production costs by replacing only necessary modules.

2. AUTOMATION OF DESIGN OF MODULAR UPPER LIMB PROSTHESES

2.1 Aim and Scope of the Work

The approach proposed and described in this work, integrating several well-known technologies, may contribute to the popularization of the use of modular prostheses, while taking into account the individual requirements of the patient. The primary purpose of the work was to develop a generative CAD model of modular upper limb prostheses to shorten and facilitate the process of manufacturing specialized prostheses by automated design tasks. Variants of the prostheses are characterized by a high similarity in geometric features in general, however, due to the individual anthropometric features of the patient, they must be properly matched to them.

To meet these assumptions authors assumed the following work plan:

- development of the concept of the KBE system;
- analysis of the structure of the modular prosthesis of the upper limb;
- development of new, parametric CAD models;
- development of databases for processing data from the 3D scanning process;
- integration and verification of the KBE system in practice.

The greatest novelty of the presented prosthesis and the new contribution is the obtained level of automation of design. It has been proven that the prosthesis model is capable of quick switching between variants for different patients, which brings forth uncanny possibilities of rapid production of fully anatomically individualized devices, unknown in existing literature.

2.2 Idea of the KBE System for Modular Upper Limb Prostheses Design

The developed KBE system shown in Fig. 2 consists of the following components: a database with design tables; intelligent, parametric CAD models of prosthesis components; and VBA (Visual Basic for Applications) scripts for automated particular design tasks. All these elements are an integral part of the modular prosthesis generative CAD model. The input data, in the form of mesh models obtained in the 3D scanning process, came from patients participating in the project AutoMedPrint. It should be noted that both amputation and healthy limbs were scanned, which were to be valuable sources of data to generate a variant of the new prosthesis.

The generative CAD model of the prosthesis was developed in the Autodesk Inventor Professional 2022 software. The construction of such models is supported by tools from the iLogic module, in this particular case design tables and the VBA scripting language. The parameterization of the designed model was developed using a file created in Microsoft Excel. A data structure template has been prepared in the program sheets, facilitating the interpretation of input data and performing their transformation to the form required by parametric models of prosthesis parts. Excel also included some design rules that allowed for automatic processing.

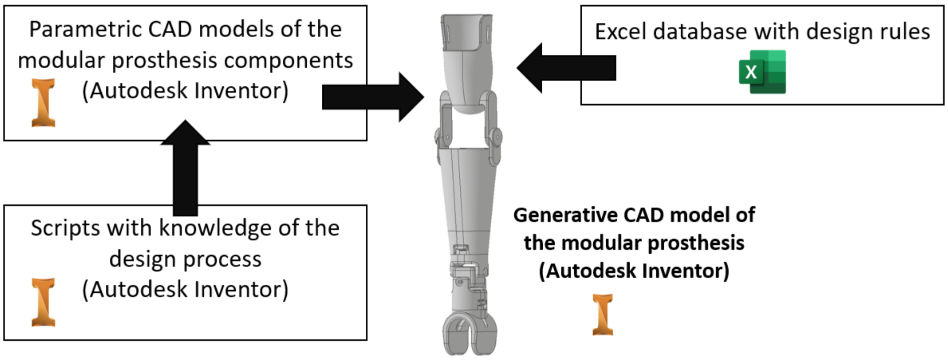


Fig. 2 Structure of developed KBE system

2.3 Basic Framework of a Modular Upper Limb Prosthesis

The prosthesis model selected for the work consists of 3 types of main components: prosthetic socket, forearm, and hand. The structure of the model is shown in Fig. 3. Each of them can exist in several different variants that can be combined in various configurations. The modular prosthesis also includes auxiliary and connecting parts: pseudo-Cardan coupling, acting as a movable wrist joint, an assembly adapter, and an elbow module, imitating flexion and extension in the frontal plane. The list of prosthesis parts is presented in Table 1.

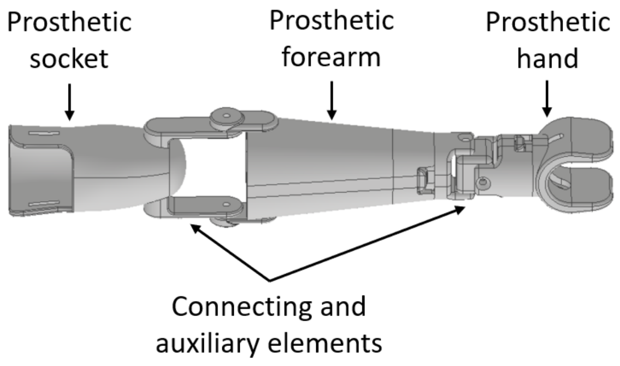


Fig. 3 Structure of a modular upper limb prosthesis

Table 1 Basic elements of modular upper limb prosthesis

Prosthetic socket	Prosthetic forearm	Prosthetic hands	Connecting and auxiliary elements
Compression and relaxation socket CRS (4 variants)	Open forearm	C-Handle	Cross joints
Open funnel (2 variants)	Open forearm with a tip dedicated to the adapter	Straight fixed handle	Adapter (2 variants)
Semi-open socket (3 variants)	Partly closed forearm with a tip dedicated to the adapter	Fixed angular handle	External model of the elbow
CRS socket for forearm amputation	Closed forearm with a tip dedicated to the adapter	Straight handle with a spring	Blocking part of the elbow joint

The base model analyzed in this step was the result of previous work of the AutoMedPrint project team, however, its form was not suitable for carrying out design automation tasks. Therefore, for all elements indicated in table 1, parametric CAD models had to be prepared and linked to an Excel sheet in which the results of anthropometric measurements would be placed.

2.4 Development of Generative CAD Models of Prosthesis Components

2.4.1 Prosthetic Socket

Modifying the base CAD model was aimed at linking its relevant parameters with data stored in Excel sheets. In addition, the basic prosthetic socket model (CRS - compression/release stabilized) had to be extended with additional variants, including an open socket, a partly open socket, and a CRS type for forearm amputations. Chosen modifications are presented in Fig. 4. Modifications had to be carried out so that, in addition to adapting to the selected values of the relevant measurement data, it could also smoothly cooperate with the forearm model.

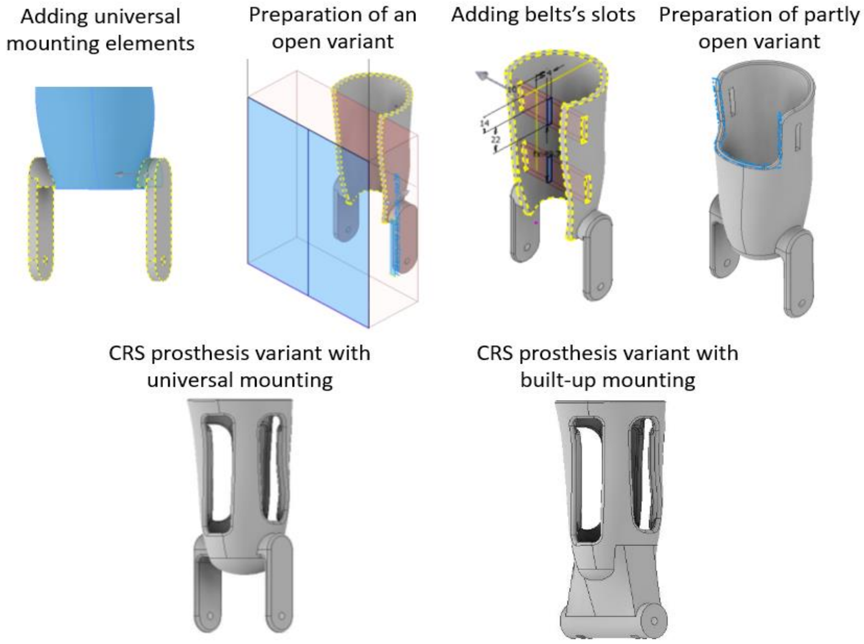


Fig. 4 Chosen modifications of the prosthetic socket

The most important modifications include the introduction of e.g. parameters and affecting the width of the location of the connecting elements with the forearm. This is measured from the plane of symmetry of the funnel, parallel to the XZ initial plane and passing through the point determining the center of the farthest section. Internal assembly of the socket relating to the forearm is usually used in the case of the youngest patients, therefore a separate parameter was introduced to determine the age of the patient. Another important modification was the addition of new socket variant geometries, improving the accuracy of the stump anatomy. An intelligent sketch of the universal fixation was also made, which ensured the possibility of adapting these geometric features when changing the input basic dimensions and changing the shape of the stump. As an alternative, a type of closed fastening has been prepared. There are also slots for mounting belts.

2.4.2 Prosthetic Forearm

The base model of the forearm is created by pulling between two sketches, the details of which are sourced from the Excel table (the first one depends on the prosthetic socket, and the second on the prosthetic hand). In order to build an appropriate connection of the forearm with a part of the hand, a parameter was prepared to automatically generate a second section of this extrusion proportional to the wrist. As a result, both parts were interconnected. The forearm model was also enriched with appropriate parameters, matching and binding them to new connecting elements. The individual geometric features of the forearm model, such as the spacing of the connection or the cutout in the bottom wall have been described so that they change their size proportionally with the change in the length of the component. The operations of creating assembly elements from the prosthetic socket have been modified and rules controlling the dimensions of the assembly hole have been added. Edge fillets were described by rules so that their values changed proportionally to the size of the entire prosthesis because constant values caused errors in the dimensional reconstruction of the model (too large radius values on small surfaces). Selected changes are shown in Fig. 5.

Appropriate changes were made one by one by making the next 3 variants of the forearm, taking into account the installation of transition elements. They were: open variant with the special ending, closed variant with the empty interior, and completely closed variant. All variants have a geometry for mounting the connecting element.

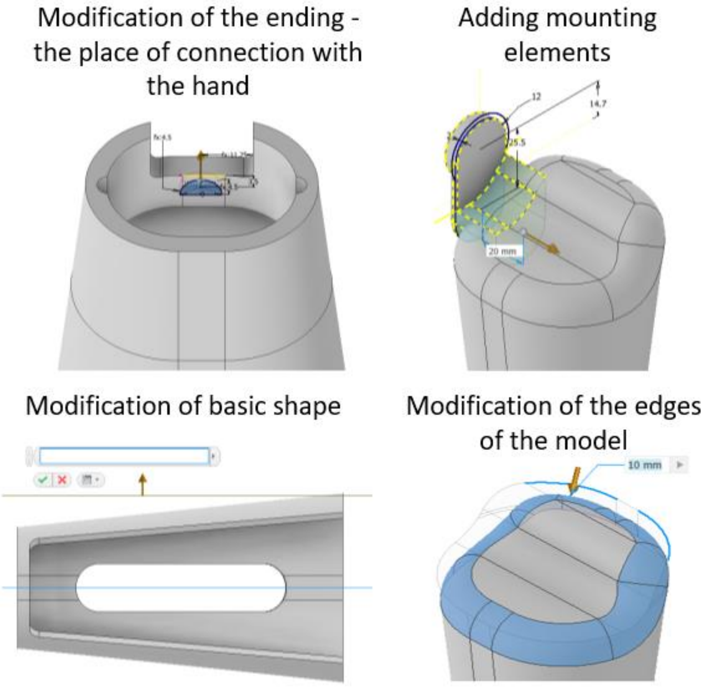


Fig. 5 Chosen modifications of the prosthetic forearm

2.4.3 Universal Elbow Joint

The first additional element of the modular prosthesis was a new, universal elbow joint, using springs and a splined lock, as presented in Fig. 6. The mechanism was placed in a closed base (external or internal part of the prosthetic socket). The base for the mechanism was made on the basis of a circle with a diameter described by parameters so that it automatically adapted to the dimensions of the selected mounting on the funnel model. The length of the element was set to the standard distribution between the fasteners. The next steps required drilling holes to attach the inner element and spring, and to connect the component to the hands and gimbals. In the execution of the mounting holes (for joints and hands), an additional parameter describing the diameter was used, which can be manipulated in the design table depending on the designer's preferences and the size of the adapter.

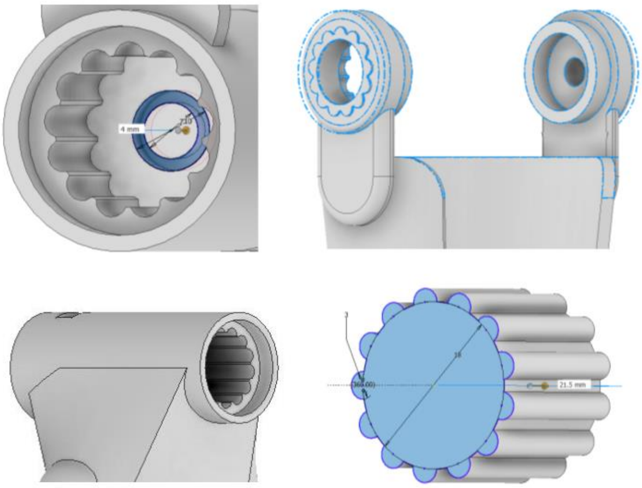


Fig. 6 Geometric features of universal elbow joint

In order to enable correct position locking, appropriate features have been added to each model of forearms, enriched with rules describing the conditions of their occurrence. Changing the value of specially prepared parameters in the forearm model automatically generates additional geometrical features that enable the connection of the forearm with the base of the elbow. These include, among others: lowering the surface of the upper end of the funnel, enlarging the proper mounting surface, creating a hole for the screw, a cut-out for the guides, shaping extrusion for blocking, etc. The dimensions of all operations were adjusted based on the activities performed during the design of the prosthesis's basic geometry and the parameters introduced at that time. An analogous rule was also applied to prosthetic sockets, automatically changing the cutouts for assembly to the base of the mechanism.

2.4.4 Prosthetic Hand and Universal Hand Holder

The work consisted of introducing modifications in the structure of the models by adding the selected 4 variants of the prosthetic hand, as shown in Fig. 7. The improvement of the gripping parts was made in terms of the possibility of parametric adjustment of the component width, introducing parameters related to the width of the hand. These values can be determined manually, but they can also come from measurements of the patient's healthy limb (also a 3D scan). Rules have been added to hand models to automatically select mounting holes, and the connection plane has been linked by rules to the appropriate universal prosthetic hand holder plane. Thanks to this, each geometric variant of the hand creates a coherent whole with it.

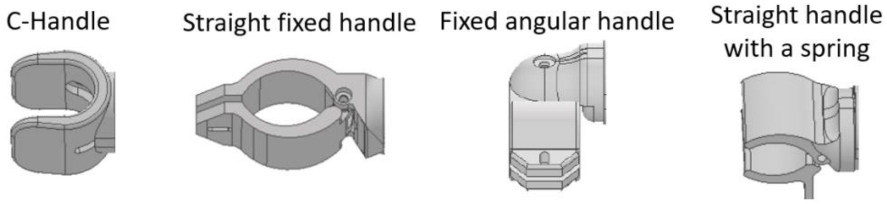


Fig. 7 Variants of parametric 3D models of prosthetic hand

Another element prepared especially for the needs of the modular hand prosthesis was a special hand holder, as presented in Fig. 8, allowing for the free transfer of the gripping parts between cardan joints and forearms, without the use of additional tools. The previous solution was designed "rigidly", which was a significant limitation because, in the case of different variants of the prosthesis, it usually required designing the adapter from scratch. The new model was enriched with specially described parameters so that the source of their data was measurements made on 3D scans.

Fig. 8 Universal hand holder

2.4.5 Cross Joints

The cross joint depicted in Fig. 9 is composed of three components and serves to connect sections of the forearm and the hand. Modifications of universal joints consisted of changing the features describing the base sketches and adjusting the mounting surfaces to the initial surface of the forearm and hand. The geometry of the hinge is the result of the relationship between the individual parameters of the model - each of the solids is dependent on the next one to form an integral whole. This is especially visible in the case of the central body, which is closely related to the width of the other two elements, which depend on the parts of the forearm and hand cooperating with them.

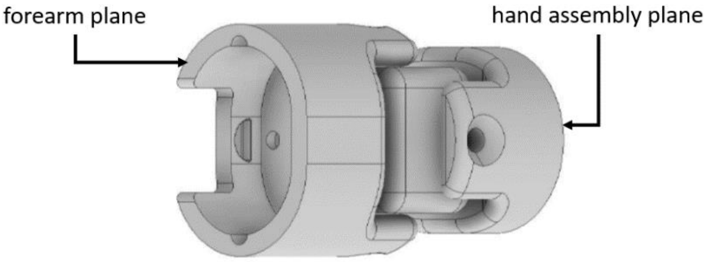
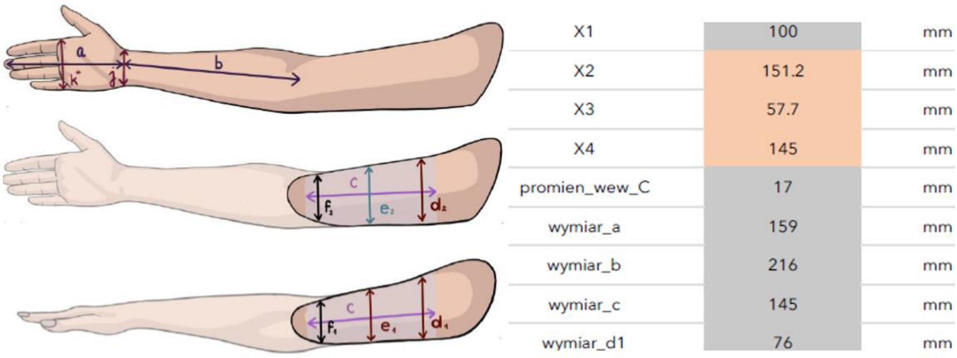


Fig. 9 Cross joint

2.4.6 Design Table and Design Rules

The design table storing and processing anthropometric data from the scanning process was prepared in Excel. A Partial view of this table is shown in Fig. 10. The table has been linked to the relevant parameters of the modular upper limb prosthesis models. The main sheet is the "Variants" sheet, which controls the selection of the prosthesis variant and thus manages the construction of CAD models. The idea of the entire system assumed the preparation of a model tailored to the patient's needs without the need to use a CAD program. The "Variants" sheet is therefore a kind of user interface. The remaining sheets are closely related to the collection of data from the process of scanning the patient's limbs. The relationships between them are intended to calculate the final values, which are then read by the CAD program and the related model parameters.



X1	100	mm
X2	151.2	mm
X3	57.7	mm
X4	145	mm
promien_wew_C	17	mm
wymiar_a	159	mm
wymiar_b	216	mm
wymiar_c	145	mm
wymiar_d1	76	mm

Fig. 10 Partial view of the design table for modular upper limb prosthesis management

The connection of the Excel file with the CAD assembly model was made using Autodesk Inventor iLogic tools. A number of design rules have been prepared to automate the process of rebuilding CAD models. The design rules contained a series of conditional instructions on the basis of which the program made decisions on how to update a given model without the designer's participation. The rules concerned, for example, the conditions of visibility of models and features or the choice of the type of relationship between the components of the prosthesis model.

2.4.7 Assembly Model of Modular Prosthesis

In the last step, the design table, prepared design rules and parametric 3D CAD models of prosthesis components shown in Fig. 11 were combined. As a result, an intelligent modular assembly model of the prosthesis as shown in Fig. 12 was created and it is the final representation of the KBE system. Generating a prosthesis variant for a new patient should start with completing the sheets storing data from the patient's measurements. However, generating another variant of the prosthesis requires only a change in the main "Variants" sheet. The CAD model rebuilds automatically, creating designs tailored to the individual dimensions and needs of a given patient.

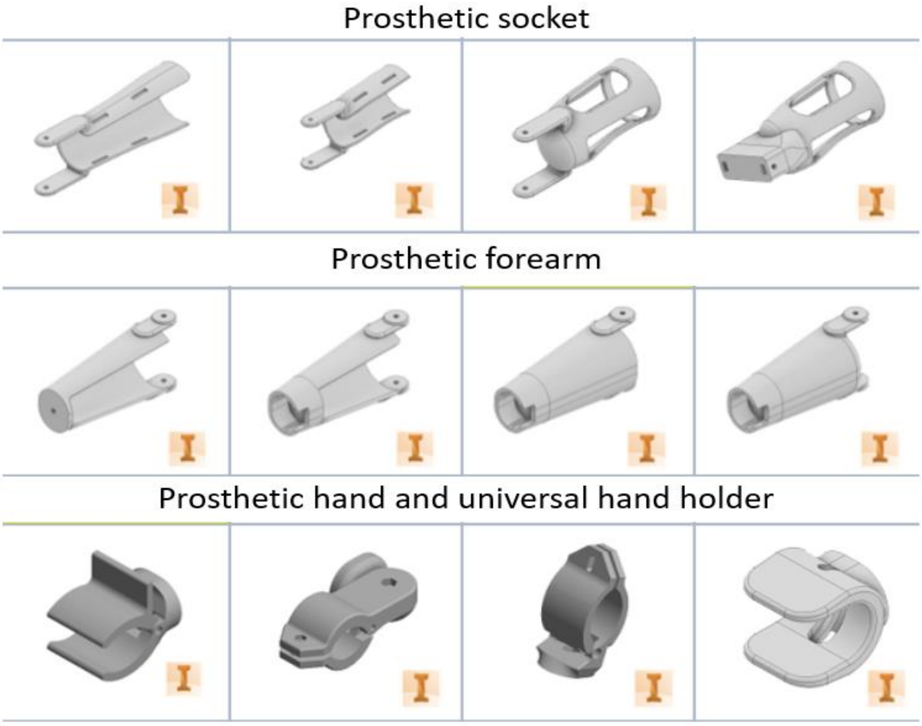


Fig. 11 Some of the geometrical variants of prosthesis components

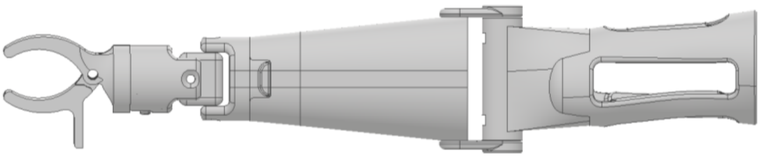


Fig. 12 Assembly model of modular upper limb prostheses

3. VERIFICATION OF THE SYSTEM FOR AUTOMATION OF PROSTHETIC DESIGN

3.1 Plan of Verification Process

Verification of the operation of the KBE system was carried out in the process of manufacturing various variants of prostheses for three patients. The research plan presented in Fig. 13 included the process of 3D scanning of the patient, data entry in the design table, selection of the prosthesis variant, automatic generation of the CAD model, and production of the prosthesis using incremental techniques.

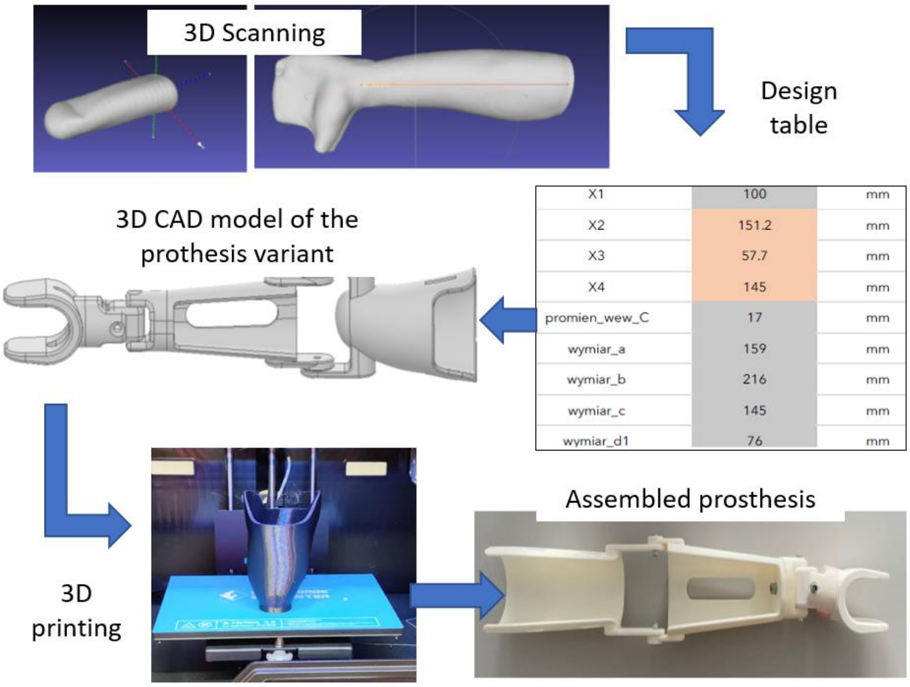


Fig. 13 KBE System verification process

The patients were of different ages, and sex and with varying disability of upper limb, but with similar anatomy of the residual limb. For each patient, four different variants of prostheses were prepared. The description of the variants is presented in Table 2.

Table 2 Variants types for the verification process

Prosthesis	Patient #1, adult male	Patient #2, adult female	Patient #3, child female
Variant #1	Closed CRS/ Open forearm / Straight fixed handle	Open funnel/ Open forearm/ C-Handle	Open funnel/ Open forearm/ C-Handle
Variant #2	Semi-open funnel/ Closed forearm/ Fixed angular handle	Semi-open funnel/ Closed forearm/ Straight handle with a spring	Semi-open funnel/ Open forearm / Straight handle with a spring
Variant #3	Semi-open funnel/ Closed forearm/ C-Handle	Semi-open funnel/ Open forearm/ Straight fixed handle	Open funnel/ Open forearm/ Straight fixed handle
Variant #4	Closed CRS/ Open forearm/ Straight handle with a spring	Closed CRS/ Open forearm/ Fixed angular handle	Closed CRS/ Closed forearm/ Fixed angular handle

3.2 Evaluation of Generative CAD Models

The models generated for patient #1 allowed us to recognize the operation of the generative CAD model in practice. The data from the 3D scanning process entered in the design table allowed for the flawless generation of individual parts of the prosthesis for variant #1. On the other hand, the reconstruction of the assembly prosthesis model resulted in irregularities in the connections between the components. The reason turned out to be errors in the prepared conditional instructions, and more precisely, the lack of certain conditions describing the joints between chosen components. These errors no longer appeared when generating variants 2-4 for patient #1.

In the next step, variants 1-4 were generated for patient #2. In this case, no new problems were identified. These appeared only when generating models for the youngest patient #3. They were related to, among others, incorrect execution of the extrusion operation in the forearm model, due to a significant change in the length of the forearm part. Errors also appeared when generating closed CRS, open and semi-open funnel with a forearm. The problem was that the section plane at the other end of the join was too high, so the projected cut edges included areas with cuts and created an unclosed sketch. After introducing changes in operations, by adding new rules, the models were rebuilt correctly.

The process of data processing in the CAD system took at least a few minutes in each case. The structure of the model and its connection with the database and knowledge described by rules makes the model generation process relatively long. In practice, this is troublesome, because frequent, iterative corrections and their verification required a lot of time.

3.3 Fabrication of the Designed Prosthesis

The paper presents the effects of the fabrication of a designed prosthesis for patient #3 in variant #1, as can be seen in Fig. 14, which can be considered as special bicycle prosthesis. Based on the results obtained from the KBE system, the selected variant of the prosthesis was made using FDM technology and PLA material. The manufactured components were assembled without major problems, and the joining surfaces were positively assessed. However, the disadvantages include the general quality of the final product - irregular layers are visible (especially on the surface of the forearm) and numerous surface roughness or material shortage in the area of the connection of the funnel with the mounting element. It is assumed that the manufacturing process will require significant modifications in the further stages of work on the system. The prosthesis was tried on and tested by the patient for cycling, as shown in Fig. 15.

Fig. 14 Variant #1 of prosthesis for patient #3

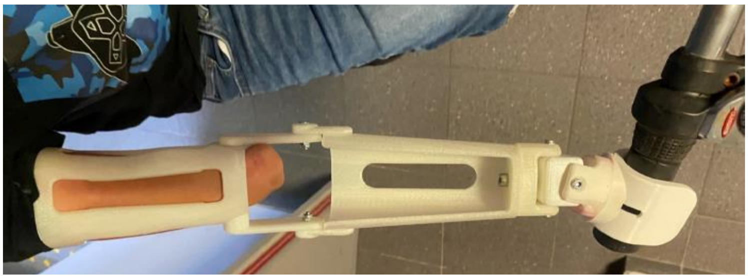


Fig. 15 Variant #1 of prosthesis for patient #3 - try-on with the patient

Despite the modular design and high functional capabilities of the prosthesis, its most important element is the socket, which requires proper fitting. The results of the fitting show some inaccuracies, revealing too much play around the residual limb - mainly in the lower and upper segments of the components. Therefore, the circumferences of the sockets should be reduced to prevent the stump from moving within their inner surface. Such a change will have to be taken into account in the assumptions for converting the results of 3D scanning measurements into specific values of CAD model parameters. In addition, due to the comfort of use, the patient #3 also indicated several comments regarding the improvement of the prosthesis functionality. Nevertheless, in his opinion, the prototype produced is very attractive and does its job, enabling him to ride a bike.

4. DISCUSSION

The result of work described in this paper is a generative CAD model of the upper limb prosthesis. While the methods of generational modeling have been known in engineering for years, in the field of prosthetic design it is a certain innovation and can be an interesting alternative to the traditional approach.

The main role in the project was played by the preparation of special parametric structures of the models, as well as the development of universal joints for prosthesis elements. The concept of the external elbow mechanism is an interesting alternative to the traditional connection, due to the possibility of using it in combination with an open socket. It offers the possibility of good ventilation of the residual limb, eliminating possible discomfort when using a fully enclosed socket made of impermeable plastic. However, the construction of the mechanical elbow joint should be subjected to further analysis and testing, especially in the long term of use. The developed concept of the mechanism made it possible to eliminate the screws previously used for angular adjustment. Increased by the ease of use of each variant of the prosthesis. In addition, it will be necessary to intensify the research and increase the number of patients, and as a result, modify the design rules so that the adjustment of the prosthesis elements to the size related to the patient's age takes place without the need for manual corrections.

The process of regeneration of new variants of the prosthesis took from several dozen seconds to several minutes. The introduction of a large number of components and relationships in the assembly model slows down the performance of Autodesk Inventor software, but there has never been a case in which it could not cope with the execution of the command given to it. Extended model generation time can also be caused by many single conditional statements contained in the iLogic rule - the program must go through each one separately to get the final result. Therefore, future research towards modular prosthesis models should focus on improving the governing rule and presenting the program contained therein in the form of a list of loops.

One of the most important elements of the built system turned out to be an extensive Excel file, allowing not only to enter measurement data from the 3D scanning process but also modifying them accordingly to the form necessary for the CAD program. Clear sheets, filled with design tables, allow easy orientation in the working space of the program. The whole thing has been designed to give each potential user maximum freedom in managing both the dimensional and construction aspects of a given device.

The data used in the research were collected in the AutoMedPrint system, however, they required manual correction to determine the correct coordinates of selected points forming sketches of sections of the residual limb. Therefore, this is an aspect that should be corrected during further activities toward the automation of the design of prosthetic sockets, through the proper determination in the structure of the algorithm of the relationship describing the distance between individual points of each generated cross-section.

The initial verification with the patients was successful and confirmed the possibility of smooth transition between the prosthetic sockets due to the unified assembly. Despite the need to introduce corrections to the overall dimensions of the device, a properly functioning prosthesis consisting of mutually matched parts was obtained. In order to finally evaluate the designed model, however, it would be necessary to produce more prosthesis components, and then test the actual operation of the implemented solutions, especially the issue of the adapter and the elbow mechanism. It would also be necessary to re-validate with the presence of a patient who would be able to assess the ease of use of the device with one hand and the continued compliance of the design with the dimensions of the healthy limb. Nevertheless, the concept of the device is a promising solution that easily allows any adjustments to the overall architecture of the prosthesis components due to the automation of the design of different variants of the prosthesis. In theory, therefore, the presented model is a useful tool to minimize human input in the general process of prosthesis generation.

5. CONCLUSIONS

The research presented in this paper demonstrates a significant advancement in the automation of designing modular upper limb prostheses. Integration of reverse engineering, generative CAD modeling and additive manufacturing, a solution was developed to facilitate the creation of modular, customized prosthetic devices. This innovative approach greatly reduces the time required for design and production but also enhances the adaptability of the prostheses to individual patient needs.

The generative CAD model proved to be highly effective in generating various prosthesis configurations tailored to the anthropometric data of different patients. The system's ability to automatically adjust the design parameters based on patient-specific measurements marks a considerable improvement over traditional manual methods. The use of parametric models and design rules embedded within the CAD environment ensured that the prosthesis components could be easily modified and adapted, facilitating rapid prototyping and iteration.

In the scope of the studies, certain challenges were identified, particularly in the fitting accuracy of the prosthetic sockets and the quality of the final printed components. These issues highlight areas for future refinement, such as improving the precision of the scanning-to-CAD data translation and enhancing the resolution and consistency of additive manufacturing outputs.

Future work should focus on optimizing the system to minimize manual adjustments and errors in the design process. Machine learning techniques could be used for that purpose, provided a sufficient number of cases to help them learn – expanding the patient pool for further testing would be crucial. Additionally, exploring advanced materials and printing techniques could improve the durability and aesthetics of the prostheses. will also provide more comprehensive insights into the system's performance and areas for improvement.

In conclusion, the developed KBE system for automated design of modular upper limb prostheses represents a significant step forward in prosthetic technology and in the domain of automated design systems. It offers a promising solution to the challenges of custom prosthesis design and manufacturing, contributing to improvement of the quality of life for disabled persons. Continued research and development in this field hold the potential to further revolutionize prosthetic care, making it more accessible, efficient, and personalized.

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