Evaluation of a Prototype System of Automated Design and Rapid Manufacturing of Orthopaedic Supplies

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Abstract. The aim of this study was to evaluate the AutoMedPrint system, which is used for automated design and rapid production of orthopaedic and prosthetic devices based on anthropometric measurements. The system was tested on a group of 21 patients. Research has been conducted to determine their needs and expectations. In the first step, anthropometric data was collected using a 3D scanner. The obtained data allowed to automatically design wrist-hand orthosis using an intelligent CAD model. Patients customized their orthoses using interactive product configurator available in the system. Some orthoses were manufactured using the necessary machines by 3D printing, and then handed over to selected patients for their opinion. The paper presents the results of usability tests and the evaluation of the technical aspects of the system. Based on these results, the main problems were characterized and ways to improve the system were suggested. Modifications are designed to improve patient satisfaction, usability, ease of use, and the enjoyment of interacting with a system or product.

Keywords: Additive manufacturing · Customization · Design automation · Medical 3D printing

1 Introduction

The rapid development of additive manufacturing technology in recent years has allowed a significant reduction in costs and time needed to implement a new product. Additive manufacturing processes make it possible to obtain physical, 3D shapes of almost any complexity, directly from a digital representation of the product (usually a model made in a Computer Aided Design - CAD system) [1]. There is no need to use any specialized tooling besides the production machine equipment. These technologies are invaluable when there is a need to quickly manufacturing of a physical prototype of a designed part [1], which is especially important in personalized medicine [2–4]. Using of 3D technology also allows to show the expected product to the patient before its production and provide him/her with flexible design options, which can be used in the process of designing and rapid production of orthopaedic devices. This allows the patient to be

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involved in the process, improves communication with the patient, and also allows to receive feedback about the device during the design phase, even before manufacturing. This makes it easier to improve the product in order to increase the satisfaction of its user. The 3D printing processes can also be useful in the field of foods and nutrition [5], patient education [6] and teaching of resident physicians [7].

A wide spectrum of additive manufacturing varieties makes it possible to manufacture products from many types of materials [8, 9]. Additive manufacturing in relation to traditional technologies (casting, machining and plastic molding) has certain limitations related to the efficiency, quality and physicochemical properties of the manufactured products [10]. However, as of 2019, the production of finished parts is much higher than in previous years [11]. One of the most widely used additive manufacturing technologies for industrial purposes is fused deposition modeling (FDM), which can be used to obtain parts from thermoplastic materials. The most commonly used building materials are acrylonitrile butadiene styrene (ABS) and polylactic acid (PLA), which provide relatively good strength and acceptable thermal shrinkage and allow for further processing of the obtained elements. From year to year, the range of available materials that can be processed with the FDM method is constantly growing [9]. FDM machines are quiet and clean, and compared to other additive manufacturing technologies, they have small dimensions and are easy to maintain, so they can be used in design offices, hospitals or medical facilities [2, 3, 12].

One of the most popular classes of 3D printed medical devices in wide use are orthopaedic supplies, primarily limb orthoses, which are medical devices designed to maintain the rigidity and safety of a selected part of the patient's body during healing or convalescence [13–15]. This is mostly achieved by immobilizing and protecting the area around the joint from deformation and physical damage. Orthoses can also be used to force a specific position and mutual orientation of different body parts [16]. The limb orthoses might be universal, which are relatively inexpensive, or personalized, much better but also a much more expensive product and made based on the patient's anatomical measurement [17].

One of the biggest problems with 3D printing custom orthopaedic supplies is engineering expertise. In the modern design process, the patient's anthropometric data are collected and digitally processed, mostly manually, which can generate many inaccuracies [20]. Many hours of advanced surface modeling in CAD systems are required to obtain the shape [18]. 3D-printing of thermoplastic products with satisfactory accuracy and strength values is difficult. The process parameters significantly affect the properties of the obtained parts [21]. Consequently, traditional plaster casting processes have not been replaced by 3D printing yet. Research is regularly conducted to facilitate data collection, processing and production in general medical practice [18, 19, 22].

Due to the problems in the subject of traditional manufacturing of individualised orthopaedic supplies, a completely new automated system, under the name of AutoMedPrint (shortly AMP) has been developed, allowing for automatic design and manufacture of orthopaedic products - limb orthoses and upper limb prostheses. This study was conducted to evaluate an upper limb orthosis using this system with a group of twenty-one people, to present detailed problems regarding the use of the system from the user-patient and user-operator perspectives, and to propose solutions to these problems and other improvements to the system [23].

2 Materials and Methods

2.1 The AutoMedPrint System

The AutoMedPrint system is used for automatic design and additive manufacturing of selected orthoses and prostheses based on patient anthropometric measurements. The system (Fig. 1) consists of a station for 3D scanning and design, a user interface station with applications supporting the scanning process and product configuration, and a station for rapid manufacturing.

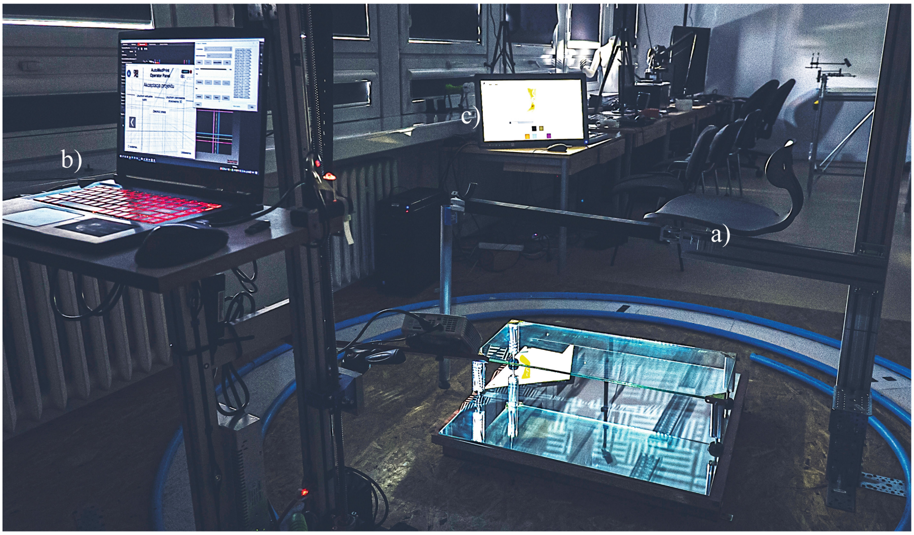

Fig. 1. The AutoMedPrint system prototype, a) 3D scanning rig; b) operator interface; c) user interface; station for 3D printing not shown

The design and manufacturing of products is based on data from the process of scanning the patient's limb. Not counting the time it takes to make the product, the whole process takes up to several dozen minutes. The time required to produce a finished product can take up to several dozen hours, depending on the type of product. The system allows defining the type of product the patient needs, taking anthropometric measurements using a non-contact 3D scanning technique, automatically designing the product based on the patient's anthropometric data, designing and visualizing the product by the recipient, and preparing and executing the rapid manufacturing process. The system's scheme of operation is shown in Fig. 2.

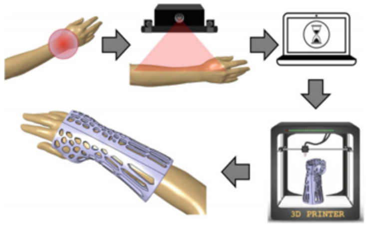

Fig. 2. Scheme of work of the proposed AutoMedPrint system [24]

2.2 Plan of the Experiments

The evaluation of the prototype AMP system was a part of its studies, performed within a scope of an R&D project. Full detailed description is presented in the work [23].

In the first stage of the research, a plan was developed, in which a method for conducting usability tests with users of the AutoMedPrint system was selected and a test course was designed, consisting of the stages of 3D scanning, design and rapid manufacturing. In the next step, a set of questionnaires evaluating particular parts of the system was developed and a leaflet was designed, handed out to the participants beforehand. Then a test group of 21 people was assembled to participate in testing the system and tests were conducted on them in the laboratory, according to the designed plan.

In the next stage, for 6 selected patients, orthoses were manufactured using 3D printing. Once all stages of the study have been completed, survey results were collected and compiled. This allowed to evaluate the system in division into the 3D scanning process, the design process, the rapid manufacturing process, the user interface and the finished product. In the final step, an overall assessment of the whole system was performed.

2.3 Methodology of Experiments

The first step of the study on the evaluation of the manufacturing system was to invite the patient to the laboratory and then hand out an information leaflet on each of the stages of testing the AutoMedPrint system. Once the participant was familiar with the study, the facilitator introduced the different parts of the system and discussed the tasks awaiting the patient and answered any questions.

The next step was the 3D scanning process. Before starting the process, it was necessary to complete the basic data on the patient. The scanning process consisted of two parts. In the first part, the participant uses an interactive application of scanning assistant, providing visual, animated information about the 3D scanning process. In the second part, the participant's upper limb was measured using a 3D scanner to create a 3D model and then a CAD model of the wrist-hand orthosis. If there was a mistake in the 3D scanning process that prevented correct results from being obtained, the process was repeated.

In the next step the participant, in accordance with his preferences, personalized his product through another interactive application – orthosis configurator. The data of the designed product was saved in the system, in a text file. Meanwhile, the operator initiated and overviewed the automated processing of 3D scans, to first obtain a 3D model of the upper limb and then of the orthosis.

Once the 3D scanning and orthotic design processes were completed, the lab testing came to an end and the participant was asked to complete a survey regarding their evaluation of the AutoMedPrint system. The survey was divided into four parts and dealed with the evaluation of 3D scanning process, evaluation of design process, evaluation of user interface and overall system evaluation – this was filled by all participants. The six participants who received the finished, 3D printed product, completed an additional online survey regarding their evaluation of the manufactured orthosis.

2.4 Methodology of System Evaluation

Methodology of 3D Scanning Process Evaluation

The 3D scanning process was evaluated from a technical point of view and from the perspective of the patient, i.e. the system user. It was checked if the scanning process was successful the first time, i.e. if a set of 3D scans needed for upper limb reconstruction is obtained for all participants, or if it should be repeated e.g. due to incorrect limb positioning during the examination. It was also verified that a correct 3D model of the limb could be created for all participants without errors occurring during the processing of the 3D scans. For the group of six for whom the orthoses were manufactured, 3D models of the limbs were inspected for resulting artifacts to assess the need for additional cleaning of the scans. In order to properly carry out further steps leading to the design of the orthosis, the necessity of removing the resulting artifacts was checked and if there is one, the artifacts are removed.

To evaluate the 3D scanning process, which consisted of using an interactive scanning assistant and measuring the upper limb with a 3D scanner, participants completed a questionnaire in which they answered questions about their familiarity with the 3D body scanning process, their comfort and convenience during the 3D scanning process, and the duration of the process. Below are sample questions from the 3D scanning process evaluation survey:

- Have you ever had a 3D body scan done?
- Did you feel anxious about the process before 3D scanning?
- Was the 3D scanning station (chair, table, armrest) comfortable for you?
- How would you rate the duration of the 3D scanning process?
- Do you find measuring your body with a 3D scanner more convenient than measuring your body with traditional methods?

In addition, the study moderator measured the time each system user used the interactive scanning assistant and each person's 3D scanning time using a stopwatch. These times were then summed to obtain the duration of the entire step of the 3D scanning process.

Methodology of the Design Process Evaluation

The design process was evaluated from a technical perspective as well as from the perspective of the patient, the user of the system. For the six patients for whom the orthoses were fabricated, it was verified that it was possible to correctly extract points from the limb model, generate autogenerated model feed sheets and CAD models of the orthoses in an automated manner.

Evaluation of the orthosis design process was done using a completed questionnaire by the participants who answered four one-choice questions. The following are sample questions from the process evaluation survey:

- Can the configurator be used to design a finished product easily and quickly?
- Is the setup process enjoyable and fun?

By answering the questions, participants indicated on a five-point scale how much they agreed with the statements regarding the use of the configurator, its operation and the ease of configuring the product. During the design of the orthosis, the moderator measured the time the system user used the configurator with a stopwatch and noted in the report whether the study participant completed the device configuration process successfully without his or her major intervention.

Methodology of User Interface Assessment

Patients evaluated the user interface by completing a survey in which they answered four questions. The questions were designed to assess the design of the configurator, the readability of icons and layout, and the ease of navigation when configuring the orthosis. They were constructed to determine the intuitiveness of using the interface. Participants determined using a five-point scale the extent to which they agreed with the interface statements that the layout is clear and understandable, icons are easy to identify and understand, the arrangement of elements on the screen promotes easy navigation, and about the visual appeal of the configurator.

Methodology of Evaluation of Manufacturing Process and Finished Product

The evaluation of the rapid fabrication process checked that orthoses were fabricated, one for each participant in the six-person group for which this stage of the study was scheduled. If an error occurred during the process, this information had to be recorded and the process repeated to produce a functional orthosis. The fabrication times of each of the two parts of the orthosis (upper and lower) were measured. User selections from the configurator that provided guidelines for fabrication included the shape of the openwork, material, colour, print orientation (horizontal/vertical), fabrication strategy, machining (with/without sanding) and assembly (with/without tape).

Patients completed a questionnaire about the finished product. The questions concerned, among others, the compliance of the manufactured product with the design and visualization with the configurator and their expectations, as well as the quality of the manufactured product.

Methodology of Overall System Assessment

In order to evaluate the system in general, participants completed a questionnaire. Sample questions from the survey are shown below:

– How satisfied are you with the services offered by the system?
– Do you find the system helpful when purchasing a personalized orthopaedic device?
– What do you think are the main advantages of the system?
– How would you rate the duration of the entire process - from 3D scanning to product configuration?
– Would you use such a system if the need arose in the future?

Questions were designed to elicit information about patients' overall impressions.

3 Results

3.1 Process Results

3D Scanning Process

Based on the evaluation of the 3D scan, it can be concluded that the process was successful the first time for every patient (21) of the study. During the experiment, 20 out of 21 correct upper limb models were obtained without interfering with the obtained partial scans.

Based on the six limb models selected for the design of the orthosis, it was found that in two patients the positioned hand for scanning was bent - the metacarpus pushed outwards. Care must therefore be taken to ensure that patients position the limb in addition to the correct position of the entire upper limb during the 3D scanning process.

The obtained limb models in most test patients had visible artifacts (Fig. 3), not corresponding to the anatomical structure.

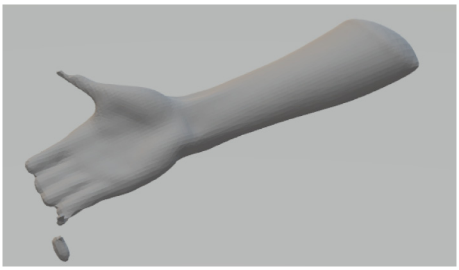

Fig. 3. Scanned right upper limb with artifacts

In order to properly model the orthosis in a further step, artifacts were removed manually using dedicated software. The total average time to use the interactive scanning assistant was 1 min and 12 s.

Design Process

For all selected products, the corresponding points from the cross-sections were generated correctly. For two orthoses, complete sheets feeding the autogenerated model could not be obtained, making it impossible to obtain a correct model in Autodesk Inventor. For the other three orthoses, the model updated in the software with errors. Problems encountered required manual intervention with sheets or models in Inventor. The selected CAD model of the orthosis is shown in Fig. 4.

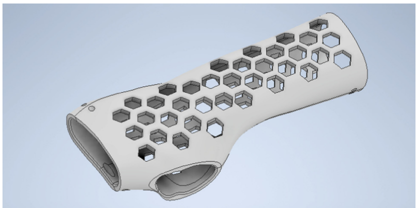

Fig. 4. CAD model of the orthosis [23]

The average design time was 2 min and 2 s. This was the time when patients configured the product according to their preferences for appearance and functionality and the operator received instructions on how to manufacture the orthosis.

On average, the patient used the scanning and design module for 8 min 26 s, and their entire study took an average of 12 min 40 s.

Rapid Manufacturing Process

This step was successfully accomplished for all selected patients, thus six orthoses, 12 parts in total, were made correctly and without errors. The processes were stable and required little operator supervision. After fabrication and basic finishing, it was checked whether it was possible to assemble the two parts together. For each orthosis, the halves fit together, so it can be concluded that the manufactured products fulfilled the role of stiffening the wrist. The orthoses that were provided to the study participants for evaluation are shown in Fig. 5.

Fig. 5. Manufactured orthoses [23]

3.2 Evaluation Results

3D Scanning Process

According to the patients' responses, most of them (19 patients) had not experienced 3D body scanning before. Although the majority of patients had not encountered 3D scanning in the context of body measurement, none of the study participants had concerns or felt anxious about the process.

The respondents were also asked to rate the duration of the 3D scanning process (everyone was asked to answer according to their feelings). Just over half of the patients (11) rated the duration of the 3D scanning process as short very short (1). For eight people, the scan time was just right, meaning neither too long nor too short.

When asked about the convenience of measuring the body with a 3D scanner than with traditional methods, respondents answered almost unanimously by indicating yes (9) or definitely yes (11) that non-contact scanner measurement is more convenient for them.

The above mentioned results are shown in Fig. 6.

Fig. 6. The results of the 3D scanning process

Patients were also asked to give their opinion on the ergonomics of the workstation, which consists of a chair, a table and an armrest, and to select the least comfortable workstation element. The results of the survey are shown in Fig. 7.

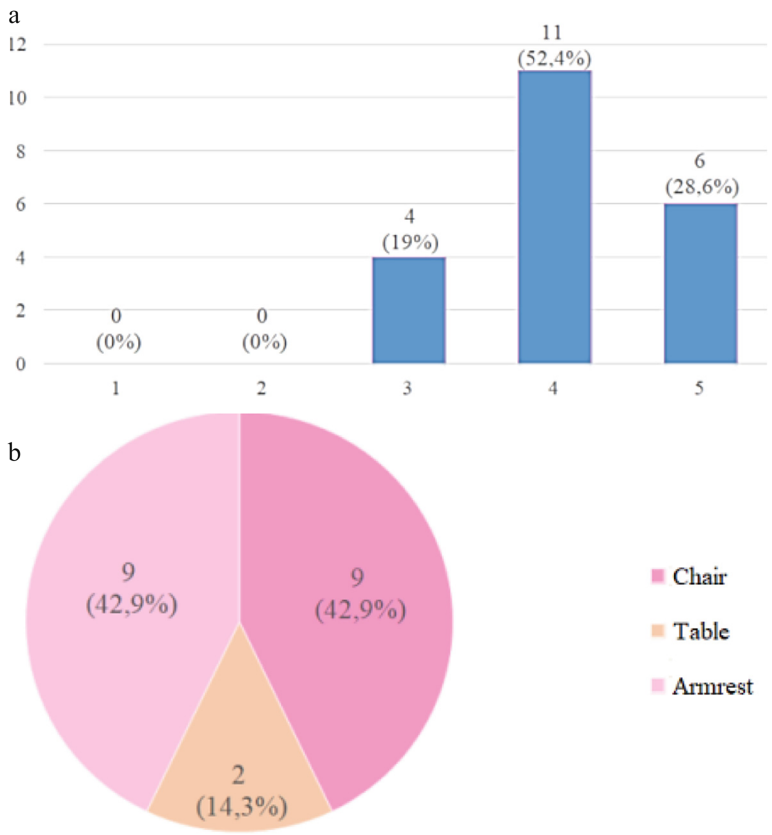

Fig. 7. Answers for questions: Was the 3D scanning station (chair, table, armrest) comfortable for you? (A) and which of the elements of the 3D scanning station was the least comfortable for you? (B)

Patients also unanimously answered the question about the convenience of measuring the body with a 3D scanner than the traditional method. As shown in Fig. 8 twenty people think that measuring with a 3D scanner is more convenient.

Customization Process

The vast majority of patients (20) stated that with the help of the configurator it is possible to easily and quickly design ready orthoses. Seventeen participants agreed that the setup process was fun and enjoyable. The results are shown in Fig. 9.

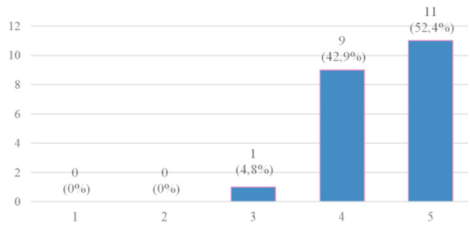

Fig. 8. Answer for question: Is body measurement using the 3D scanner more convenient for you than measuring the body using traditional methods?

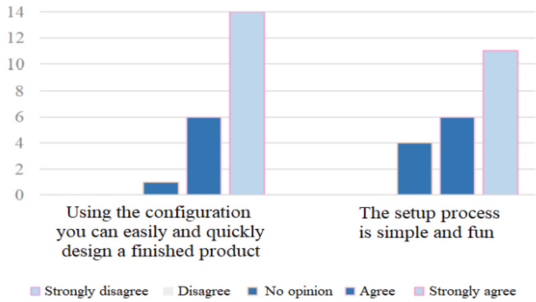

Fig. 9. Results of a survey on the orthosis design process

User Interface Assessment

Based on the responses, it can be seen that a large majority of the respondents (20) believe that the interface is clear and understandable (Fig. 10).

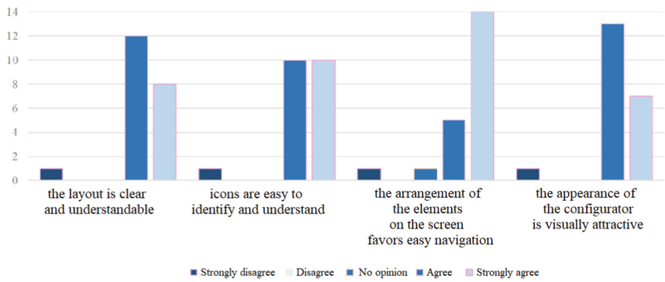

Fig. 10. The results of the user interface evaluation survey

Product Evaluation

Based on the questionnaires of the patients who received the orthoses for evaluation, it can be seen that most of the testers are either satisfied (2) or very satisfied (2). As for the compliance of the manufactured product with the expectations, almost all respondents were satisfied (3) or very satisfied (2) (Fig. 11).

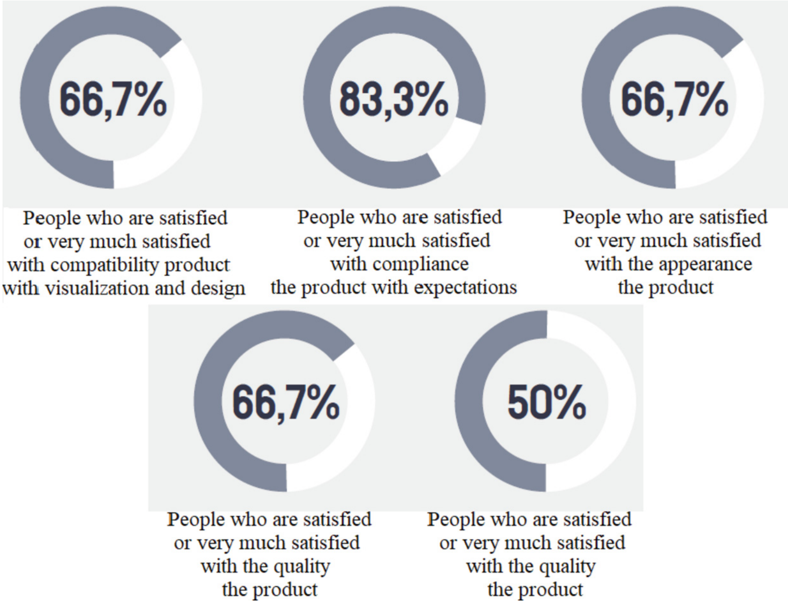

Fig. 11. Finished product evaluation

Overall System Assessment

All patients were satisfied with the services offered by the system. The majority of respondents (17) strongly believe that the system is helpful when purchasing a personalized orthopaedic device. According to almost all respondents (20), the main advantage of the system is the ability to personalize the product. Among the main advantages, most of the respondents mentioned the possibility of performing all the activities in one place - from 3D scanning to ordering the configured orthosis.

Each respondent expressed a willingness to use such a system should the need arise in the future. Test patients were asked to choose three main advantages system and the results are presented in Fig. 12.

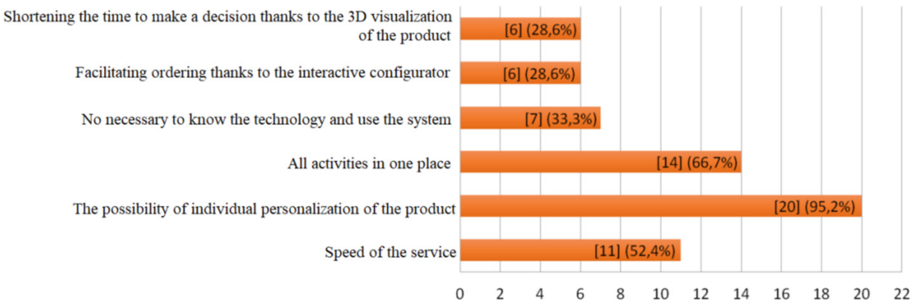

Fig. 12. Answer for question: What are the main advantages of the system in your opinion?

3.3 Discussion

The main objective of the study was to test and evaluate the performance of a prototype AutoMedPrint system for automated design and manufacturing of incremental orthopaedic and prosthetic supplies based on anthropometric measurements. Tests and questionnaires were carried out to evaluate the system with a group of test patients according to the planned scenario for the selected product - openwork wrist orthosis. The three main activities performed as part of the system operation, namely 3D scanning, design and rapid manufacturing, were tested.

Moving the scanner and starting the scanning depended on the operator controlling the movement of the device from the position of the laptop. This results in scan times that are operator dependent. Proper clothing for limb scanning is also important and should be communicated to the patient prior to the test. Wearing a blouse with or without short sleeves would improve patient comfort.

As a result of the evaluation of the scanning process, it was also suggested that some parts of the bench be repainted black, and that a black elastic thumb sleeve be worn during scanning. Black surfaces are not scanned, avoiding the need to manually clean scans and remove unnecessary artifacts. This approach has been already implemented and tested with success.

Errors in the CAD model and problems with generating data caused the authors to change the methodology of spline curve creation in the basic CAD model of the orthosis (original approach presented in [30]). The model was improved and in the tests conducted afterwards, orthoses were successfully generated (some with very minor errors) for all the patients.

The fabrication time mainly depended on the size of the orthosis as well as the printing strategy and orientation chosen by the patient. The orthoses for women were smaller than those for men, thus less material was used for them, making the printing time much shorter. In order to shorten the production time of the whole orthosis, both parts were printed in parallel on two machines.

The measured times show that the production time for one orthosis is not long and therefore future patients can receive the finished products the next day. Traditional methods of orthosis manufacturing do not offer this possibility.

The fit of the manufactured product was also controversial, as it can be concluded from the results that the orthoses did not fit every other person. For half of the patients (3), the orthosis proved too tight when attempted to be fitted. During the design process the offset from the limb was set at 1 mm. This value was verified in further studies on a group of several patients, and for adult patients was set at default of 3 mm, which was proven to fit all the patients, while not being too loose.

3.4 Conclusions

In conclusion, the results of the study showed that it is possible to obtain a fully functional and affordable orthosis in less than one working day utilizing an automated design process, allowing the patient to start the rehabilitation process immediately. Just one visit is enough to create a custom orthosis. In case of failure at any stage, it can be easily reproduced to get the correct result. This is a worldwide unique capability of the AutoMedPrint system.

Another advantage of the system is the possibility of operating in one location, as well as the lack of requirements for specialist knowledge of modern technologies on the part of both the operator and the patient. It would therefore be possible to implement such a system in medical facilities, without the need for skilled engineers or technicians. The patient has the possibility to actively personalize the product and the visualization of the product helps them to make decisions. Considering the results of the questionnaire completed by the study participants, patients are satisfied with the services offered by the system and express their willingness to use such a system if needed in the future.

The research results and conclusions were used in further stages of AutoMedPrint system testing. Further studies on the system are conducted with a younger group of patients, as well as individuals after a wrist joint injury requiring real treatment. This will help to discover other service and fitness issues and refine the system's performance.

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