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Orthoses Development Using Modern Technologies

Branko Štefanovič, Mária Danko, Monika Michalíková, Lucia Bednarčíková, Viktória Rajtúková, Teodor Tóth, Marianna Trebuňová, Radovan Hudák and Jozef Živčák

Abstract

The aim of this study was to design, manufacture and verify orthoses using innovative methods. 3D scanning, additive manufacturing and CAD/CAM software are applied during the development process. Target group of the study are subjects with insufficient gripping and manipulating functions of the arm and forearm. Positives are obtained using a hand-held 3D scanner Artec Eva. Specific 3D scanning methodology is applied during this process. Individual orthoses are designed in an open-source CAD software Meshmixer and manufactured by FDM (Fused Deposition Modeling) additive technology from a biocompatible plastic material. All models are inspected and verified in an analysis software VGStudio MAX. Given methodology can be used not only for this specific purpose, but also for orthosis development in general.

Keywords: orthosis, additive manufacturing, 3D scanning, CAD/CAM, fused filament fabrication

1. Introduction

An orthosis or orthotic device is a device applied to the body to replace lost function of locomotor systems or to help restore lost or damaged function, to stabilize or immobilize a part of the body, to improve alignment, prevent deformation, protect against injury or assist in movement, or function [1].

Orthoses are used, to:

- align or position limb segments to enhance voluntary limb movement and improve function (e.g., an ankle-foot orthosis [AFO] to provide prepositioning of the foot during swing limb advancement and stability during the stance phase of gait);
- minimize the influence of abnormal tone on posture and movement (tone-inhibiting designs);
- provide individuals with a variety of comfortable and safe positions in which they can sleep, eat, travel, work, or play;

- promote joint alignment and minimize risk of contracture development and other secondary musculoskeletal sequelae (especially in growing children);
- protect a limb following orthopedic surgery performed to correct deformity or instability;
- enhance alignment following pharmacological intervention with botulinum toxin;
- provide alternative methods for mobility [2].

These are orthopedic devices that affect the function of the musculoskeletal system: they keep body parts in the desired positions or bring them into the necessary positions, sometimes replacing lost functions, or bringing the disability to a tolerable condition. Furthermore, they are devices attached to the patient's body, which affect the condition and operation of the musculoskeletal system. This means that they do not compensate for the anatomical loss of the limb, but partially compensate for the lost function. The Committee for Prosthetic Research and Development (CPRD) categorized orthoses with respect to anatomical segments and joints. It created, firmly established and implemented a system of abbreviations derived from the first letters of the name of the orthosis in English for each category. Within the international Standards By ISO, the technical committee TC 168 has introduced the mentioned terminology, which is accepted worldwide [1, 3–5].

These devices are manufactured individually or in series production, from different materials and in different sizes according to the expected length of use and the burden also related to the patient's lifestyle. When using mass-produced orthopedic-prosthetic devices (in a sufficient size range based on the anthropometrically determined dimensions of healthy people), the choice and application of a suitable device does not pose a problem. In some cases, this device may require only minimal adjustments (e.g. adjustment of the fastening strap) during the test by a qualified person (orthopedic technician, doctor). Another case is an orthosis made to measure according to the individual requirements of the individual. The traditional production process consists of the phase of taking the necessary measurements, the phase of production of the model (gypsum positive, which is made by casting gypsum) and then the creation of an orthotic device from the required materials [1, 3].

In the final phase, it is necessary to take into account the specific physiological, kinesiological and biomechanical properties that will be placed on the orthosis, structural and material characteristics, use of joints, locks and other biomechanical elements, so that the orthosis fulfills its purpose [1, 5, 6].

The goal of an orthotic device is to help a person with a disability achieve the highest level of functional independence and integration into the community. The design, manufacture and installation of orthoses and ancillary equipment is an important part of the treatment regimen [1, 4, 7].

Of course, an orthopedic device must always be prescribed by a specialist. Because, it is an aid that acts and influences the function of the locomotor system, it can harm the patient can lead to progression of the damage. It is therefore necessary that the technician who equips the patient with orthopedic aids understands the work well and is sufficiently prepared in the field of craftsmanship.

For the technician to be able to determine the correct functional type of orthosis and its optimal design, he needs to be able to assess the overall physical condition of the patient, or the affected segment. Basic examination methods, which include manual muscle testing (MMT), range test (ROM) and sensory testing, thus provide

the technician with important information for an individual design of the structure and structure of the device [1, 8–10]. This knowledge, combined with the technical skills required in the manufacturing process and installation of these devices, lead to successful outcomes for patients [1, 4, 7].

1.1 Materials

Depending on the type of orthosis, the location of its action, the type of treatment, a combination of different materials (metals, plastics, leather, composites, foams, rubber and other materials) is chosen. The material is often selected to achieve the desired clinical result, while guaranteeing the required technical strength and environmental resistance [3, 10].

The choice of material for a given design depends in part on an understanding of the basic principles of mechanics and materials, force concepts, deformation and failure of structures under load, improving the mechanical properties by heat treatment, the manufacturing process and also has an impact on the proper functioning of the orthotic device. Among the traditionally used materials we can mention metals (connecting materials), they are also plastics, textiles, rubbers and leather have a wide range of uses. Development of new materials, especially the possibility of using new composite materials (plastic matrix with reinforcing fibers), which provide better mechanical properties and aspects of biocompatibility [3].

When using plastics, a distinction is made between low and high temperature plastics, while their use depends mainly on the location for which the orthosis is intended and the purpose of its use. In the area of the forearm and hand, low-temperature thermoplastics are usually sufficient, which can be modeled directly on the patient's body surface after heating to the working temperature (60 to 70° C). Especially orthoses intended for the fixation of affected joints, it is suitable to use either high-temperature thermoplastics, or low-temperature thermoplastics, but with a greater thickness (3.2 mm). These types of upper limb orthoses are also produced by lamination, but they are mainly those that are intended for long-term application in permanent disabilities. Large progress is being made mainly due to the wide range of materials currently available to the orthopedic technician. The ability to produce custom devices with very complex accuracy has improved the customization of the devices. Materials with a high strength-to-weight ratio have made the equipment lighter and materials that bend smoothly have improved achievable functions and performance. Knowledge of materials helps the technician in the production process and in the use of new techniques, such as additive production. As technologies and materials are constantly advancing, it is important that the orthopedic technician is constantly informed about innovations, technological procedures and materials, so that he can provide the patient with adequate care for progress [3].

1.2 Fabrication

1.2.1 Conventional production of orthoses

Upper limb orthoses are manufactured using plastics, while the production of low-temperature and high-temperature thermoplastics has a significantly different technological process. With low-temperature thermoplastics, processing is faster and easier. A shape is cut from the plastic or cut out according to the choice of the orthosis, which is then heated to a temperature of 60 to 70°C (depending on the thickness of the material and its properties). The material can be heated to the operating temperature in either a water bath or by dry heating. After isolation of the

patient's body, the plastic is formed directly on the limb, where the knowledge and experience of an orthopedic technician are necessary for the final position of the segment of the affected segment to be correct. Gypsum positives are used as a basis for the production of orthoses from high-temperature thermoplastics. However, before starting the plastering itself, it is necessary to fill in the measurement sheet. For an orthopedic technician, it is important to assess the range of motion in terms of mobility in a targeted way to create a design for a functional orthopedic device. Based on the initial examinations, the maximum correction position of the given segment is assessed. According to the required function of the orthosis, the maximum correction position of individual segments and its time tolerability are determined. If the joints are physiologically loaded, the properties and construction of the orthosis must not change this loading situation. When plastering in practice, plaster bandages are most often used, which are attached to the limb that will be plastered and shaped at the same time. It is important to pay attention to the load points and correct the shape before the plaster hardens. It is also very important to draw landmarks and painful areas on plastered parts of the body. When removing a plaster cast, it is very important to note and mark all bone growths (bumps) that protrude to the surface or are well palpable under the skin, as some of them are important landmarks. They are marked with a dermo-graphic pencil so that they are well pressed onto the gypsum casting. Although the casting itself is in principle accurate, if the patient moves or adjustments are not made correctly, this will affect the shape or function of the orthosis. This is the case when the skill of an orthotist is shown. With the gypsum positive finished, it is necessary to decide whether to use a high-temperature thermoplastic or to make the orthosis by lamination [5, 11].

The techniques used to make traditional metal and leather orthoses and thermoplastic orthoses have not changed. What has changed is where these devices are made and whether they are made for a specific patient or mass-production. In the search for production efficiency and cost savings, along with the limitations of established production technologies, many prosthetics manufacturers have chosen the "multi-model for all" approach. They basically create several different standardized sizes and a neutral look (in terms of color, texture, etc.). Using these so-called stencils, thousands of aids are produced every year.

Due to developments in data collection and software development, the use of computer-aided design (CAD) and computer-aided manufacturing (CAM), including additive manufacturing (AM), has increased for orthoses. At present, CAD/CAM methods are available for the smallest orthotic workplaces and can be used to speed up assembly as well as to facilitate off-site production in a specialized production center [5].

In order to achieve the optimal clinical result of the application of orthoses, it is necessary to make compromises in the field of choice of materials and individual components from which the choice of production method and assembly is derived [3, 8].

1.2.2 Innovations in the technological process of orthoses production

The innovation of the technological process of making an orthosis may consist in the use of modern technologies in the collection of measurements and subsequent conventional production or in the modernization of the entire process of data obtainment or production. The innovation of the technological process of collecting measurement data consists in the use of 3D scanning and computer processing of scanned data into a 3D model, which replaces the gypsum positive and the subsequent use of subtractive or additive methods of positive production. In this way, we get the basis either for drawing high-temperature thermoplastic or for the following

lamination process (conventional production). The innovation of the entire technological process of orthosis production also consists in digital sampling of measuring data (3D scanning) and subsequently a specific shape of the orthosis is designed in the relevant software, which is manufactured using additive technologies. Due to the cost of the purchase price of digital imaging equipment and subsequent subtraction or additive production, large companies provide the possibility of external design and production of aids, while the orthopedic technician takes the appropriate specified measures necessary for production. The process of obtaining measurement data for “branded”, i.e. the orthoses patented by the manufacturer, has been simplified by using developed measuring tools. Their use in practice is conditioned by the training of the staff who gather these measurements and their use reduces the risk of error in production. This increases the adjustment and function of the orthoses and reduces the number of aids that need to be redesigned. Despite many advances in materials and manufacturing techniques, clinical judgment and the technical skill of the orthopedic technician in the conservative treatment of the patient remain the most important elements in creating a well-equipped, highly functional orthosis [3, 5, 10].

The modern approach to the creation of devices begins with the digitization of the human body and its parts in order to obtain input data from the patient's body for the needs of modeling an orthopedic device in CAD software, following its final production. In the hands of experts, this innovative method replaces the unpleasant and time-consuming plastering. Thanks to this technological process, it is possible to achieve greater accuracy, speed of device production, a new level of comfort for the patient and functionality for the field of ortho-prosthetics. Two techniques are used for data collection: measurement and scanning. The data is processed by a computer program that creates a three-dimensional image of the model. The technician then converts the data and image to adjust the positive model. Software tools allow the practitioner to accurately apply a wide range of adjustments, including bends, rotations, scaling, alignment, and adding pressures or reliefs [5].

Digitization brings to the system of orthopedic practice better control over the creation of the device and at the same time respects the know-how of the traditional method of production and the creativity of the orthopedic technician.

In general, digitization allows:

- non-contact, immediate and comfortable obtainment of measurement data via a 3D scanner,
- modification of the model thanks to a CAD software,
- the finished 3D model of the device can be made in an innovative way of production.

Most of the software used for the design of orthopedic aids use features such as templates and macros (pre-recorded sequences of adjustments) of selected orthosis designs, which further speed up design work and ensure consistency. Other features focus on the design of the final device, not just the positive form. The information is exported to a CAM machine, which is used to manufacture a modified positive model that will be used to make the orthosis [5].

The creation of digital models also brings other possibilities how to analyze possible problems that may arise as a result of design, choice of material and in connection with the production process. The computer definition of the product to be manufactured includes all dimensions and material [3, 10].

The production of positives by the subtraction method can be realized by means of multi-axis milling machines and robotic arms. The control of multiple milling cutters is simpler, but it is possible to produce mostly only less complicated shapes, which means that they are suitable for the production of models of the forearm, shoulder, or elbow joint, but not detailed models of the hand and fingers. There is a need to use robotic arms that can incorporate even the details of the positive. The semi-finished model for production can be gypsum or polyurethane blocks of material, of different sizes depending on the location. Polyurethane blocks are usually produced in different densities according to the purpose of subsequent use.

Although CAD/CAM production is currently widely available, high initial costs (scanner, software, milling machine, 3D printer) limit its use even in small orthopedic and prosthetic operations. This leads to the centralized production of orthotic devices, but it also brings limitations in the use of this technology. This also leads to new problems arising from the fact that the experts themselves do not have control over the actual construction of the equipment, as this is done by technicians at a remote production site [10].

A general feature of additive manufacturing (AM) methods is that the production is not carried out by removing the material as in a milling machining, but by gradually adding the material in the form of powder or melt in small layers. The basic principle of 3D printing is that the computer interpretation of the object serves as a direct input to the 3D printer, which creates the required physical object without special tools [12].

Thanks to AM, it is possible to produce such products that are otherwise unusable, or their price would be very high. For parts manufactured by AM, the complexity is not what the final price is based on, it is mainly based on the material used and its properties and accuracy of 3D printing. The second big advantage is production without molds and tools. The third advantage is the possibility of production from demanding, problematic materials.

There are several ways of 3D printing, which differ in technology, materials used, print speed, accuracy and strength of products or price.

At present, various 3D printing technologies are available, with material extrusion and SLS technology having the greatest application and use in the field of prosthetics and orthotics.

FDM (Fused deposition modeling) is the most common and widely used 3D printing technology today. It is an extrusion 3D printing, in which models and prototypes are formed by layering step by step from various non-toxic thermoplastic materials. The plastic fiber is guided to the printer head, where it is melted and applied in layers that gradually solidify.

The material used in the SLS (selective laser sintering) and SLM (selective laser melting) printing methods is in the form of a powder (plastic, metal, ceramic or glass powder). The printer applies a layer of powder material to the substrate by means of a built-in roller, over which a laser (for example a laser based on carbon dioxide) moves, which selectively welds it into the lower layer. Subsequently, the roller applies another layer of material until a complete 3D model is created. The resulting models are characterized by high strength.

Orthoses made with additive technologies require postprocessing, which most often consists of surface treatment (roughness, appearance, polishing, painting, etc.), which differs depending on the technology used. With FDM technology, it is advised to smooth out the layers that remain present to the print to a greater or lesser extent. The need for postprocessing in the case of SLS printing is significantly reduced compared to FDM technology.

2. Method

2.1 Modern method

Mohammed et al. [13] reported that 3D scanning method of positives obtainment and CAD design of splints is quicker, non-invasive and provides greater accuracy in reproduction. On the other hand, they also report that AM splint requires longer fabrication time, which is still acceptable but less than desirable with respect to it potentially meaning an additional visitation by a potential patient. The disadvantage of longer production time is also reported by Buonamici et al. [14], however, they suggest the adoption of modern method due to the incredible benefits in terms of weight, expected comfort, breathability and the possibility of washing the immobilized segment. Barrios-Muriel et al. [15], Fitzpatrick et al. [16] and Chen et al. [17] also support this theory. Li et al. [18] proposed a splint design method, which reduces the duration of the modeling phase and reduces the manufacturing phase by using multiple 3D printers to produce individual parts of the orthosis. When comparing production costs of orthoses produced by AM or conventionally, in an analysis done by Fernandez-Vincente et al. [19] the cost of AM thumb orthoses is reduced by a half compared to the traditional method of production. When producing larger orthotic devices, Redaelli et al. [20] reported that the AM fabrication of back braces can provide a valid alternative to the current fabrication methods. The overall production time from initial scanning to delivery to the patient took approximately a full working day, similarly to what is required by the thermoforming process. However, the total man-hours are reduced because of the minimal supervision necessary during the 3D printing. The cost of the AM back brace is therefore competitive compared to the production cost of a thermoformed back brace, that typically ranges from 250 to 500 euros due to the long labor time. Also, Hale et al. [21] found out that scanning to delivery of an individual AM neck brace, which takes approximately 6 weeks to produce by the traditional way, was approximately 72 hours, and the production costs of both methods is comparable.

These facts confirm the practical application of modern methods in orthoses production. The goal of this study is to apply these modern methods in the production of individual arm and forearm orthoses and propose a methodology.

2.2 Positives obtaining

3D scanning technology, specifically the Artec Eva (Artec 3D, Luxembourg, Luxembourg) handheld scanner, was used to create the positive of the patient's upper limb segment. A handheld scanner is a device that constantly creates images of an object by creating real-time images of the scanned object in the software of the given scanner. Using this modern method of data acquisition, we can generate a 3D model of the patient's body segment, for which an orthosis will be designed. One of the advantages of a handheld 3D scanner is that the device is compact, light-weight, portable and requires only 1 person and a laptop to operate.

The subjects' arm and forearm were scanned with the entire upper limb being abducted with 30° rotation in the shoulder joint and 100° flexion in the elbow joint, with the thumb in opposition to the fingers and wrists at a 10° to 20° extension, and the elbow placed on a table for better support (**Figure 1**). All subjects had sufficient strength to hold the segment in position for the time which the area of interest was scanned. The scanning frequency was set to 8fps (frames per second) and no errors occurred during the positives obtaining. For this experiment, as seen in **Figure 2**, the arm and forearm of 10 adult subjects were scanned and processed.

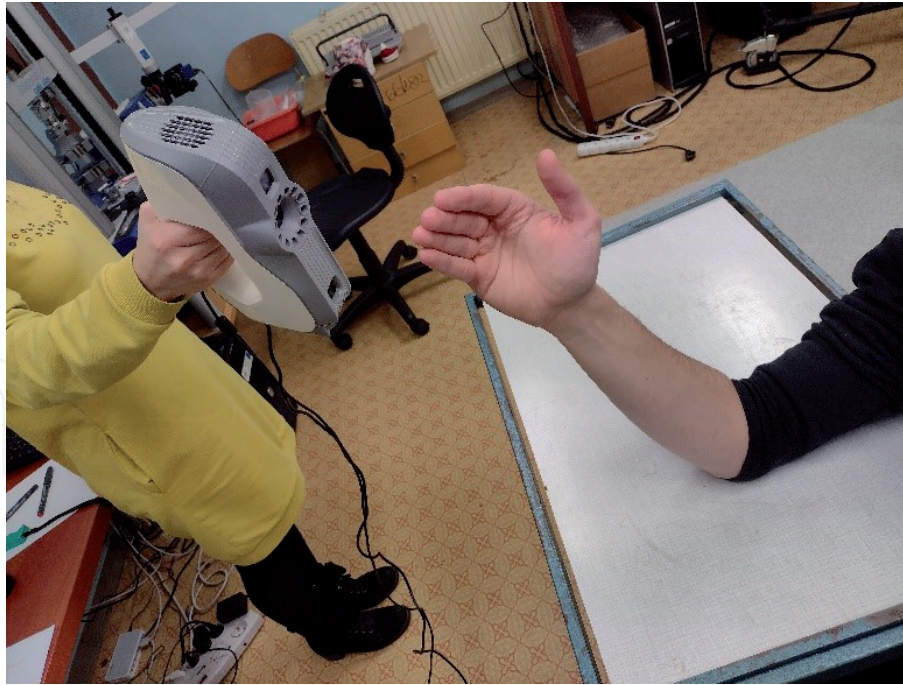


Figure 1.
Arm and forearm scanning process.

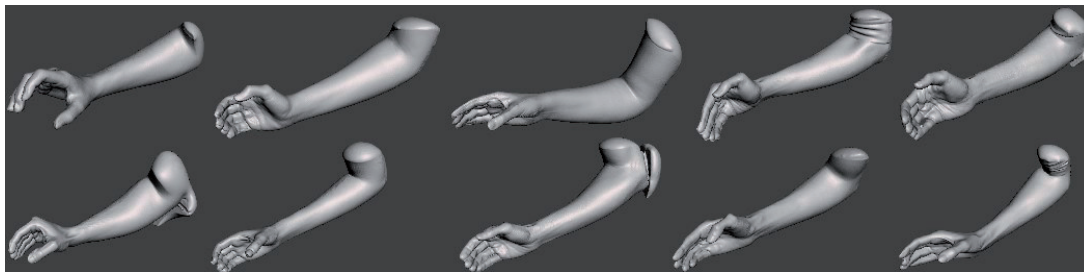


Figure 2.
Obtained models of 3D scans.

2.3 Orthoses 3D modeling

The Autodesk Meshmixer (Autodesk, Inc., San Rafael, CA, USA) software was used to create a digital model of the orthosis. It is a freely available modeling software in which it is possible to create and edit 3D objects. The shape of the device was sketched directly on a 3D model of a patient's upper limb segment, which we obtained by 3D scanning. When creating the contour of the device, we had to consider the coverage of the area of the segment sufficient for the orthosis to secure the wrist, thumb and the overall attachment of the device to the forearm.

The sketch of the orthosis' surface was then copied and placed on the 3D positive to create a 0.5 mm gap between the device and the area of interest. The creation of such a gap, or "offset", is important so that after the application of a real device to a given segment, there is no surface pressure, which would result in negative effects on the patient's upper limb. We can correct the size of the gap regarding whether a bio-compatible lining, which eliminates skin irritation, will be applied to the orthosis (**Figure 3**).

After creating a copy of the orthosis surface and applying the offset, the material thickness was set. Thickness of 2 mm was chosen when designing the orthosis. The thickness and choice of material is important in terms of strength and flexibility to avoid damage during use and repeated application to the given segment.

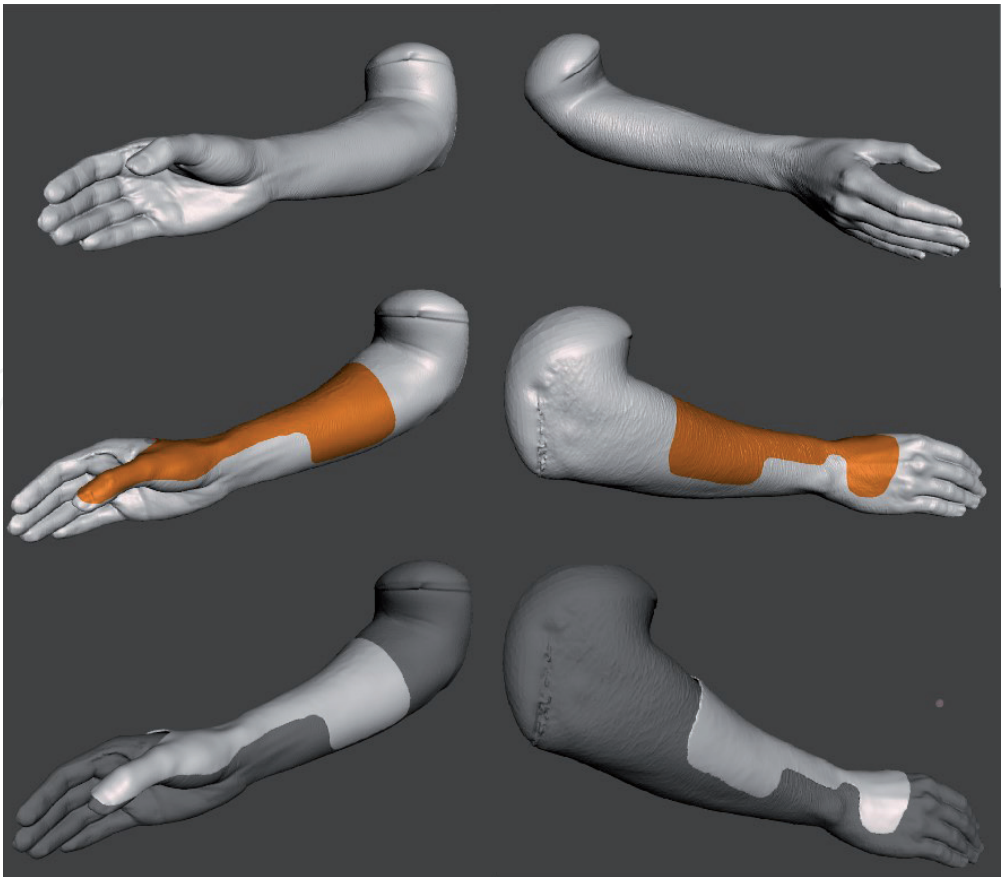


Figure 3.
Orthoses design process.

In the last step, the surface and edges of the model were smoothened, and the design of the final model was revised. Ten individual orthoses were designed and produced using FDM additive manufacturing technology.

2.4 Orthoses additive manufacturing

All models were manufactured on the Fortus 450mc (Stratasys Ltd., Rehovot, Israel) professional 3D printer using ABS-M30i bio-compatible polymer with a T16 tip and SR-30 support material with a T12SR30 tip. Since this printer has pre-set printing parameters for individual materials, the settings were not edited. Printing settings are listed in **Table 1**.

All models were printed one-by-one and positioned on the removable printing plate, which is stuck on the printer bed with the dorsal side oriented on the bottom (**Figure 4**).

After the manufacturing process, the printing plate was removed from the printer, all orthoses have been manually extracted and the support structures have

Slice height	0,010 mm
Infill	100%
Part interior style	Solid
Visible surface	Normal
Support style	Box

Table 1.
Printing settings.

been thoroughly removed. Final orthoses, as seen in **Figure 5**, have not been post processed chemically, or sand blasted.

2.5 Orthoses 3D scanning

All orthoses were 3D scanned in order to compare them to their actual 3D models. The Artec Eva scanner was used for this process. Individual orthoses have been fixed in a clamp by their proximal end and positioned vertically in order to capture the external and internal surface of the models (**Figure 6**).



Figure 4.
Fortus 450mc 3D printer (left) and an example of an orthoses manufactured by this machine (right).

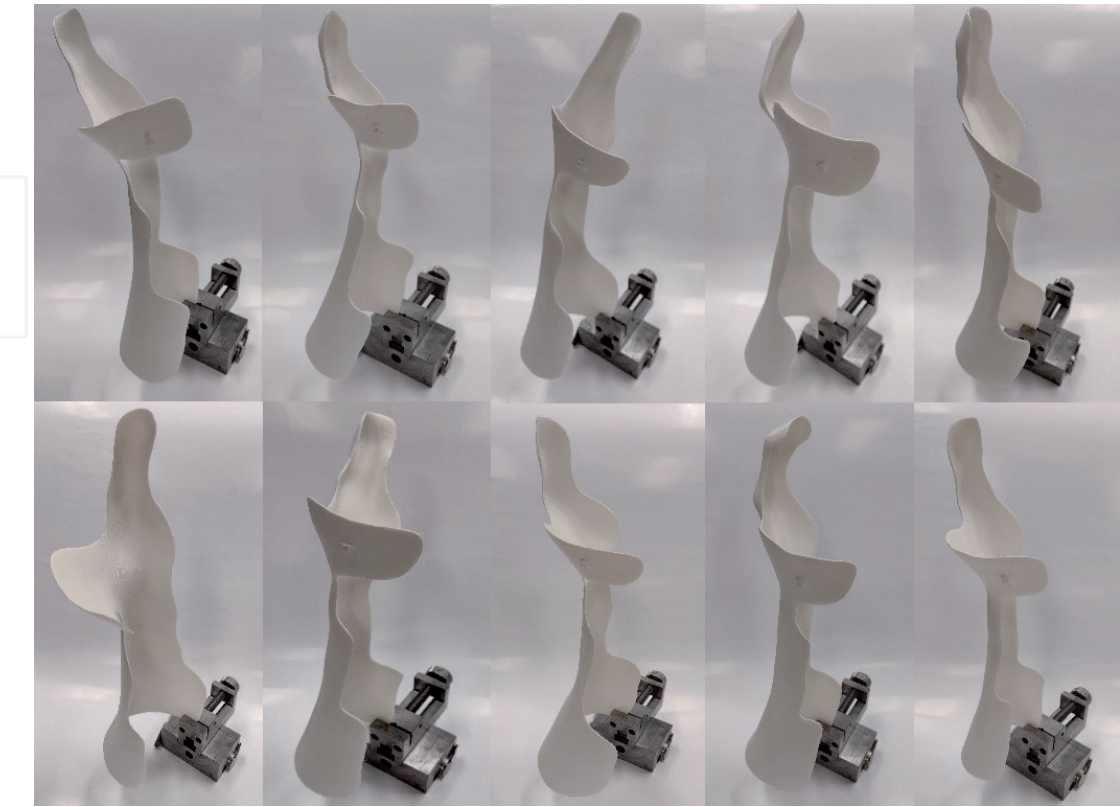


Figure 5.
Final orthoses.

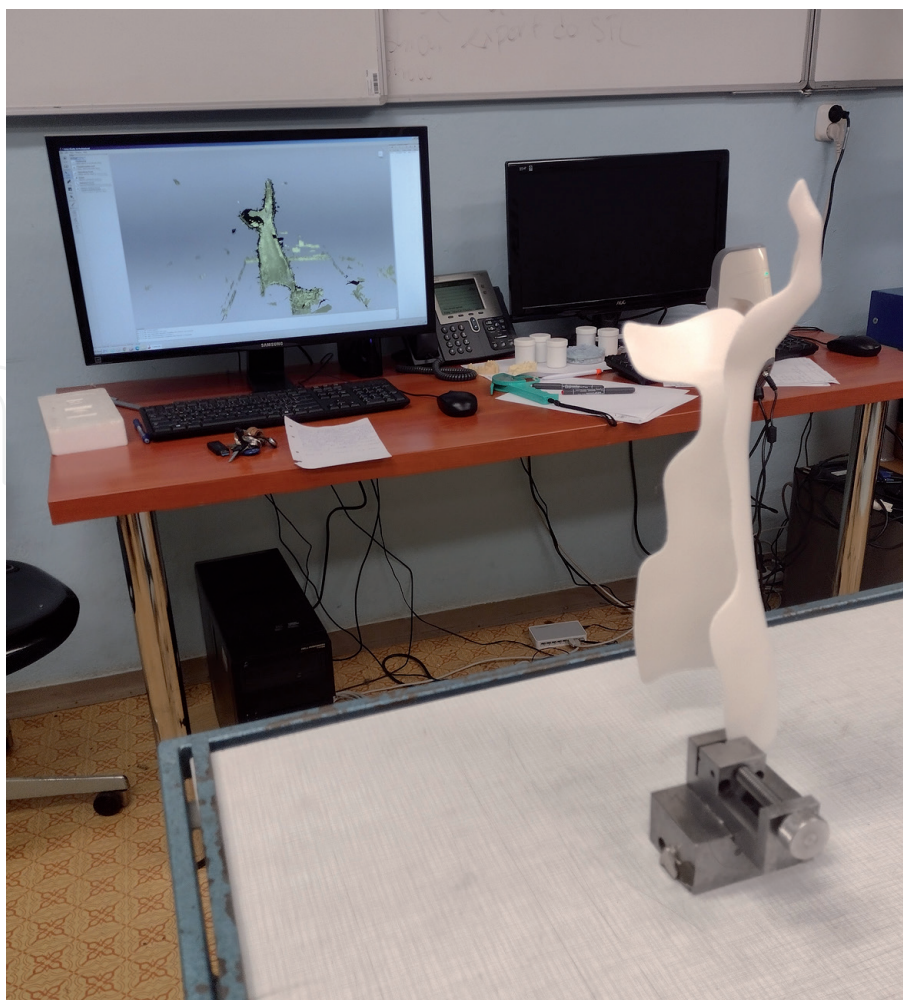


Figure 6.
3D scanning of the final orthoses.

The scanning frequency was set to 8 fps (frames per second) and no errors occurred during the positives obtaining. Scanning of 1 orthosis took approximately 10 minutes, where the scanning took approximately 5 minutes and the postprocessing of the acquired data also 5 minutes. While postprocessing the acquired data in Artec Studio13 (Artec 3D, Luxembourg, Luxembourg), artifacts surrounding the 3D scan have been constantly generating when fixing the holes in the scan. To eliminate these defects, hole filling in the software has been disabled and the scan processing has been finished in Meshmixer software, where the scans were converted to solid models (**Figure 7**).

The edges of individual models have not been smoothened to preserve the generated shape. After the finalization, all 3D models of the scans were compared to their actual STL models in VGStudio MAX (Volume Graphics, Germany) software.

2.6 Actual to nominal 3D model comparison

When comparing actual to nominal models we must first determine what models we are comparing. The first step was to find out if there is a difference between the models generated from the 3D scanner software and digitally solidified 3D scan models. One of these 2 models was then chosen as the actual model. These models of the orthoses were then compared to their nominal models, which are the original orthoses models designed in Autodesk Meshmixer. After the actual to nominal model comparison, the thickness of the orthoses was also verified.

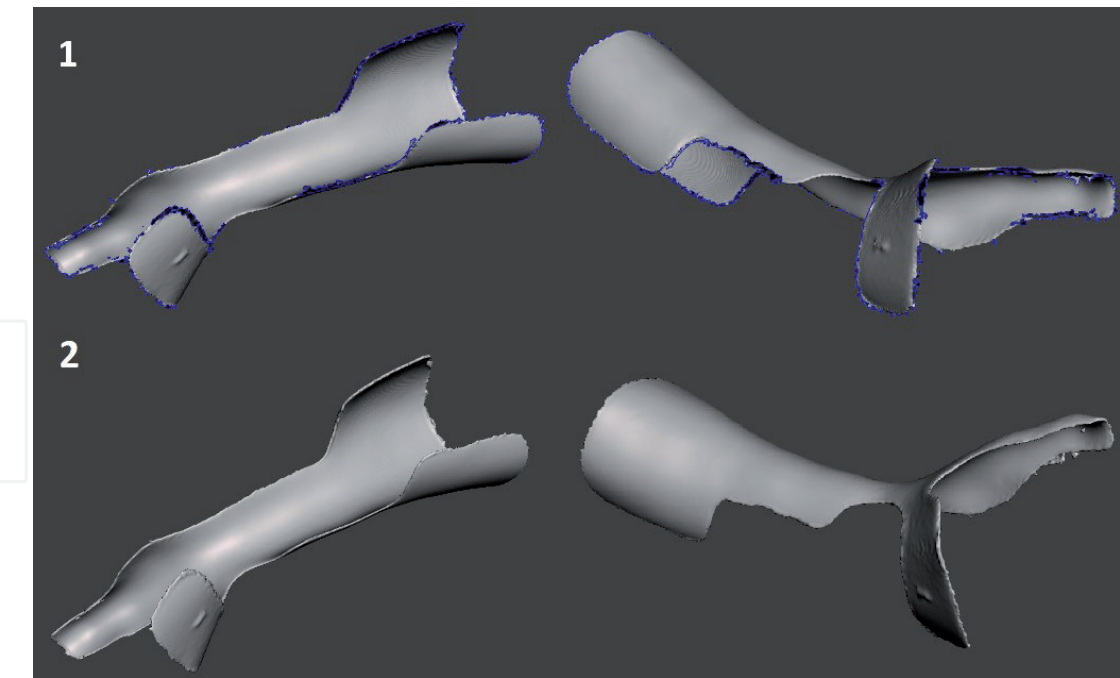


Figure 7.
Model of the scan generated from Artec Studio13 (1) and solidified 3D model of the scan (2).

3. Results

3.1 Time and material consumption

As a result, an orthosis design methodology is proposed. Time consumption of individual steps of this process has been recorder to calculate the average length of orthosis production by modern technologies.

Overall duration of the scanning and data postprocessing of individual subjects is summarized in **Table 2**. Based on these results the average duration of the arm and forearm scanning is 2 minutes and 20 seconds, and the duration of data postprocessing is 5 minutes and 20 seconds. While scanning the area of interest no complications and errors have occurred. All collected data has satisfactory quality of the surface necessary for orthosis design.

Subject	Scanning (mm:ss)	Postprocessing (mm:ss)
Subject 1	02:49	05:50
Subject 2	02:30	05:23
Subject 3	02:36	05:32
Subject 4	02:27	05:33
Subject 5	02:15	05:47
Subject 6	02:21	05:12
Subject 7	02:02	05:05
Subject 8	02:12	04:49
Subject 9	02:05	05:09
Subject 10	02:09	04:58
Average time	02:20	05:20

Table 2.
Subject scanning and data postprocessing duration.

No extra modifications of the scan 3D models were necessary during the orthosis design phase. Thanks to this fact, the design process of orthoses took approximately 3 minutes. Design duration for each orthosis is summarized in **Table 3**.

When positioning individual orthoses models on the virtual building platform of the 3D printer, the software automatically calculates the volume of the used model material, support material and the overall time of production. Average volume of model material used for the orthosis production is 65,94 cm³, 57,40 cm³ of support material and the average time of production is 5 hours and 18 minutes. These data are summarized in **Table 4**.

3.2 Verification results

The results of comparing models generated from the 3D scanner software and digitally solidified 3D scan models shows that from the deviation in the range of ±0.050 mm the models are identical. Only differences are on the edges of the

Orthosis model	Design duration (mm:ss)
Orthosis 1	03:12
Orthosis 2	03:20
Orthosis 3	03:05
Orthosis 4	02:58
Orthosis 5	02:52
Orthosis 6	03:13
Orthosis 7	03:07
Orthosis 8	02:53
Orthosis 9	03:23
Orthosis 10	03:16
Average time	03:11

Table 3.
Orthoses design duration.

Orthosis	Model (cm ³)	Support (cm ³)	Time (hh:mm)
Orthosis 1	60.91	65.33	05:22
Orthosis 2	55.23	50.43	04:58
Orthosis 3	63.25	34.60	04:30
Orthosis 4	72.87	70.33	06:31
Orthosis 5	70.85	63.29	05:37
Orthosis 6	77.58	71.48	05:56
Orthosis 7	58.56	59.67	05:05
Orthosis 8	69.47	49.41	05:03
Orthosis 9	75.67	61.74	05:51
Orthosis 10	55.04	47.68	04:25
Average value	65.94	57.40	05:18

Table 4.
Orthoses printing parameters.

models. An example is shown in **Figure 8**. Digitally solidified scan models were chosen for the actual to nominal comparison.

In **Table 5** the average deviation of solidified scan models to actual scanned models are summarized. To evaluate the differences between the actual scan model and the solidified model, the maximum deviations for 75%, 90% and 95% surface coverage were determined. These data indicate that for e.g. 95% of all values are the maximum deviation. By the deviation values of Orthosis 4 all comparisons have a deviation of less than 0.01 mm at 75% coverage, so there are only minimal changes compared to the actual model. At 90% this value is less than 0.03 mm and at 95% less than 0.08 mm. In these cases, the sets of deviations are already affected mainly by deviations caused by the closing of edges of the solidified model and possible defects.

When designing orthoses, the wall thickness was set to 2 mm. The actual thickness was measured in the “Wall thickness module” of VGStudio MAX. As a result of the analysis, the actual values range from 2.006 mm to 2.097 mm and the standard deviation is less than 0.24 mm (**Table 6**).

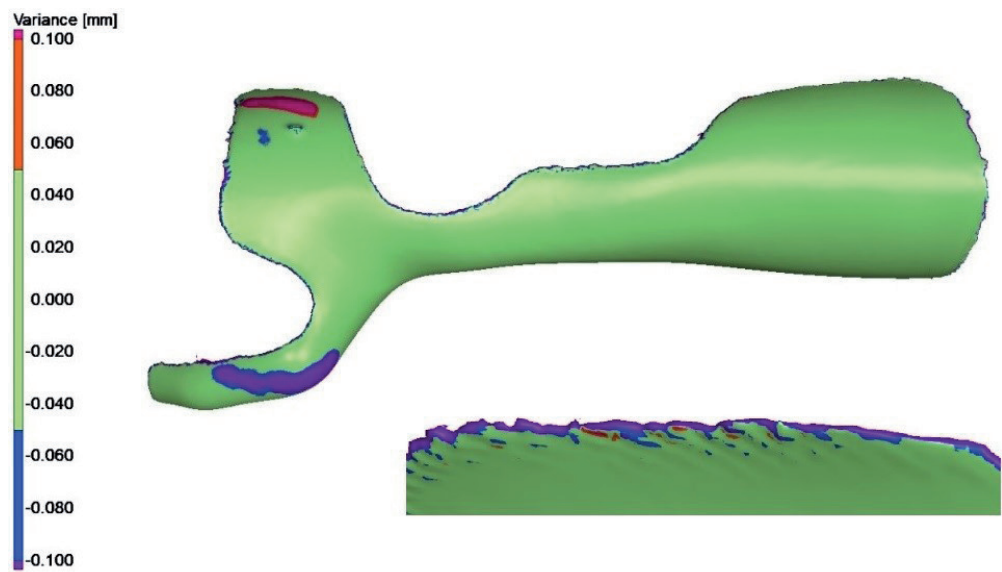


Figure 8.
Original scan model and solidified scan model comparison with a detail on the edge of the model.

Orthosis model	Average deviation [mm]	75% deviation [mm]	90% deviation [mm]	95% deviation [mm]
Orthosis 1	−0.0110	0.0058	0.0131	0.0319
Orthosis 2	−0.0120	0.0059	0.0129	0.0290
Orthosis 3	−0.0110	0.0063	0.0124	0.0345
Orthosis 4	−0.0057	0.0078	0.0286	0.0793
Orthosis 5	−0.0110	0.0068	0.0132	0.0300
Orthosis 6	−0.0075	0.0059	0.0128	0.0290
Orthosis 7	−0.0098	0.0057	0.0120	0.0317
Orthosis 8	−0.0097	0.0076	0.0194	0.0527
Orthosis 9	−0.0095	0.0063	0.0153	0.0362
Orthosis 10	−0.0096	0.0052	0.0103	0.0284
Average value	−0.0097	0.0063	0.015	0.0383

Table 5.
Average variation values of solidified scan models to actual scanned models.

Solidified orthosis model	Average [mm]	Standard deviation [mm]
Orthosis 1	2.031	0.190
Orthosis 2	2.042	0.134
Orthosis 3	2.040	0.224
Orthosis 4	2.054	0.231
Orthosis 5	2.065	0.196
Orthosis 6	2.006	0.157
Orthosis 7	2.027	0.163
Orthosis 8	2.097	0.234
Orthosis 9	2.082	0.154
Orthosis 10	2.047	0.174
Average value	2.049	0.186

Table 6.
Actual wall thickness values.

When the scan model is compared with the actual orthosis model, it is necessary to perform their mutual alignment before performing the analyzes, as the scanned orthosis has a different coordinate system than the designed model created in the Meshmixer software. Due to the shape of the orthosis (absence of planes and simple shapes such as cylinders, etc.), their mutual alignment is possible using the Best-fit and RPS methods (reference positioning system). When using the RPS method, the Best-fit of the objects is the first step, and second the subsequent transfer of points to the current model (orthosis scan), after which the alignment itself is performed. The **Figure 9** shows an example for Best-fit alignment and RPS alignment. The figure above compares the scan of the orthosis to the solid model using the Best-fit method and below using the RPS method.

Figure 10 shows the deviations between the two methods of alignment. It can be seen from the histogram (**Figure 11**) that the deviations are almost symmetrical with respect to zero, i.e. the two alignments are rotated relative to each other, which can also be seen in the figure.

Significant differences in models (orthosis shape) do not allow the distribution points to be distributed on all orthoses in the same way. To eliminate the effect of point placement for RPS alignment, the orthosis scan model and actual model were aligned with each other using the Best-fit method.

Table 7 shows the data for the average deviation of the original individual orthoses model with respect to the solidified model. To evaluate the differences between the solidified scan model and the original orthosis model, the average deviation value and the maximum deviations for 90% and 95% surface coverage were determined. The average value of the deviation is close to zero and thus the distribution of deviations has the character of a normal (Gaussian) distribution. The average value for 95% coverage is 0.419 mm and 95% coverage 0.576 mm.

To control the quality of production, the thickness of the orthosis over its entire surface was also evaluated. The results in **Table 8** show that the average thickness is 1.956 mm and the standard average deviation is 0.206 mm. Compared to the nominal solidified model, the average wall thickness of the actual manufactured orthosis is smaller by 0.0931 mm and the value of the standard deviation is greater by 0.0203 mm, which are negligible differences.

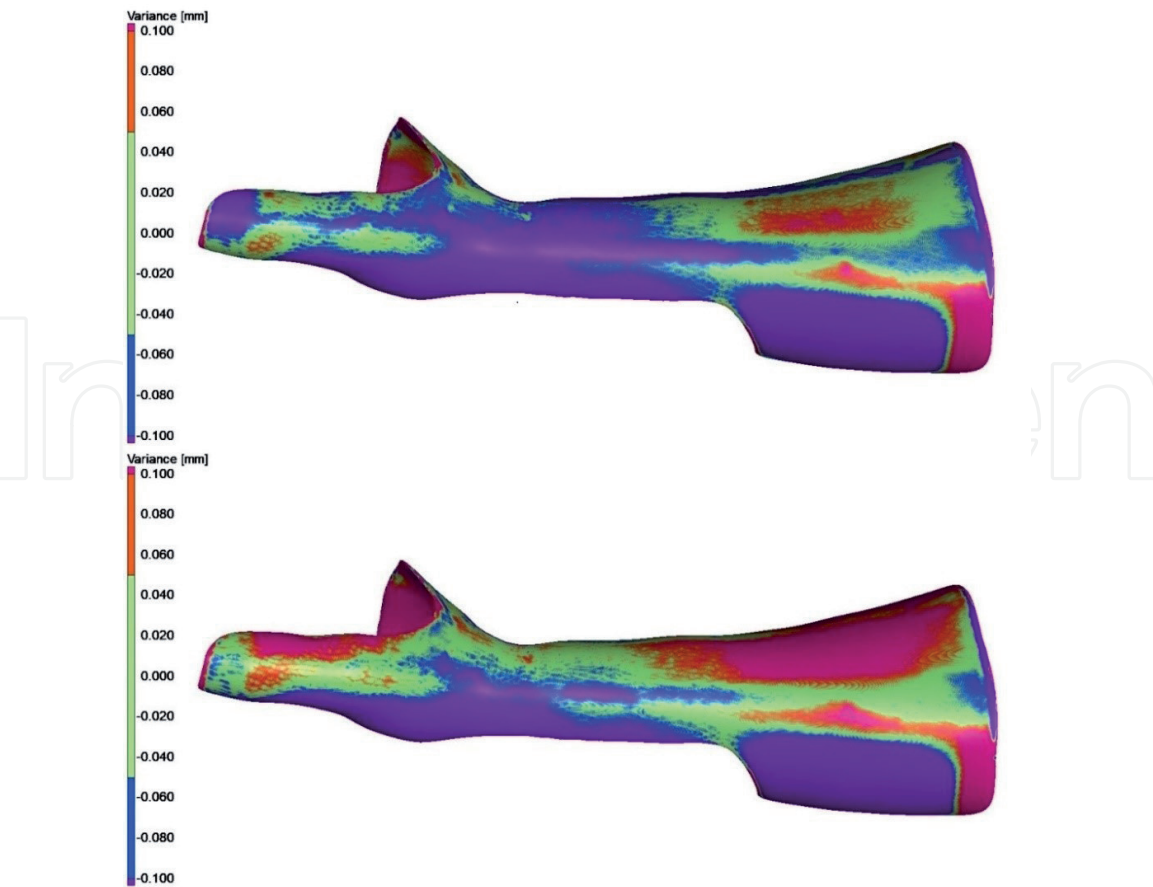


Figure 9.
Best-fit alignment (up) and RPS alignment (down).

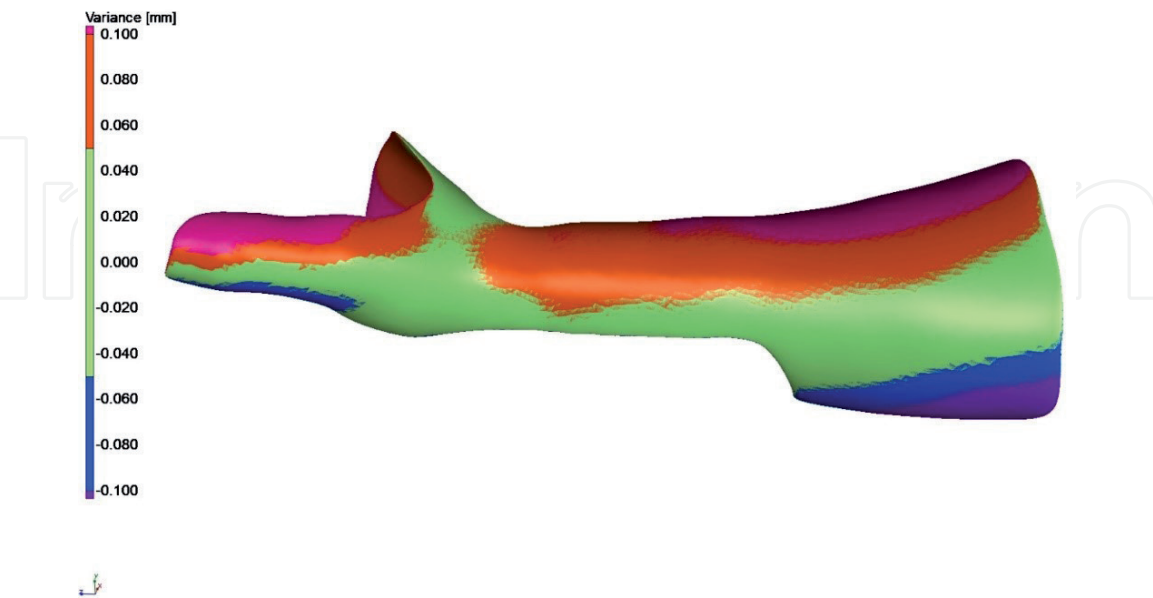


Figure 10.
Deviation between the best-fit and the RPS alignment.

Duration of the inspection and verification process has not been recorded, since it is not a part of the design methodology. Only the results of this process are relevant.

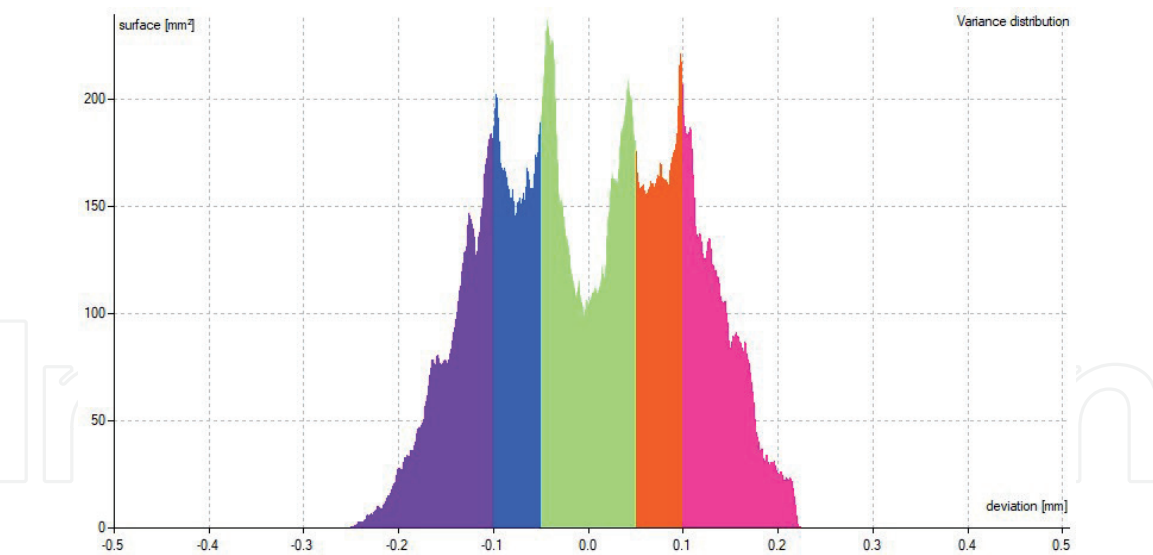


Figure 11.
Histogram representing the deviations of the 2 alignment methods.

Orthosis	Average deviation [mm]	90% deviation [mm]	95% deviation [mm]
Orthosis 1	0.006	0.69	0.86
Orthosis 2	0.013	0.24	0.33
Orthosis 3	0.037	0.26	0.38
Orthosis 4	0.026	0.30	0.46
Orthosis 5	0.011	0.73	0.90
Orthosis 6	−0.001	0.46	0.57
Orthosis 7	0.022	0.15	0.22
Orthosis 8	−0.014	0.81	1.25
Orthosis 9	0.041	0.32	0.43
Orthosis 10	0.033	0.23	0.36
Average value	0.017	0.419	0.576

Table 7.
Average deviations of the original model to the solidified scan model.

Orthosis	Average [mm]	Standard deviation [mm]
Orthosis 1	1.95	0.20
Orthosis 2	1.95	0.13
Orthosis 3	1.94	0.27
Orthosis 4	1.94	0.27
Orthosis 5	1.97	0.19
Orthosis 6	1.97	0.18
Orthosis 7	1.97	0.18
Orthosis 8	1.93	0.28
Orthosis 9	1.97	0.17
Orthosis 10	1.97	0.19
Average value	1.956	0.206

Table 8.
Average thickness values of the orthoses surface.

4. Discussion

When developing custom orthoses by modern technologies it is necessary to follow the steps of the method proposed in this study. First important step is the positive obtainment. Method of 3D scanning has shown to be very practical, fast, clean, precise and comfortable for the subject and the scanning staff. Working with a handheld 3D scanner is very intuitive and simple. Only 1 person and a laptop or a PC is required for the scanning process. Since the scanner is portable, it is not necessary that the subject must be in a special work environment. This fact is very important, if the subject is immobile or has movement difficulties and it's a great advantage when compared to the traditional plastering method. The positives obtainment with the postprocessing of the acquired data took less than 10 minutes average, which is much quicker than the traditional way.

Body segment positioning before scanning is important. It is necessary to stabilize the segment of interest in order to capture the desired shape. It depends on what physical health the subject is in. If the subjects have movement restrictions or have weak body strength, it is important to provide them some form of support or stabilize the scanned body segment with the help of an assistant. The assistant can help stabilize the subject, but must support the areas, which are not important for orthosis development. When scanning subjects with no movement or force limitations it is still helpful to give them some type of support, for example, in this study the subjects had their elbow joint resting on a desk, while the arm and forearm had been scanned.

Artec Eva 3D scanner, which has been used in this study is an expensive, professional scanner used mainly for scanning larger objects and structures in mechanical, design, architectural, automotive and similar industries. Nevertheless, it is also applicable in prosthetics and orthotics. In one of our studies [22], we concluded that a high-end 3D scanner is not necessary and that low-cost scanners can capture important body segments with sufficient precision for orthosis development.

Capturing the segment in its correct shape is mandatory when designing an orthotic device. If the scanned model has defects, deformities or other artifacts it cannot be used as a positive. The original model must be clean and precise so that there's no editing needed. If the 3D model of the scan is edited, it could end up in a difference between the surface of the orthosis and the body surface, which would lead to an incorrectly designed aid.

One of the objectives was to use an open-source 3D modeling software. We chose Autodesk Meshmixer, as it has functions suited to prosthesis and orthosis design. In a few easy steps it is possible to design simple orthoses suited for additive manufacturing. The design process of an arm and forearm orthosis in this software took less than 4 minutes. The interface is very clear and organized and the user does not need any special training. However, when designing medical devices, it is necessary that a skilled prosthetist operates the software. Main disadvantage of the software is that it does not have medical certification, so the models should be used only for educational and research purposes.

Choosing the correct material for the production is important from the point of manufacturing and application. Since the orthoses are meant to fix and stabilize the arm and forearm and skin contact is unavoidable, the used material needs to be strong and biocompatible. Also, the Fortus 450mc printer uses cartridges of materials suited only for this type of printer, so the range of materials is limited by the manufacturer. For these reasons the ABS-M30i has been chosen as the most suitable material. Other materials like PETG or PLA can be used for orthosis production [20], but since this 3D printer does not support these materials, they were not chosen for this study.

All models have been positioned with the dorsal side facing the printer bed. The meaning of this was to avoid support generation on the inner shell of the models to minimize support material volume and reduce postprocessing difficulty. Support structures on the inner shell could also deform the surface during the production process. From the results of the nominal to actual comparison of some models it is clear that the parts of the models that arch above the inner shell have deformed during printing. For this reason, it is advised to put support structures even on the inner shell of the models to avoid deformation.

The maximum time length of an arm and forearm orthosis produced by high or low-temperature thermoforming set by the public insurance company in Slovakia is 5 and a half man-hours. The manufacturing of a single 3D-printed individual orthosis took less than 5 and a half hours. When we add the average time of actual labor, which was approximately only 10 to 15 minutes, the whole process took less than 6 hours, which is the approximate time of an orthosis production by conventional methods for a single patient. This means, that by using proposed innovative methods, the technician can save time and design other orthotic devices, while the previous ones are producing. This time length can vary depending on the technologies used in single steps, or the number of models being developed. Duration of conventional and proposed production of arm and forearm splints is summarized in **Table 9**.

From the results of the analysis we can see that the difference between the produced orthosis and the 3D model is negligible from the point of view of orthotic application. After postprocessing and application of straps and maybe lining, these orthoses are fully functional and ready to use.

Since the manufacturing technology used in this study is a high-end, professional 3D printer, it is possible for hospitals, or prosthetic workshops, to produce their orthoses externally. Price of 1 orthosis, considering the material and applied technology, is approximately 70 euros. The maximum cost of an arm and forearm orthosis produced by high or low-temperature thermoforming set by the public insurance company in Slovakia is 166 euros (including materials, technology and man-hours). This means that there is a 96-euro gap between the conventional orthosis price and the 3D-printed orthosis manufacturing cost. This gap can be used to compensate the scanning, designing process and labor payment. Cost of conventional and proposed production of arm and forearm splints is summarized in **Table 9**.

If these institutions can acquire their own low-cost 3D scanner and maybe a 3D modeling software, the development process is faster, simpler and more practical, which means that the amount of produced individual orthotic devices grows. This is a favorable state not only for these institutions, but mainly for the patients themselves.

The proposed methodology, which contains orthoses design and additive manufacturing, is an adequate method for orthoses production. This method could also be used for design and manufacturing of individual prosthetic sockets for lower or upper limb prosthesis, trunk orthoses, orthotic seating systems and disability aids.

Method	Duration (hh:mm)	Cost (euro)
Conventional	05:30	166.00
Proposed (modern)	05:28	70.00

Table 9.
Production duration and cost of conventional and modern arm and forearm orthoses.

5. Conclusions

An orthoses development methodology using modern technologies has been proposed. Whole process consists of positives obtainment using a 3D scanner, orthosis design in a 3D modeling software and production using additive manufacturing technology. This methodology has been analyzed and verified by reverse engineering in an adequate software with data obtained by a proper 3D scanning device. In conclusion, it can be stated, that the proposed methodology is suitable for the use in orthotic practice.

In the future, it is planned to compare different results gained by applying other types of 3D scanners and 3D printers in the development process. The use of different types of materials is also possible if other 3D printers are used. Orthoses manufactured from different types of materials can be mechanically tested to determine, which material is most suitable for this application.

Acknowledgements

The present article was elaborated under the support received from the project APVV-19-0290, KEGA 041TUKÉ-4/2019, KEGA 023TUKÉ-4/2020 and Stimulus for research and development 12/2018-2112/2021.

Conflict of interest


All authors declare no conflict of interest.

Author details

Branko Štefanovič*, Mária Danko, Monika Michalíková, Lucia Bednarčíková, Viktória Rajtúková, Teodor Tóth, Marianna Trebuňová, Radovan Hudák and Jozef Živčák
Faculty of Mechanical Engineering, Technical University of Košice, Košice, Slovakia

*Address all correspondence to: branko.stefanovic@tuke.sk

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