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Methodology of CAD design and CAM production of transtibial prosthetic sockets

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Abstract: The digitization of the design process of lower limb prosthetic sockets seems to be necessary. Using modern CAD procedures and CAM technologies, it is possible to produce functional, individual prosthetic aids that bring many benefits compared to commonly used methods. However, the disadvantage of using CAD/CAM procedures can be the input costs for production technology and software. The aim of this research is to propose a low-cost solution for individual transtibial socket design and production. Modern methods and technologies like 3D scanning, CAD design and additive manufacturing have been applied. As a result, a transtibial stump positive and custom socket design methodology is proposed. In conclusions a total value of a custom transtibial socket design and production was calculated.

1 Introduction

The current trend in various areas of medicine and rehabilitation is the digitization of measurement and production processes using software applications. In the field of prosthetics and orthotics in the Slovak Republic, however, conventional methods of designing and manufacturing lower limb prosthesis sockets still prevail. Despite the significant progress in medicine, the number of amputations performed has a constantly increasing tendency, while the number of amputee patients in Europe is expected to increase from the current number of 750-850 thousand to 3,5-4 million individuals over the next 15 years. Among the most common indications that lead to this rapid increase in planned amputations of the lower limbs are diseases such as diabetes mellitus, ischemic disease of the lower limbs, cancer and amputations as a result of trauma. The number of amputations due to civilizational diseases will continue to increase due to the aging of the population. Approximately 70-80% of amputees are older than 50 years, and in 75-80% of cases, amputations of the lower limbs are involved [1,2].

For these reasons, digitization of the design process of lower limb prosthesis sockets seems to be necessary. Using modern CAD (Computer Aided Design) procedures and CAM (Computer Aided Manufacturing) technologies, it is possible to produce functional, individual prosthetic aids that bring many benefits compared to commonly used methods [3-7]. The main advantages are lower costs for the production of prosthetic devices and a fast, non-contact and wasteless device development process [8]. However, the disadvantage of using CAD/CAM procedures can be the input costs for production technology and software, which can be discouraging for CPOs (certified Prosthetist Orthotist) and O&P (Orthotic and Prosthetic) companies from lower income countries like Slovakia.

The aim of this research is to present the use of the freely available CAD software Meshmixer (Autodesk Inc., San Francisco, U.S.A.) for the design of individual transtibial sockets of lower limb prostheses, which are suitable for production through the low-cost FDM (Fused Deposition Modeling) additive manufacturing technology.

2 Methodology

The design of an individual transtibial socket of the lower limb prosthesis in Meshmixer software consists of 2 steps:

1. Editing of the obtained 3D scan of the stump and creation of an individual positive.
2. Design and creation of a 3D model of the transtibial socket.

2.1 *Editing of the obtained 3D scan of the stump and creation of a virtual positive*

A low-cost handheld optical 3D scanner Creality CR-SCAN 01 (Creality 3D Technology Co., Ltd., Shenzhen, China) is used to acquire the positives. The resolution of the device must be sufficient for use in the field of prosthetics and orthotics [9-11]. With the help of a 3D scanner, the topography of the place of interest is obtained, in this case it is the area of the stump on the lower limb. Some types of 3D scanners can also record the texture (color) of the scanned surface, according to which we can divide the methodology into:

a. Creation of an individual positive without texture,
b. Creation of an individual positive with texture.

Before the actual scanning, it is advisable to wrap the area of interest with food foil in order to create a stump surface with overall surface compression. If it is a scan with a 3D scanner capable of recording texture, it is possible to mark the cutting line of the proposed socket and compression and relieved places on the foil-wrapped stump with a marker. It is also possible to highlight sensitive or painful areas. These sketches on will be helpful in creating an individual positive.

Correct positioning of the given segment is important during scanning. The positioning of the subject depends on the type of scanned stump. When scanning the transtibial stump of the lower limb, it is necessary for the scanned subject to sit and have the segment of the given limb in extension. Subsequently, a scan is performed in the transverse plane of the segment in order to capture the surface of the residual part of the limb. Emphasis is also placed on the distal end.

The obtained 3D scan of the stump of the residual limb, exported in the correct format, is further modified in a suitable CAD software. This 3D scan model is used to create a virtual positive of the stump on which the CAD socket of the prosthesis is designed.

2.1.1 Creating an individual positive without texture

First of all, it is necessary to remove artifacts and unnecessary areas of the obtained 3D scan model (Figure 1-1). Subsequently, the reduction is applied to the given model:

1. 3-5% in the transverse plane (XY plane) for the entire 3D model.
2. 5% to the distal end (approx. 5-7 cm long) longitudinally to the axis of the bone.

After performing the reduction, it is necessary to generate loadable and relieved places (Figure 1-2). A negative extrusion of -3 mm is applied to generate load-bearing areas and a positive extrusion of +1,5 mm is applied to unloaded areas (Figure 1-3). It is important that the borders of these places have smooth transitions to the undeformed zones of the positive (Figure 1-4). Finally, it is possible to make a superstructure on the dorsal side of the positive (Figure 1-5), which is positioned individually according to the shape of the positive. After the final inspection and final smoothening of the details, it is possible to start designing the 3D model of the socket (Figure 1-6).

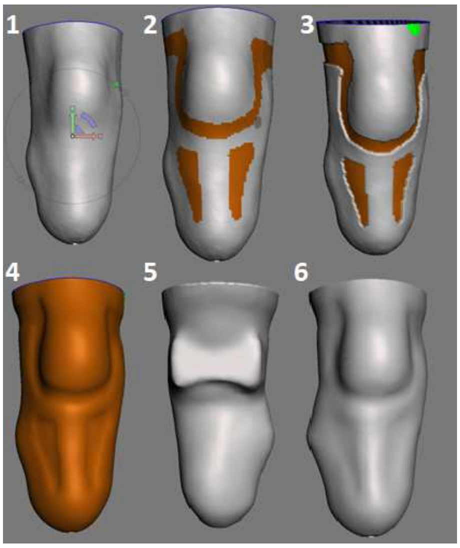

Figure 1 Editing of the obtained 3D scan of the stump and creation of a virtual positive

2.1.2 Creating an individual positive with texture

First of all, it is necessary to remove artifacts and unnecessary areas of the obtained 3D scan model. Subsequently, the reduction is applied to the given model:

1. 3-5% in the transverse plane (XY plane) for the entire 3D model
2. 5% to the distal end (approx. 5-7 cm long) longitudinally to the axis of the bone

After the reduction is done, it is necessary to generate the loaded and unloaded places using the sketches captured on the 3D models of the scan (Figure 2-1). Negative extrusion with a value of -3 mm is applied to the load-bearing areas and positive extrusion with a value of +1,5 mm for relieved areas (Figure 2-2). It is important that the borders of these places have smooth transitions to the undeformed zones of the positive (Figure 2-3). After the final inspection and final smoothening of the details, it is possible to start designing the 3D model of the socket.

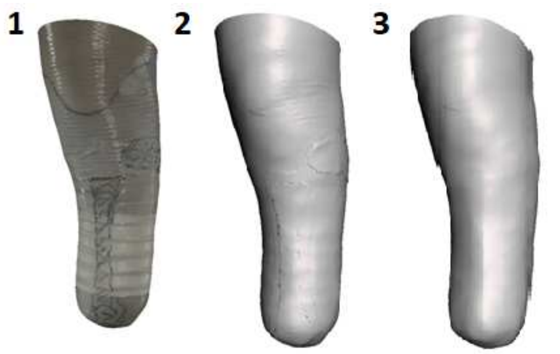

Figure 2 Creation of a virtual positive from a scan 3Dmodel with texture

2.2 Design and creation of a 3D model of the transtibial socket

Design of an individual transtibial socket can be made by 2 methods, according to the method of virtual positive creation. These methods are:

1. Design and creation of a 3D model of a transtibial socket from a positive without texture.
2. Design and creation of a 3D model of a transtibial socket from a positive with texture.

2.2.1 Design and creation of a 3D model of a transtibial socket from a positive without texture

The process of creating a transtibial CAD socket from a positive without texture (Figure 3) consists of 5 steps:

1. Sketch of the cutting line of the socket and marking of the inner surface of the socket.
2. Formation of the inner surface of the socket (extraction of the obtained inner surface of the socket from the virtual positive by a distance of 0 mm).
3. Creation of a 3D model of the socket and separation of the 3D model of the socket from the positive (displacement of the obtained surface by a value of +3 mm).
4. Creating a hole for the valve (inner diameter of the hole = 10 mm, outer diameter of the hole = 13 mm).
5. Surface smoothing and final inspection.

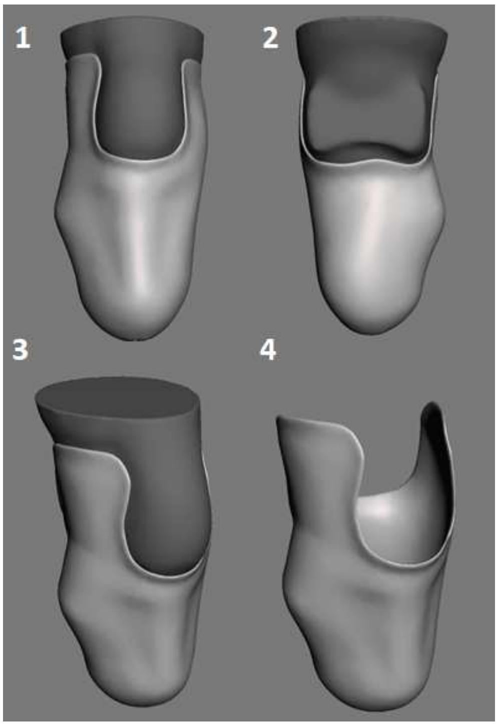

Figure 3 3D model of the transtibial socket (1 – front view, 2 – rear view, 3 – side view, 4 – side view without positive)

2.2.2 Design and creation of a 3D model of a transtibial socket from a positive with texture

The process of creating a transtibial CAD socket from a positive with texture (Figure 4) consists of 5 steps:

1. Sketch of the cutting line of the socket and marking of the inner surface of the socket according to the sketch on the positive.
2. Formation of the inner surface of the socket (extraction of the obtained inner surface of the socket from the virtual positive by a distance of 0 mm).
3. Creation of a 3D model of the socket and separation of the 3D model of the socket from the positive (displacement of the obtained surface by a value of +3 mm).
4. Creating a hole for the valve (inner diameter of the hole = 10 mm, outer diameter of the hole = 13 mm).
5. Surface smoothing and final inspection.

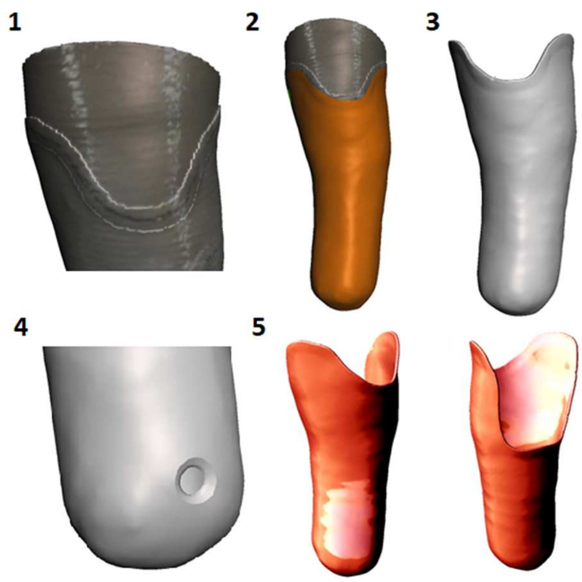

Figure 4 The process of creating a transtibial CAD socket from a positive with texture

2.3 Additive manufacturing of a transtibial CAD socket

The preparation of CAD models for additive manufacturing consists in uploading the model to the software intended for setting individual parameters of 3D printing. The choice of software depends on the additive manufacturing technology used. Since prosthetic sockets are designed for production using FDM technology, suitable software for setting printing parameters is, for example, freely available PrusaSlicer (Prusa Research, Prague, Czech Republic).

In the first step, it is necessary to choose the type of printer used for the production of the 3D model, the printing accuracy setting, the type of filament used for the production of the object and the density of the filling of the object being produced. After establishing these basic conditions, it is necessary to import a 3D model into the software interface. After importing the model, it is necessary to check and possibly overwrite the print settings. These can be set manually, or preset software parameters for the given material can be selected. The printing parameters change depending on the material used.

After choosing the printer, filament and printing parameters, it is necessary to correctly position the 3D model of the prosthetic socket. This type of model is oriented in a way that the axis of the model is perpendicular to the working platform of the printer (Figure 5).

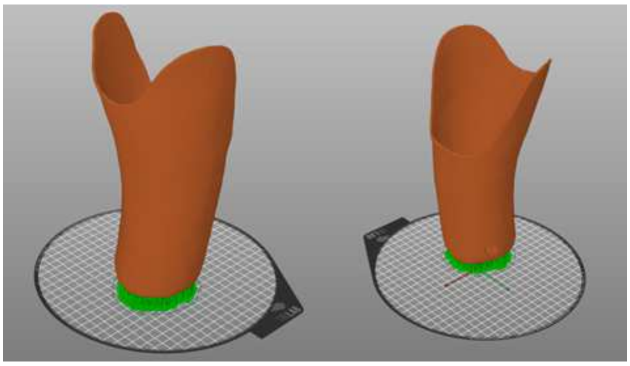

Figure 5 Correct positioning of the 3D model of the socket on the work platform of the FDM printer

3 Results and discussion

Since the data acquired while 3D scanning is used to design prosthetic devices, it is ideal to scan at the lowest possible frequency (minimum 3 fps) to avoid random errors during scanning and to reduce the amount of data acquired. The disadvantage is that these scanners are connected to the PC with cables. Therefore, it is recommended to have free space around the scanned subject for movement and manipulation of the scanner. It is advisable to perform a scan of the area of interest on the 1st attempt, which removes the random surface deformation of the 3D model during subsequent merging of multiple scans. For beginners, it is not recommended to interrupt the scan (by pausing) in order to avoid manual merging of the scans in the software, where the scans could be misaligned.

The parameters set in the individual transtibial CAD socket design methodology is stated based on the experience of CPOs in COP, s.r.o. company in Kosice, Slovakia. These parameters can vary depending on the specific subject, for which the socket is being designed for.

The individual positive of the transtibial lower limb stump creation methodology can be used not only as a basis for CAD socket design, but also for stump positive production using CNC (Computerized Numerical Control) milling machines. Using this technology it is possible to combine modern and traditional way of socket production.

Correct positioning of models on the 3D printer's virtual work platform is very important in terms of printing efficiency and output quality. Depending on how the model is positioned, the support structure is generated and the orientation of the layers is also determined. From that point of view, it is important to position the socket model so that no support structures are created on the contact surfaces of the models. Support structures can affect the quality of the surface in these places, which can deform the shape of the contact surface and thus negatively affect the overall quality of the model. However, the orientation of the layering is important in terms of the strength and quality of the model's surface. Since the possibility of breakage must still be taken into account between the individual layers, it is important to position the aids in such a way that cracks do not appear on the aid after the action of external forces (mainly bending). Layering also affects the local surface quality of the models. Since with FDM 3D printing, the accuracy is higher in the X and Y axes, the surface of the model is more accurate on surfaces oriented horizontally to the work platform.

When positioning the prosthetic socket model, it is important to orient the model so that the axis of the model is perpendicular to the working platform of the printer. In that case, no supporting structures will be generated on the inner surface of the socket, and due to the orientation of the layering, the contact surface will be of better quality. Since in the additive manufacturing of the prosthetic socket it is important that the surface quality is the greatest on the inner surface, it is important to position the model so that its distal end is in contact with the working platform and the socket walls are oriented perpendicular to it. In this way, no support structure is generated on the inner surface of the socket. With this positioning, due to the orientation of the layers, there will be no weak spots for bending, thus preventing the occurrence of cracks.

A total value of a transtibial CAD socket has been calculated, since the goal was to propose a low-cost solution for custom transtibial socket design and production using modern approaches. A total of 7 individual transtibial sockets have been designed by the proposed CAD socket design methodology. Data regarding the material and time consumption of designing and manufacturing these CAD sockets have been used to calculate and average value of a single transtibial CAD socket (Table 1).

The value of a 3D scan is around 50 euros for 1 hour, while the 3D scanning process of the lower limb does not exceed this length. Work with data, adjustment of the virtual positive and the design of the transtibial socket can be evaluated as a CAD modeling service, the value of which is usually in the range of 30-40 euros per hour. The design of the transtibial socket using the proposed methodology can be created in 1 hour, in a complicated case in 2 hours.

From this evaluation we can state that the value of a 3D scan and CAD design of a transtibial socket can be set at

80-120 euros, depending on the condition of the subject, for which the CAD socket is being made.

The price calculation using FDM technology was done with a setting of 100% density of the model filling with an activated support structure on the work platform. Materials selected for calculation:

a. PLA Prusament (27.99 euros per kg),
b. PETG Prusament (22.49 euros per kg).

Table 1 Individual transtibial socket material and time consumption by FDM production

Socket	Material weight [g]	Material lenght [m]	Time of production [hh:mm]
S1	206.59	69.27	23:36
S2	420.97	141.14	52:35
S3	296.25	99.33	35:24
S4	239.88	80.43	28:42
S5	234.20	78.52	28:21
S6	331.56	111.17	43:50
S7	279.68	93.77	35:17
Average	**289.59**	**96.23**	**35:23**

The approximate value of the material needed for transtibial socket production using FDM technology is 6.50 euros when using PETG (Polyethylene terephthalate glycol) material and 8 euros when using PLA (Polylactic acid) material. To this value, it is necessary to add the value of the preparation of the 3D printer, which is normally 3.50 euros per hour. Preparation can take 1-2 hours (max. 7 euros).

The final value is calculated by adding the maximum determined value of the CAD design to the average value by selected type of production using selected materials (Table 2).

Table 2 Total value of a transtibial CAD socket manufactured using FDM technology

Technology-Material	Design [euro]	Manufacturing [euro]	**Total [euro]**
FDM-PLA	120	15.00	**135.00**
FDM-PETG	120	13.50	**133.50**

4 Conclusions

From the statistical point of view the digitization of the design process of lower limb prosthesis sockets seems to be necessary. Using low-cost 3D scanning and CAD/CAM technology it is possible to design and produce individual transtibial sockets. As a result, a transtibial stump positive and custom CAD socket design methodology is proposed. From the calculation that has been made we can state a total value of a transtibial CAD socket design and production using low-cost CAD/CAM solutions. This value is important for CPOs or O&P companies for considering using the proposed methodology in their practice.

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