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TEMPLATE DESIGN FOR TRANSFEMORAL PROSTHETIC SOCKET DEVELOPMENT

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Abstract: The presented paper aims to design 3D templates of the sciatic muscle and thigh to simplify and speed up the process of modelling TF (transfemoral) sockets using the CAD/CAM method. A proposal for a general procedure for modelling the proximal part of the TF socket and a thorough description of the proximal part and the types of sockets that are used is presented. Ten individual scans of positives of TF amputated limbs were obtained from which ten mounting ring templates were designed via CAD modelling in the Autodesk Meshmixer software. In the last step a production simulation was generated in PrusaSlicer software for the overall price evaluation.

1 Introduction

The prosthetic socket is a component that secures the prosthesis on the residual limb. Due to the functionality of the prosthesis socket, personalization is necessary, considering individual measurements. Currently, the latest measurement and production methods available in the field of prosthetics and orthotics are increasingly being used [1]. In the design of prosthetic aids, digital data obtained with the help of 3D scanning technology are used, based on which the CAD (Computer Aided Design) modelling of the aid and subsequent CAM (Computer Aided Manufacturing) production are approached. The use of this innovative method prevents the creation of a plaster positive of the residual limb and the conventional production of the socket itself [2]. The introduction of computer-supported tools also reduces the time and costs of the entire development process. These tools make it possible to evaluate different variants of the same product faster and cheaper [3].

Specifically, the transfemoral socket of the lower limb prosthesis is one of the most complex custom-made prosthesis components from a design point of view [4-7].

The process of designing a prosthetic socket can be divided into three levels:

- Preparatory phase of modelling (import of patient data, import of 3D model of the femur, adjustment of the scale of femur circumferences, creation of 3D surface of the socket, optimization of the distal part of the socket)
- Stage of personalized modification of the model (marking important areas of the 3D model of the stump, virtual sculpting of the stump, adjusting measurements)
- Final phase and completion of the geometric model of the socket (modification of the surface of the 3D model of the socket, FEM (Finite Element Method) analysis of the pressures acting on the socket)

Each level of production is personalized, as important adjustments need to be made directly to each individual patient. It is caused by the different shape of the stump. Currently, from a functional point of view, 3 types of transfemoral beds are produced (Figure 1):

- Quadrilateral (transverse oval socket) - using support on the hump of the sciatic bone [8,9].
- Ischial (longitudinal oval socket) - using fixation of the hump of the sciatic bone [10,11].
- Subischial - using fixation by compression of the soft tissue [12-14].

The most complicated part in the design of the socket is the mounting ring, which surrounds the 5-6 cm long proximal part of the thigh. The design is complex due to the curvatures of the surface of the given body segment and the complexity of its 3D scanning. Scans of this area may be unusable depending on the weight and body shape of the subject being scanned. Places and points important for the design of the mounting ring may be indistinct, thus it is not possible to use the CAD/CAM method for its design and production.

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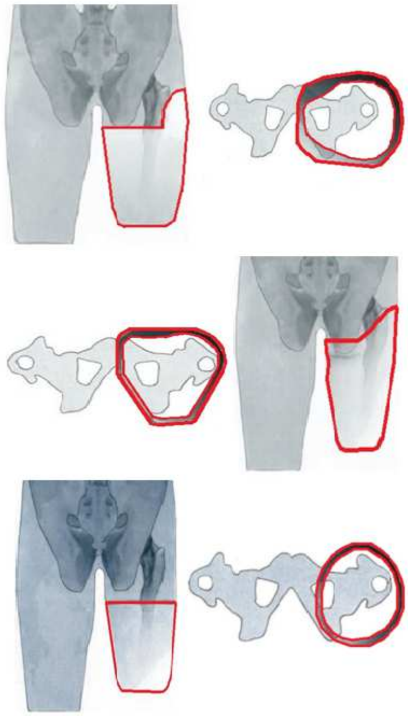

Figure 1 Quadrilateral (top), ischial (middle) and subischial (bottom) transfemoral sockets [9]

For this reason, it is important to design and manufacture mounting ring templates of various shapes and sizes that can be fixed on the subject during scanning to avoid its CAD designing.

2 Methodology

Positive models of transfemoral amputated limbs were obtained using the 3D scanning method using the M4D 3D scanner (Rodin4D, Merignac, France). The result was 10 transfemoral 3D scans of positives in STL (Standard Triangle Language) format. Editing of the obtained 3D models of the positives and the design of the mounting rings were conducted in the CAD software Autodesk Meshmixer (Autodesk, Inc., San Rafael, CA, USA).

Before designing of the ring, itself, it is necessary to modify the model of the 3D scan of the positive on which it will be designed. The first step is to align the model in the software's Cartesian coordinate system so that the frontal, transverse, and sagittal planes of the femur model are identical to those in the software. Subsequently, it is necessary to reduce the number of triangles that make up the surface of the 3D model of the positive. The lower the number of triangles is, the faster the software can work. We perform the reduction as needed. It is necessary to be careful that a too high reduction does not deform the shape of the surface of the model. Next, it is advisable to remove parts of the positive model that are not essential when designing the mounting ring. Thus, a part of the model 5-6 cm distal from the indicated proximal edge of the socket is removed by a transverse incision (Figure 2).

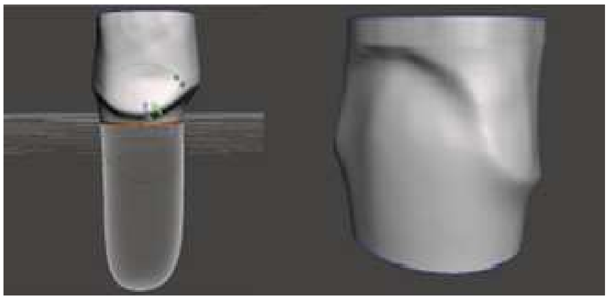

Figure 2 Preparation of the 3D positive model

When designing the ring itself, it is necessary to indicate the area that will represent its inner surface area. This surface is located distal to the proximal edge of the socket. The marked area is then extruded to a height of 5 mm, which results in a 3D model of the mounting ring (Figure 3). In the last step, it is necessary to smooth out the surface of the model and its sharp edges, which may have arisen during the creation of the 3D model.

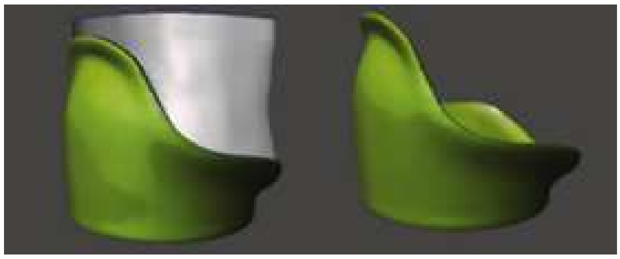

Figure 3 Mounting ring model

3 Results

The result of the modelling is ten templates of the mounting ring of the TF (transfemoral) socket in a digital form, which is ready for CAM production. When making a template, it is important to analyse 3D printing from an economic point of view. The CAM simulation of the production of individual rings was created in PrusaSlicer (Prusa Research a.s., Prague, Czech Republic) software. The low-cost FFF (fused filament fabrication) type 3D printer TRILAB DeltiQ2 (TriLAB, Brno, Czech Republic) with PLA (polylactic acid) and ABS (acrylonitrile butadiene styrene) materials were chosen as the device for model production.

Before printing itself, several parameters need to be considered, namely the time of modelling using CAD software, preparation of the model for 3D printing, printing time and the amount of material consumed. The simulation results are summarized in Table 1.

Table 1 Mounting ring templates production simulation results

Model number	Used PLA materi-al [kg]	Length of production (PLA)	Used ABS materi-al [kg]	Length of producti-

				on (ABS)
1	0.475	1d 18h 55m	0.398	1d 18h 55m 1135
2	0.418	1d 16h 32m	0.350	1d 16h 18m 978
3	0.325	1d 7h 34m	0.273	1d 7h 38m 458
4	0.357	1d 10h 49m	0.300	1d 10h 56m 656
5	0.344	1d 9h 16m	0.292	1d 9h 20m 560
6	0.292	1d 4h 6m	0.245	1d 4h 11m 251
7	0.415	1d 15h 37m	0.274	1d 9h 25m 565
8	0.430	1d 18h 15m	0.361	1d 18h 23m 1103
9	0.342	1d 9h 13m	0.287	1d 9h 21m 561
10	0.433	1d 18h 27m	0.363	1d 18h 25m 1105
Average	**0.383**	**1d 12h 52m**	**0.314**	**1d 12h 17m**

4 Discussion

Meshmixer software allows the user to quickly create models of prosthetic aids and devices using appropriately selected features. Using available programming tools, it is also possible to automate the design workflow [15].

The advantage of this software is its availability, as it is a freely downloadable software that contains several functions and tools that speed up the TF socket modelling process compared to the classic conventional manufacturing method. The software is linked to a 3D printer so that the TF socket can be printed directly after the modelling process is completed. From the point of view of developments in the field of prosthetics and orthotics, this method of modelling and subsequent 3D printing is very advantageous in terms of financial costs, but also the time saved, thanks to which the given TF socket reaches the patient much earlier.

Designing and modelling in this software was timesaving. The design of one template took an average of 20 minutes. From 10 3D positives, which are remarkably similar in shape but different in size, it was not possible to create S, M and L (small, medium, and large) template sizes. A larger sample of 3D positives would need to be used to create standardized sizes. The main advantage of these templates is speeding up and simplifying the 3D scanning process when obtaining a virtual positive of the stump and working on the CAD design of the TF prosthesis socket.

Based on the shape of the stump, the orthopaedic technician selects a suitable template with the required size and then adjusts the proximal part of the stump as needed. The evaluation of the total value of the material had to be determined using the PrusaSlicer software, where the average amount of material used for 3D printing was calculated in the case of PLA and ABS filaments. The output of the calculation was the determination of the total price for the material. It was found that the material price for one template made from PLA material is 12,26 euros and from ABS material 8,79 euros. This means that PLA material is 3,47 euros more expensive than ABS. However, the total price for the template would be higher because it is necessary to consider other production expenses, such as a surcharge for the design, device, preparation for 3D printing, energy consumed during 3D printing and so on.

5 Conclusions

Using the presented procedure, ten mounting rings were designed to simplify and speed up the process of 3D modelling TF sockets using the CAD/CAM method. The goal was to create templates that should be in selected sizes to be used as a template for a professional technician. Based on the shape of the bone, he selects a suitable template with the required size and then adjusts the proximal part as needed.

In the future, it is necessary to obtain a larger sample of 3D positives, so that it is possible to design the average sizes of the mounting ring templates according to them. It would also be appropriate to simulate production on other types of CAM technologies and compare the results with the results of this research.

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