Acta Mechanica Slovaca **26 (2): 6 - 11,** June **2022**
https://doi.org/10.21496/ams.2021.028

Acta Mechanica Slovaca
ISSN 1335-2393
www.actamechanica.sk

Design of an Individual Cover for a Lower Limb Prosthesis

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Abstract: One of the modern trends in prosthetics and orthotics is the production of design covers for lower limb prostheses. Thanks to the advantages of CAD/CAM, there are no limits to the design of these covers. At present, there are companies that provide design covers produced by additive manufacturing, but their price is relatively high. In this work, the motivation and design procedure of an individual cover for a lower limb prosthesis for a specific user is discussed. The aim of this study is to propose a design methodology of an individual lower limb prosthesis cover using freely downloadable CAD software based on 3D scanning data, which will be produced by additive manufacturing technology.

Keywords: Prosthesis, cover, lower limb, CAD/CAM, 3D scanning

1. Introduction

The use of modern technologies and methods has great application in the field of prosthetics and orthotics. Using additive manufacturing in combination with 3D scanning and reverse engineering, we can produce a variety of traditional prosthetic aids and devices with the benefits and improvements of innovative technologies [1]. Using 3D scanners, we can capture a copy of the subject's body surface, and this method is faster, more accurate and much more convenient than the traditional method of plastering [2][3]. The whole process is contactless, clean and if a handheld 3D scanner is used, then the presence of the patient at a specialized workplace is not required. The data obtained by this method can be used in CAD design of individual aids and special devices models, whose shapes are too complicated for production by conventional technologies [4][5][6][7][8][9]. These models are produced by additive manufacturing (AM). AM allows the production of such devices, while the time and cost of production is in some cases comparable or lower than the length and price of production by conventional methods [10][11]. Depending on how the device is used, it is possible to select the appropriate type of material and the specific type of 3D printer [12][13].

One of the modern trends is the production of designer covers for lower limb prostheses. Thanks to the advantages of AM, there are no limits to the design process. This allows the user to specify the requirements for the properties and characteristics that the cover should meet.

Currently, there are companies that provide designer covers made using AM or plastic molding [14][15]. The client fills out a form that includes important information for cover production, chooses the colour, finish and sends the order. The disadvantage, however, is their high price. Some covers can cost more than 1000 euros, and if we

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compare them with classic covers from commercial companies, the price does not differ significantly.

An alternative is to download a freely available 3D model of the cover, which someone designed and shared online. However, the person must arrange the production himself. This can mean that the costs will be significantly lower, but the final product may not fit the device or meet the user's preferences, as it is not an individually designed cover.

The Department of Biomedical Engineering and Measurement at the Faculty of Mechanical Engineering, Technical University in Košice received a request for the design of a personalized cover for a lower limb prosthesis. The prosthesis user is a 45-year-old male. In 2018, he had his left lower limb amputated in the thigh area due to a devastating injury caused by a car accident. Subsequently, it was equipped with a transfemoral prosthesis with a knee joint controlled by a C-leg microprocessor. It is an active user who, despite his disability, works and plays sports. Its current cover is considerably worn with minor damage, which the user tried to remove by laminating with carbon tape. However, its current state does not meet the requirements in terms of mechanical properties (strength), does not provide sufficient protection (does not prevent the penetration of various impurities, such as dust or water) and aesthetic function.

Therefore, the aim of this study is to propose a design methodology of an individual lower limb prosthesis cover using freely downloadable CAD software based on data from 3D scanning, which will be produced by additive manufacturing technology.

2. Methods

The methodology is divided into 2 main phases of the research:

1. *3D scanning,*
2. *Computer aided design (CAD)*

2.1. 3D scanning

The first step in creating custom models using the reverse engineering method is to obtain a virtual copy of the object being edited. This copy of the surface will further serve as a basis for model creation of the final product. Due to the complicated surface, an optical 3D scanner Artec Eva (Artec 3D, Luxembourg, Luxembourg) was used to capture the shape [16].

The scan frequency was set to 16fps (frames per second) and the duration of the whole process was approximately 30 minutes. The subject was scanned standing with lower limbs slightly apart. Both lower limbs of the subject (healthy and amputated) were scanned. The residual left lower limb with the prosthesis was scanned, focusing on the prosthetic knee joint. The prosthesis with the cover attached was also scanned. The focus while scanning the right limb was on the physiological area of the knee and foreleg. The subject was sufficiently informed about the course of the scan and signed an informed consent. The scanning process went smoothly and the outcomes (Figure 1) are suitable for work in CAD modeling software.

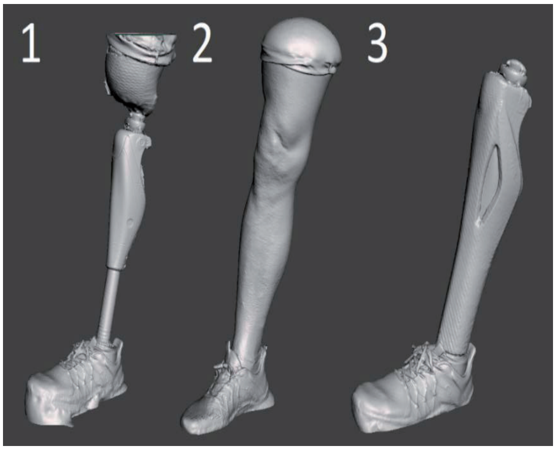

Figure 1: (1) Scan of the residual left lower limb with the prosthesis attached. (2) Scan of the healthy right lower limb. (3) Scan of the prosthesis with the polymer cover.

2.2. Computer aided design (CAD)

The design also considered the material and technological requirements for the production of the cover, as well as the personal requirements and needs of the subject.

Prosthetic cover requirements set by the user:

3. *1.The design of the prosthesis cover should have the shape proportions of the physiological forefoot and at the same time should give the impression of a futuristic appearance.*
4. *2.The method of applying the cover to the prosthetic limb must be simple and timesaving.*
5. *3.The cover must be securely attached to the tubular adapter due to the natural tension of the cover and must not come loose.*

The prosthesis cover was designed using Fusion 360 modeling software (Autodesk Inc., San Rafael, CA, USA).

2.2.1. Importing a 3D scan

Correct placement and definition of 3D scanning in software space (so that the size of the scan corresponds to the actual size of the scanned element) requires determining at least one parameter of the assessed prosthesis. In our design, the diameter of the prosthetic tube adapter (d = 35mm) was used as the assessed parameter. The size of the parameter of the inserted 3D scan was adjusted so that the size of the scan corresponded to the actual size of the prosthesis. Subsequently, the 3D scan of the prosthesis was concentrically aligned with the medial and frontal planes of the central modeling space. After alignment, the scan was further modified to ensure even distribution of points and removal of unwanted artefacts that arise during scanning.

2.2.2. Matrix and basic model design

The design of the matrix or base surface for the shape of the prosthesis cover without a specified thickness is the first and most important design step, because it defines the initial appearance of the cover. The basic requirement of the design was to cut the prosthesis cover as a futuristic imitation of the real shape of the foreleg, therefore a mirrored scan of the user's healthy limb was used, which in combination with the prosthesis scan forms the basis of the overall matrix shape. The appearance of the matrix was then determined using five sketches, which precisely defined the shape of the mirrored scan of the healthy limb and set aside space for the functional parts of the knee prosthesis system. The sketches were made in five horizontal planes. The horizontal planes were evenly spaced along the vertical axis in the foreleg area. By connecting the individual sketches, the basic shape surface of the cover was created (Figure 2).

With subsequent construction of tangential planes with sketches in the lower part of the matrix surface, the shapes of futuristic-shaped holes were designed. Auxiliary surfaces were created by spatially extending the proposed shape of the holes. The penetration of auxiliary surfaces through the surface of the matrix defined the projection of the holes on the matrix. Subsequently, the matrix was trimmed at the points of penetration of the auxiliary surfaces. This way the holes were formed in the shape of a matrix.

Another part that had to be constructed within the matrix was the upper shaped surface, which is essential for anchoring the cover to the upper edge of the functional part of the knee prosthesis system. The sketch of the upper surface was defined by a horizontal plane, which was incorporated into the highest part of the cover by means of a three-point handle. Subsequently, an upper surface shape was formed from the sketch. Finally, the upper surface shape was connected by an asymmetrical arc to the total surface of the matrix (Figure 2).

The last step in creating a basic shape of a prosthesis cover from the shape of a matrix is to define the wall thickness. The wall thickness was set to 4.5 mm. This created the basic model of the prosthesis cover, which will be further modified in the next steps.

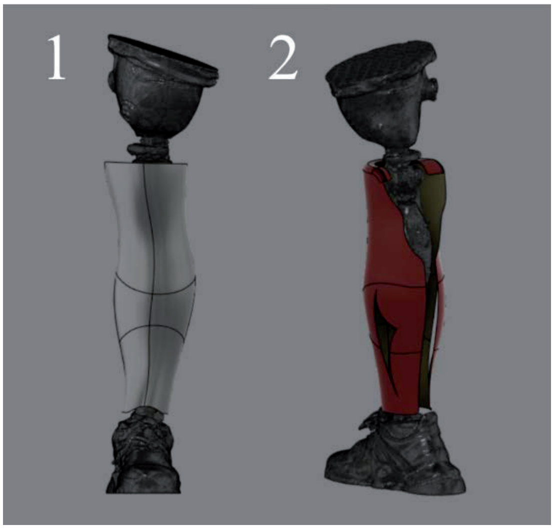

Figure 2: (1) Basic design of the matrix shape according to a mirrored scan of a healthy lower limb. (2) Complete matrix.

2.2.3 Connection system design

The body of the prosthetic cover was divided into three parts, which are interconnected into one unit. Requirements were placed on the design of joints between individual parts of the cover in terms of mechanical properties (sufficient flexibility of the cover walls) and construction (uneven shape of the surface) due to the way the cover is clamped to the prosthesis, as well as aesthetics (requirement of futuristic appearance). The proposed connection is defined as a wing connection. Since the joint had to be placed in an asymmetrical surface, the modeling of the part was performed as an offset. This form of design was chosen because it was evaluated as the most effective. First, centric surfaces were created that define the concentric distance from the central point of the object (Figure 3). Subsequently, sketches of auxiliary surfaces were made on the respective horizontal and vertical planes. By creating extruded auxiliary surfaces from the sketches, the shapes of the handles on the centrically offset surfaces were defined (Figure 3). By combining centric, offset surfaces with the auxiliary surfaces of the sketches, individual layers of wing holders were gradually formed by trimming as fragments of a surface without thickness. The thickness of the designed brackets was set to 2 mm (Figure 3). Finally, the parts of the proposed handles were connected to the correct parts of the body of the prosthesis cover.

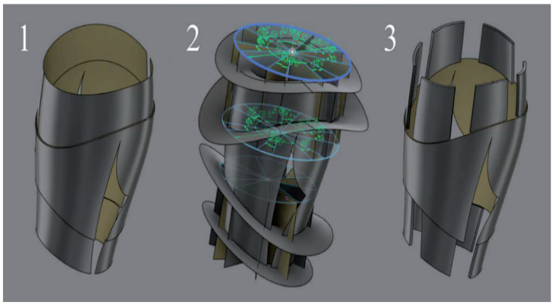

Figure 3: (1) Centrically offset surfaces.
(2) Horizontal and vertical auxiliary surfaces.
(3) Connecting wings created by mutual cutting of centric offset and auxiliary surfaces.

To connect all three parts, it is necessary to design the anchoring sockets in the upper and lower part.

By subtracting the mass of the body of the wing holders from the mass of the body of the upper and lower part of the cover, the socket cut-outs were formed into the remaining two parts.

The wings of the sockets at the upper and lower part of the cover were created by the same method of offsetting and trimming by means of auxiliary surfaces as in the creation of wing holders at the middlepart of the prosthesis (Figure 4).

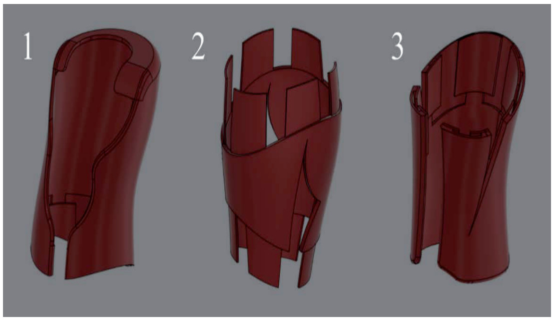

Figure 4: (1) The upper part of the cover. (2) Middle part of the cover. (3) The lower part of the cover.

2.2.4. Grip design

The oval structure of the grip must be designed in such a way that, after fitting the cover to the tubular adapter of the prosthesis, it acquires a circular shape with a sufficient pressure force. For this reason, it is necessary to design a split handle, the shape of which will be elliptical. When modeling the grip, it is necessary to design horizontal sketches of individual parts of the brackets at the highest and lowest point of the tubular adapter. By pulling out the shape of the sketches to a height of 10 mm, the body of the grip was made. It is also necessary to design the shape of the projections and their auxiliary surfaces by means of sketches placed on vertical planes in places where the grip will be connected to the body of the cover and thus create cut-outs through which the grip will be attached to the prosthesis cover (Figure 5). After the design of a suitable connection body, the grip design is complete. However, care must be taken into the shape of the connecting body, so it does not interfere with the space of the functional apparatus of the knee joint on the prosthesis (Figure 5).

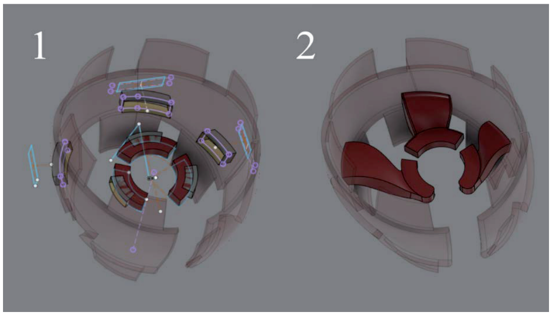

Figure 5: (1) Sketches of auxiliary surfaces and grip auxiliary surfaces. (2) Finished grip body attached to the cover surface.

The last part of the design was the creation of filets of the edges of objects. Filets were made on all three fabricated parts. The primary function is to create optimal comfort when connecting parts of the cover into one unit and when fixing the cover to the prosthesis. The secondary function is to further adjust and emphasize the futuristic appearance of the cover (Figure 6).

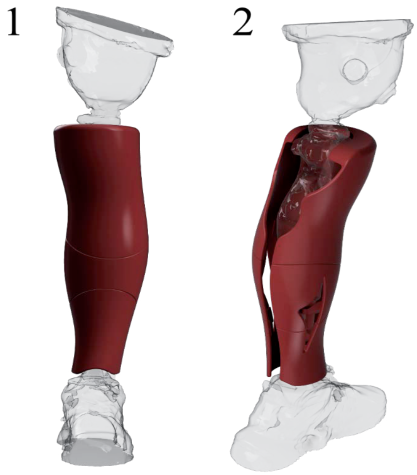

Figure 6: Finished prosthesis cover. (1) Front view. (2) Axonometric rear view.

3. Results and Discussion

Using the proposed methodology, an individual lower limb prosthesis cover that meets the requirements set by the user has been designed. 3D scanning has proven to be a very practical, timesaving, and convenient way to collect CAD data. A professional optical 3D scanner was used for data collection. In the future, it would be appropriate to use low-cost 3D scanners and find out whether the data obtained by these devices would also be suitable for use.

CAD software Fusion 360 was used to design the cover model, the license of which can be freely downloaded from the internet if the software is used only for non-commercial purposes. Commercial software, like SolidWorks (Dassault Systèmes SolidWorks Corporation, Waltham, USA), which includes similar tools and features, may also be used. To verify this design in practice, it is necessary to obtain data from several subjects and replicate this methodology.

The proposed model of the prosthesis cover was divided into three parts, which are connected to each other by a simple mechanism into one unit. Originally, the cover was designed as a whole, but to streamline the production of the cover, the model was additionally modified with dividing planes and a specific connection system. Thanks to this division, we can produce individual parts of the cover simultaneously on 1 or more 3D printers, which will speed up the production time of the cover. To compare the price of our designed cover and commercially available covers, the production of individual parts on a professional FDM (Fused Deposition Modeling) printer Fortus 450mc (Stratasys Ltd., Rehotov, Israel) and a desktop FFF (Fused Filament Fabrication) printer TriLAB DeltiQ 2 (TriLAB Group, Brno, Czech Republic) was calculated. The PC (polycarbonate) material on the FDM printer and PLA (polylactic acid) material on the FFF printer were selected for production [17]. Advantage of Fortus 450mc is that the building space is large enough to manufacture all parts in one print, so the parts´ production is more efficient than when they were built separately. However, it is clear from the results (Table 1), that a better choice for the cover production is to build individual covers´ parts simultaneously on 3 table FFF printers. It is less financially demanding and took approximately the same time to manufacture than on a professional FDM printer.

Table 1: Calculation of time and cost of production of individual parts of the cover.

Machine	Model	Time (hh:mm)	Price (euro)
Fortus 450mc	Lower part	12:53	160,09
	Middle part	18:53	227,13
	Upper part	29:12	404,83
	All together (1 print)	***57:01***	***738,89***
TriLAB DeltiQ 2	Lower part	13:33	77,20
	Middle part	20:39	113,42
	Upper part	25:05	136,16
	All together (3 prints)	***59:17***	***326,78***

The production price of the given individual cover is approximately 330 euros. The time set for subject 3D scanning and CAD design of the cover is 16 hours, i.e., 2 working days. The price of the CAD process can theoretically be set at 160 euros (if 1 standard hour is valued at 10 euros). That comes to a total of 490 euros for the proposed cover. Compared to the price of commercial, branded or designer 3D printed covers, which is approximately 1000 euros, we have a difference of approximately 510 euros, which is a half of its price [15]. This means that the cover we propose can compete with commercial companies engaged in the production of lower limb prosthesis covers.

4. Conclusions

In this work, the motivation and design process of an individual cover for the lower limb prosthesis is discussed. The use of modern technologies such as 3D scanning and CAD software in the design of such a model has proven to be very practical and effective. Continuation of development will consist in the use of additive production technology for the cover production and subsequent practical testing. After practical tests, the final modification of the 3D model will be performed, and various types of 3D printers will be used for the prototypes production. Furthermore, the results of mechanical tests of individual prototypes will be compared and, after practical testing, the ideal variant of the cover will be determined. Finally, the fair value of our proposed individual lower limb prosthesis cover will be calculated.

Acknowledgments

This article was prepared based on the support obtained from projects APVV-19-0290, KEGA 041TUKE-4/2019, KEGA 023TUKE-4/2020 and Stimuli for research and development 12/2018 - 12/2021.

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