Automatic Below-Knee Prosthesis Socket Design: A Preliminary Approach

Giorgio Colombo[1], Giancarlo Facoetti[2(✉)], and Caterina Rizzi[3]

[1] Department of Mechanical Engineering, Polytechnic of Milan, Milan, Italy
giorgio.colombo@polimi.it
[2] BigFlo s.r.l. (BG), Dalmine, Italy
giancarlo.facoetti@bigflo.it
[3] Department of Management, Information and Production Engineering, University of Bergamo (BG), Dalmine, Italy
caterina.rizzi@unibg.it

Abstract. In this work we present a preliminary study on a system able to design automatically sockets for lower-limb prosthesis. The socket is the most important part of the whole prosthesis and requires a custom design specific for the patient's characteristics and her/his residuum morphology. The system takes in input the weight and the lifestyle of the patient, the tonicity level and the geometry file of the residuum, and creates a new model applying the correct geometric deformations needed to create a functional socket. In fact, in order to provide the right fit and prevent pain, we need to create on the socket load and off-load zones in correspondence of the critical anatomical areas. To identify the position of such critical areas, several neural networks have been trained using a dataset generated from real residuum models.

Keywords: Lower limb prosthesis · Neural network · Prosthetic socket · CAD

1 Introduction

The most important part of a lower-limb prostheses is the socket. The socket is the component that links the patient's residual limb to the whole prosthesis. A correct socket geometry is fundamental to provide the right comfort and mobility level to the patient. Thus, particular care is necessary during the design of this component since it, requires a custom design; in fact, the socket has to be realized starting from the specific patient's anatomy.

The socket should fit the patient's residuum and create load and off-load zones. Load zones are required to provide the right pressure and stability during daily activities, while off-load zones are needed on specific anatomical areas, in order to prevent pain [1]. Figure 1 shows the correct load and off-load zones on a below-knee residuum. As we can see in the Fig. 1, we need to lower the pressure on the crest and the terminal of the tibia, on the head of the fibula and on the lateral femoral condyle, while we need to apply a certain pressure on the areas marked in green that usually depends on the residuum tonicity [3].

Furthermore, in order to create the right fit between the residuum and the socket, the socket has to be smaller than the residuum. This size difference depends on the patient's weight and lifestyle.

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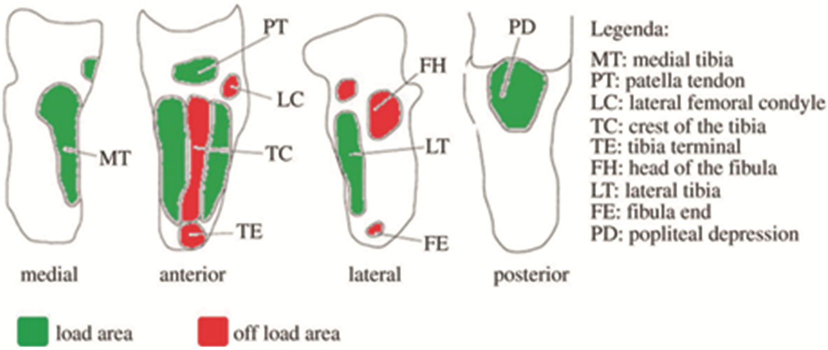


Fig. 1. Anatomical zones of below knee residuum

The traditional prosthesis design process is mostly hand-made, through a set of positive and negative plaster casts, and strongly depends on the technician's skills and experience, following a trial and error approach.

To improve the whole process, in previous works we proposed a new design framework [1] where is possible to design and validate lower limb prosthesis, below and above-knee both, in a virtual environment, with a set of CAD-CAE tools that permit to replicate all the traditional design steps. The new framework focuses on the patient characteristics and guides the orthopedic technician through a semi-automatic workflow that embeds domain knowledge and design rules. Furthermore, the system uses FEM analysis and virtual humans simulation to validate the generated models.

2 Automatic Socket Creation

In this work, we focused the attention on the automation of the socket geometry design to make this important phase a predictable and repeatable process. We are developing a system that takes in input some patient's characteristics and his/her residuum geometry, and automatically generates a socket applying the correct geometric operations. The workflow of the procedure is based on the following steps (Fig. 2):

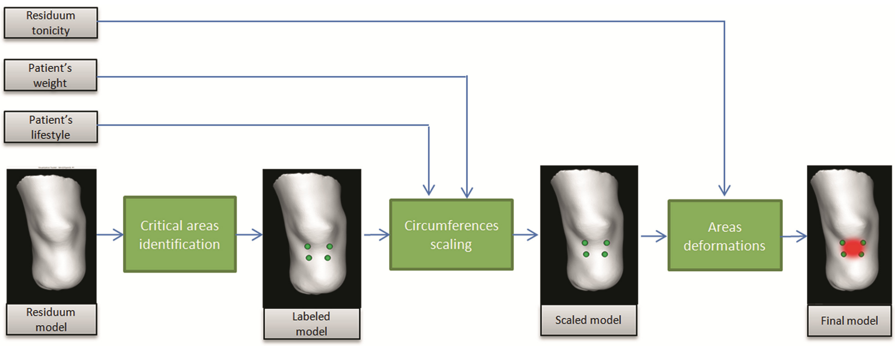


Fig. 2. Workflow of the system

- Identification of the critical anatomic areas;
- Circumference scaling;
- Application of the correct deformation on the critical anatomic areas.

The size of the circumference scaling and the depth of the deformations are determined by the residuum tonicity and by patient's weight and life style. In particular:

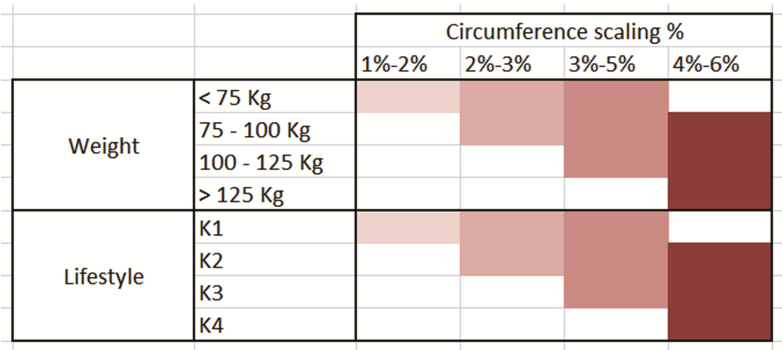
1. **Patient's residuum tonicity** that is divided in 4 qualitative levels. In the traditional socket manufacturing process, this value is used to size the depth of the deformations on the load and off-load zones. The more the deformation is depth, the more the pressure will be high. Deformations are also created on the off-load zones, in order to lower the pressure in such areas. Table 1 shows the relation between tonicity level and the deformations depth required.

Table 1. Tonicity - deformation depth relations

Tonicity	Deformation depth [mm]
Low	1–2
Normal	3–4
Good	5–6
Very good	7–8

2. **Patient's weight and life-style.** These two parameters determine the size of circumference scaling, which usually spans from 1 % to 6 %. The scaling is not uniform, but starts with 1 % at 4 cm over the residuum top, and it increases gradually going up to the residuum upper part. Patient life-style is represented with the K-levels ranking system published by the US Health Care Financing Administration's (HCFA). Table 2 shows the relation among patient's weight-lifestyle and the circumference scaling required.

Table 2. Patient's weight-lifestyle and circumference scaling required



		Circumference scaling %			
		1%-2%	2%-3%	3%-5%	4%-6%
Weight	< 75 Kg				
	75 - 100 Kg				
	100 - 125 Kg				
	> 125 Kg				
Lifestyle	K1				
	K2				
	K3				
	K4				

Finally, the **patient's residuum geometry** is acquired from MRI or laser scanning, reconstructed and converted in STL file format.

3 Anatomical Zones Recognition

First, the system exploits a neural network trained to identify on the patient's residuum geometry the location of the anatomical areas on which to apply the load and off-load zones [4, 5]. To this end, we expanded a prototype system presented in a previous work, in which we showed how to convert a 3D shape in an input suitable for a neural network, through a ray-casting process [2].

We created the dataset needed to train the neural network as follows: we used 5 STL files acquired from 5 different below-knee amputees, and labeled by human experts. In the labeling phase the experts was asked to put on the residuum model 4 different markers representing the perimeters of a given area. In particular, in this preliminary study we focused on the crest of the tibia, the patella and the patella tendon (Fig. 3).

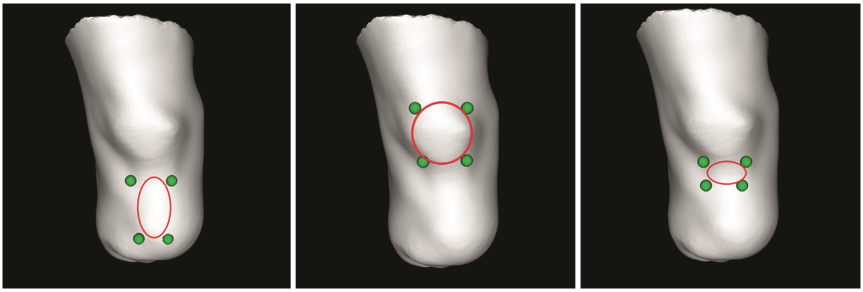


Fig. 3. Crest of tibia, patella and patella tendon critical areas

The 3d geometry has been converted in a grid of points on its surface, and the input feature vector of the network has been composed of the normalized distances of these points from a reference plane (Fig. 4).

As the size of the dataset was quite small, we generated a new synthetic training dataset using the 5 labeled original models as starting seed for the creation of new labeled

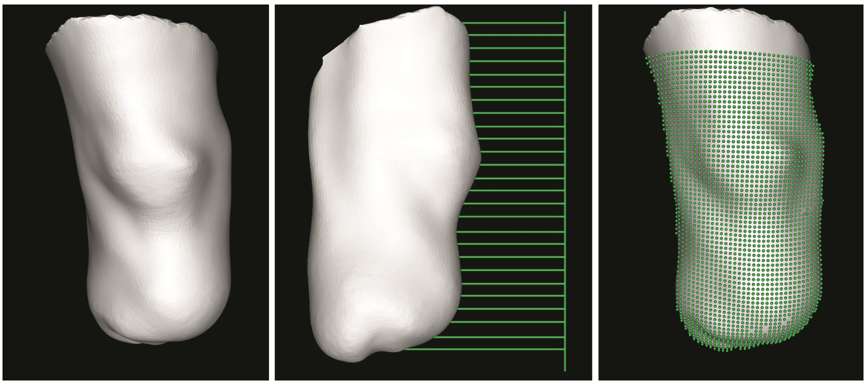


Fig. 4. 3d geometry - grid points conversion

geometries, through geometrical transformation operations such as scaling, skewing and rotation. This technique is often used in classification system for optical character recognition [6]. Finally, the artificial neural network has been trained with the back-propagation algorithm.

The neural network architecture consists of 1 input layer, 1 hidden layer, and 1 output layer. The input layer has 600 nodes corresponding to the 600 (30 * 20) points of the grid. In particular, the input value of each node consists of the distance of the residuum surface in that point from the reference place that lies in front of the residuum (Fig. 3). The distances have been normalized in range (−1, +1).

The output layer has 8 nodes, corresponding to the x and y coordinates of each of the four marker used by the experts to label the model. (x1, y1, x2, y2, y3, x,3, y4, x4).

Regarding the number of nodes of the hidden layer, generally, there are no strict rules for deciding how many nodes it's necessary to assign to the hidden layer. Too few nodes could lead to a high error during the prediction phase, while too much nodes could create a model that can't generalize well (overfitting).

One design best practice suggests to use, for the hidden layer, a number of nodes that is equal to the geometric mean between the number of the input layer and the number of the output layer. In this specific case, we found out that the number of hidden layer that leads to the minimum test error and then provides better results is 70 (Fig. 5).

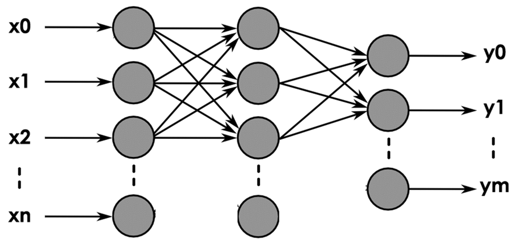


Fig. 5. Neural network architecture: Input layer (600 nodes), 1 hidden layer (70 nodes) and 1 output layer (8 nodes).

The final training dataset was composed of 400 labeled models of below knee residuum. In this study we trained a single neural network for a single critical area to be identified. Thus we have a neural network trained to recognize the area of the patella, one for the patella tendon, and another for the crest of the tibia.

Table 3. Final test errors

Anatomical area	Mean test squared error
Patella	62.15
Patella tendon	64.022
Tibia crest	60.25

The dataset has been split randomly into two parts: 80 % for the training set and 20 % for the validation set. The algorithm for the training has been the back-propagation with early stopping. Finally, the performance of the network has been tested on another residuum model, never used during the training phase. Final test errors are represented in Table 3.

4 Load and Off-Load Zones Creation

Once the geometry residuum areas have been identified, the system performs geometric deformations to create the required load and off-load zones. As previously said, the depth of the deformation is driven by the residuum tonicity that is divided in four levels: low, normal, good and very good.

Depending on the tonicity value, the deformations depth spans from 1 to 8 mm. A residuum with a good tonicity requires a less tight socket than a residuum with low tonicity. The deformations are smooth without hard steps and are generated by a Gaussian function with high variance. Figure 6 shows the example where the red zone is the created load zone for the patella tendon critical area.

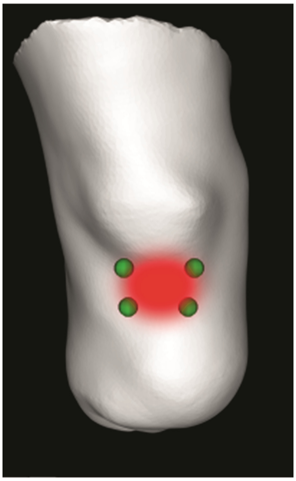


Fig. 6. Load zone creation on the patella tendon area

The final outcome is a new geometric model that replicates the shape of the residuum, except the areas in which deformations have been applied and load and off-load zones have been created. This new geometry represents the internal surface of the prosthesis socket. By adding a uniform thickness we can generate the final socket model.

5 Results, Conclusions and Future Steps

This work is a preliminary test to verify the feasibility of the approach. To validate the automatic deformation, we compared the output of the system with a validation dataset.

It consists of 5 sockets designed manually by professional technicians through a commercial prosthetic CAD system.

Results are promising, but there are several issues to be addressed in the future. First, we need to improve the precision of the identification algorithm. The total cumulative squared mean error is about 60 squared mm; this error is the sum of the errors of the 4 markers positions, this means that each marker is placed with a mean error of about 3.8 mm, this could be acceptable but expanding the dataset with new case studies could lead to a better predictive model. Secondly, we need to deal with the shaping of the upper border of the socket. Some commercial prosthetic CAD systems use reference templates as starting shape, but we have planned to investigate the possibility to apply automatic procedures also to this design phase.

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