Knowledge-based System for Guided Modeling of Sockets for Lower Limb Prostheses

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ABSTRACT

This paper presents a 3D CAD system to design sockets of lower limb prostheses, both transfemoral and transtibial. The proposed system, named Virtual Socket Laboratory, can be seen as a virtual laboratory where the user has at her/his disposal virtual tools that permit to emulate the procedures applied by orthopaedic technicians during the traditional socket manufacturing. The module is centred on the digital model of the patient and is based on the specific domain knowledge to guide the user during socket modelling suggesting the most appropriate design rules and procedures. First, main steps of the new design-modelling process and system functionalities are presented. Then, for each step, procedures carried during the traditional process, how they are executed with the new module and tools specifically developed are described.

Keywords: 3D Socket modelling, knowledge-based system, artificial prosthesis design.
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1 INTRODUCTION

Nowadays in orthopaedic products industry there is a large availability of standard products, which are approximately adapted to the different patients' anatomies. However, due to an increasing demand of personalized products by patients themselves, this sector has started to develop new methods or apply existing ICT technologies to manufacture custom fit products; in particular those totally realized on the patient's morphology. In this field we have considered the case of lower limb prostheses, products which are composed by both standard and custom fit components.

In particular we have considered transtibial and transfemoral amputees, where transtibial is an amputation of the lower limb between the ankle and the knee, and transfemoral between the knee and the hip [1]. Modular lower limb prosthesis is principally composed by a liner, a socket, a knee (only for transfemoral patients), a tube, a foot and different typologies of locks and joints to assemble the various modules [1], [3], [7], [10-11]. An example of transfemoral prosthesis is shown in Figure 1. Most of these products are standard components which are chosen from commercial catalogues, apart the liner which can be both standard and custom fit, and the socket which is always manufactured expressly in relation to the specific anatomy of the patient.

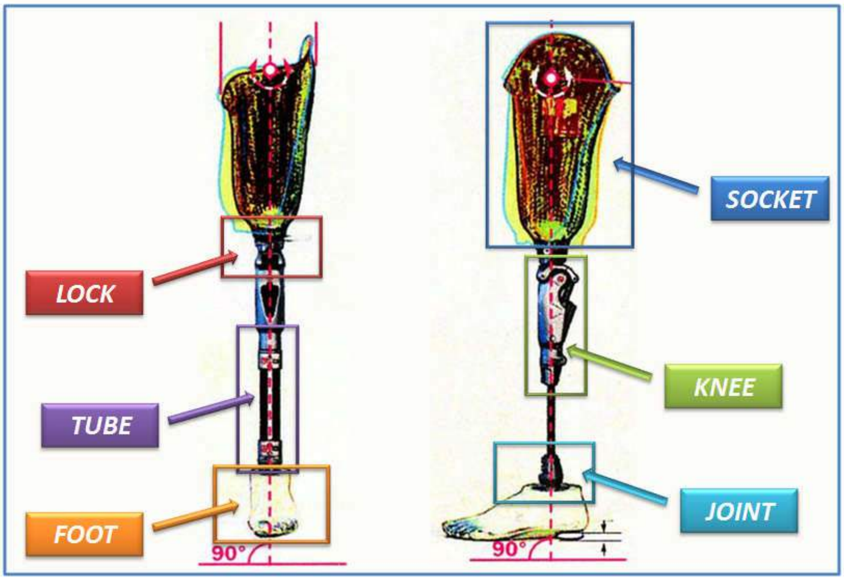


Fig. 1: Example of a transfemoral prosthesis, frontal (left) and lateral (right) views.

We decided to focus the attention on the socket because it is the most critical component; in fact it is totally customized and it is distinctive to obtain a well fitting and functional prosthesis. In detail, we have considered two specific typologies of socket: a TSB (Total Surface Bearing) socket for transtibial amputees and a CAT-CAM (Contoured Anterior Trochanteric-Controlled Alignment Method) socket for transfemoral amputees [1], [3], [7], [10-11]. Figure 2 shows the upper and the frontal views of a TSB and of a CAT-CAM socket. These socket styles have been chosen since they are the most comfortable for any kind of patient, allowing a total surface contact between the stump and the socket itself, and avoiding skin rubbing and other similar problems. Besides we have considered only prosthesis with a liner, since this guarantees a better distribution of the contact pressure between limb and socket.

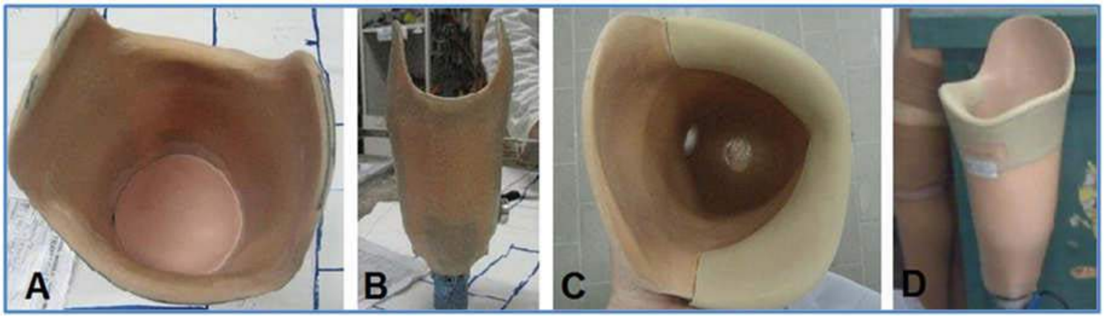


Fig. 2: Top (A) and frontal (B) view of a definitive TSB socket; top (C) and frontal (D) view of a definitive CAT-CAM socket.

In this work we want to present a 3D CAD system, based on the specific domain knowledge, which allows the orthopaedic technician to model the definitive socket of both transtibial and transfemoral prosthesis, directly on the 3D digital model of patient's stump, guided in automatic or semi-automatic mode by the system itself. The considered 3D model of the residual limb includes the external skin, the muscles and the internal bones and, once created the virtual model of the socket it can be used to study the interaction socket-stump with FE tools.

All the design rules and knowledge implemented into the system were acquired studying and analyzing the traditional socket manufacturing process at a high-qualified orthopaedic laboratory.
We first give a general overview of the current state of the art, then the new design process and the related CAD system showing modelling steps and procedures.

2 STATE OF THE ART

In the following we introduce a brief overview of the traditional socket manufacturing and ICT tools available for the sectors.
Nowadays most of the small/medium orthopaedic laboratories to realize a socket first create a negative plaster cast directly on patient's stump. Then, they realize a positive plaster cast from the negative one and, after having applied some manual modifications, they manufacture on it a thermoformable check socket. This check socket is tested with patient, and after the necessary changes on the plaster positive model, the final socket is realized and tested with the amputee. Thus the socket manufacturing relies on the correct realization of the plaster casts. It is important to notice that it is often necessary to manufacture more than one check socket before to obtain a comfortable and well fitting shape. Besides the residual limb undergoes continuous changes during the passing of time, and on average at least every two years the amputee needs a new socket.
On the market we can find some commercial CAD/CAM softwares (for further detail see [14-19]) which can assist the orthopaedic technicians in some steps of the development process. Figure 3 lists some of these systems.

COMPANY	SYSTEM	
BioSculptor	Acquisition Tech.	Laser scanner with 2 cameras, a miniature transmitter for the body and scan-through-glass technology, or manual measurements
	Acquired Data	External shape of AK and BK residual limb
	Stump/Socket Modelling	AK: starting from a library of templates -> external shape of the socket
		AK/BK: using oblique, transverse and circumferential measurements -> automatic generation of the check socket
infinity CAD systems	Acquisition Tech.	Laser reflection scanner with 1 or 2 cameras
	Acquired Data	External shape of AK and BK residual limb
	Stump/Socket Modelling	BK: proximal brim and shape utilities help to transform areas anywhere on the acquired shape -> external shape of the socket
		AK: standard shapes from a library, tools to change volume, length, circumferences -> model of the socket
Orten	Acquisition Tech.	Structured light projection, digital camera or manual measurements
	Acquired Data	External shape of AK and BK residual limb
	Stump/Socket Modelling	BK: on the geometry of the residual limb in defined areas you can apply compression or create build-up areas -> external shape of the socket
		AK: the desired shape is created using a protocol based on manual measurements -> positive model of the socket
ÖSSUR	Acquisition Tech.	Digital camera or manual measurements
	Acquired Data	External shape of AK and BK residual limb
	Stump/Socket Modelling	BK: calculate circumferences and volume of the stump and allows to modify the acquired shape -> positive model of the socket
		AK: measurements taken from the residual limb -> model of the check socket
RODIN4D	Acquisition Tech.	Laser scanner with 1 camera
	Acquired Data	External shape of AK and BK residual limb
	Stump/Socket Modelling	AK/BK: starting from a shapes library, adding check measurements, checking volume and circumferences -> positive model of the socket
VORUM	Acquisition Tech.	Manual measurements and an appropriate proximal brim
	Acquired Data	External shape of AK and BK residual limb
	Stump/Socket Modelling	AK/BK: fitting an appropriate brim to the patient, and taking circumferential measurements, supported by a variety of socket styles -> model of the socket

Fig. 3: Some CAD/CAM prosthetic systems available on the market (AK=Above Knee, BK=Below Knee).

Some of them are used only by the company which produces them to develop different prosthetic components. Most permits to acquire through Reverse Engineering techniques the external shape of human body parts; in the case of residual limb, these systems derives the geometry of the check socket or the positive chalk from the external shape of the stump, also using libraries of standard models. Then, the realisation of the positive model is guided with a CAM module, onto which the socket is thermoformed. This procedure is always linked to the production of a check socket which is tested on the patient and then modified. However they don't consider the possibility to use the systems to analyse and optimise the product such as CAE tools for FEA and multibody analysis. At this regard in literature we can find various experience related to the use of FEM/FEA tools for the analysis of the behaviour of prosthetic components [5], [8-9], [12-13] adopting different models for the materials (linear and not linear), simulating different situations However, these kind of tools are still less diffused within orthopaedic laboratories, especially small and medium ones.

3 VIRTUAL SOCKET LABORATORY

The proposed system is called *Virtual Socket Laboratory* (VSL) since the technician can work in a virtual laboratory using virtual tools that permit to emulate the traditional procedures applied for socket manufacturing. In VSL the socket design is centred on the data and on the digital model of the patient integrating the direct management of experts' knowledge in order to guarantee a high level of product quality and improve the amputee's quality of life.
VSL is part of a new design framework specifically conceived to support and guide the orthopaedic technician during the prosthesis development process providing rules and suggestions to execute design tasks. This framework integrates ad hoc tools for domain technical knowledge management both of product and process, virtual modelling of components both standard (e.g. pylons and tubes, prosthesis feet) and custom-fit defined directly on the body digital model or its parts, and tools for behaviour simulation (e.g. by means of FE and multibody techniques) to investigate component-human body interaction. In this context VSL focuses on the process milestone, the socket design phase, where an excellent mastery of expert's knowledge is necessary to realize a correct and functional product.

Figure 4 shows the main difference between the traditional process and the one proposed with VSL.

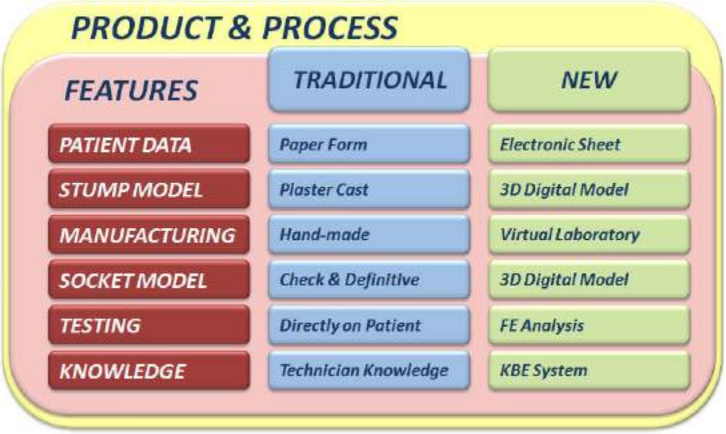


Fig. 4: Scheme of difference between the traditional process and the new one proposed with VSL.

In VSL, a specific module, named Socket Modelling Assistant (SMA) guides the technician during each step of the socket design process on the base of the patient's characteristics, in correlation to the implicit experts' knowledge and process rules implemented in the system. The procedures to model the socket can be divided in 4 steps (Figure 5):

1) *Patient case history*: all the amputee data, related both to the general patient and to the detailed stump characteristics, are acquired;

2) *Preliminary modelling*: the patient stump digital model is imported into the system and a list of preliminary procedures is applied on it to prepare the model for the more distinctive operations made in the next step to reach the final socket shape;
3) *Customized modelling*: a sequence of manipulation procedures is applied to the model to be perfectly shaped on the patient taking into account the physical and morphological characteristics;
4) *Finalization modelling*: the last operations to finalize the socket model are applied and the model is finally ready to be exported into a FE system to check the interaction between the stump and the socket digital models.

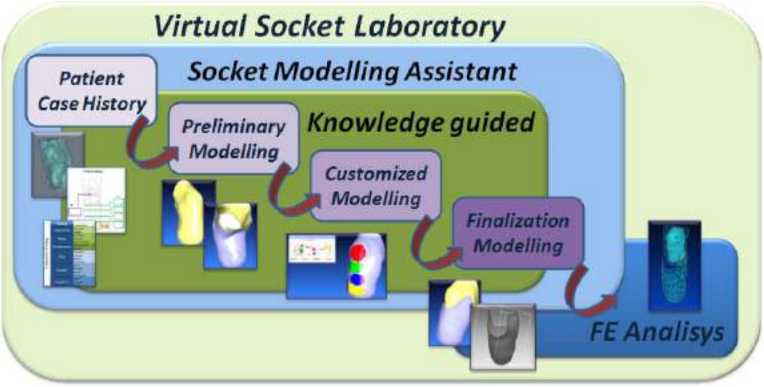


Fig. 5: Virtual Socket Laboratory workflow.

This process requires, as said, a digital model of the stump. In previous projects we have identified the Reverse Engineering equipments and techniques to properly generate the stump geometric model [4]: the external shape of the patient's stump is acquired by a non-contact laser scanner, while the internal parts are obtained by Computer Tomography (CT) for bones and by Magnetic Resonance Imaging (MRI) for soft tissues and muscles.
The SMA has been developed in C++ language. The 3D geometry visualization has been created using graphics API OpenGL, while the user interface has been implemented with Microsoft Foundation Class (MFC) framework. The software is object-oriented, and in particular it has been created a family of tools to allow the addition of new functionalities in a more efficient way. Fig. 6 portrays the mind map [2] of the software architecture. In detail, The `BaseDoc` class manages all the application work flow; within the frame work it is hosted a `SceneManager` class instance, which contains all the functionalities to create and to import 3D objects into the scene, modelled by `Object3D class` instances. Besides the `BaseDoc` class contains the `ToolManager` class, which manages all the tools set for `Object3D` objects deformation and connects the active tools with the `SceneManager` objects. The `BaseDoc` class gives also the rendering data to the 3D visualization class, `OpenGLView`, and manages the user input flow. The patient data and variables calculated and used during the virtual socket creation (e.g. scaling measurements, offset measurements, etc.) are managed by a module inside the `BaseDoc` class. The `Object3D` class represents the 3D objects of the application (e.g. residual limb and socket); geometry can be polygonal or NURBS (`PolyObject` and `NurbsObject sub-class`), depending on the used type of 3D model manipulation. There are two conversion class between NURBS and polygonal objects, called respectively `NurbsToPolyConverter` and `PolyToNurbsConverter`. An `Object3D` object can use an auxiliary class, called `Markers`, which allows setting zones on the geometric model zones that should be deformed according to patient characteristics.

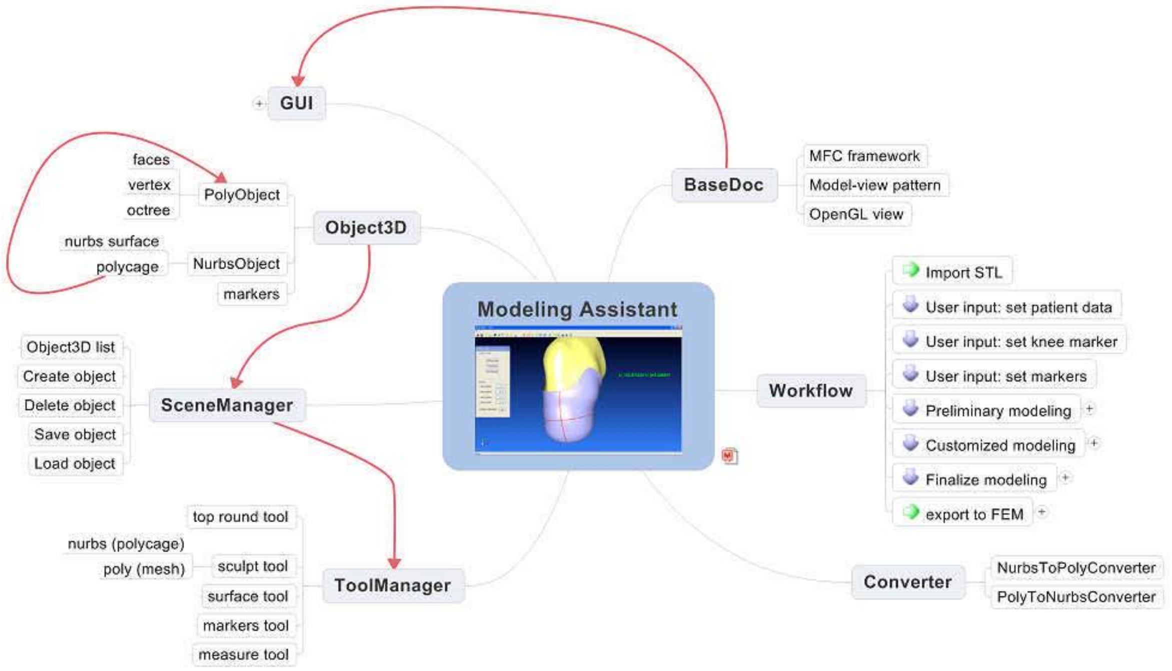


Fig. 6: Mind map of the software architecture.

Figure 7 shows the user interface. In the upper part there is a toolbar which allows selecting the available tools divided into: file management, preliminary modelling, customized modelling, finalization modelling, visualization tools and help. It is shown also an example of the workflow wizard which guides the user step by step during the socket design process.
In the following we describe the mentioned steps of the new process and the system functionalities. For each step we illustrate how each procedure is done in the traditional process, and how instead is executed with the new module and which new functionalities have been added to the process.

4 PATIENT CASE HISTORY

The first step consists in collecting patient case history. The patient characteristics are necessary in the next phases to apply rules and/or suggest the most appropriate procedures to the user during each step of the socket design process. In fact, the intersection of this information is essential to obtain a prosthesis which is totally realized not only in relation to the physical characteristics of each amputee, but also accordingly to his/her lifestyle and daily activities. For example, the socket must be more fitting for young or recently amputated patients, since the muscles and the body in general are still strong and tonic. Instead, for elderly or long standing amputated patients, where the muscles and the body are not anymore fully efficient, the socket needs to be more comfortable and not too much close fitting to allow an easier deambulation or physical therapy. Besides, on the base of the patient daily activities, s/he needs different properties from the prosthesis. For example, a young amputee, who is always on the go, needs a held socket but also quite comfortable; while an older patient, who just walks short itineraries every day, needs a more comfortable socket, but also a more self confident prosthesis.
During the analysis of the orthopaedic technician work for the traditional socket manufacturing, we have identified two categories of data: the general patient data and the stump characteristics. Figure 8 reports all the data necessary to have a complete view of each patient case.

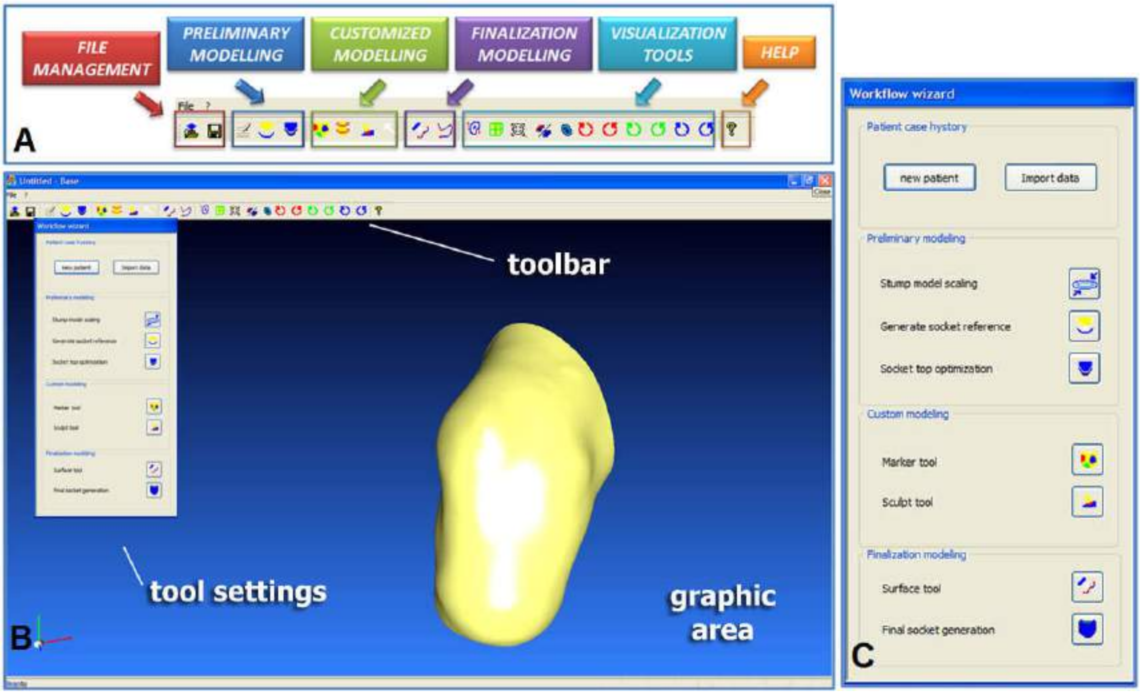


Fig. 7: The SMA user interface: the toolbar (A), the graphic area (B), and the workflow wizard (C).

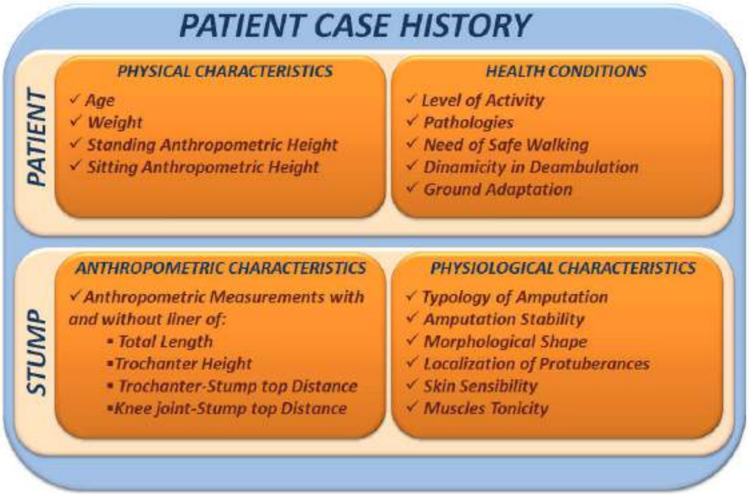


Fig. 8: Patient characteristics.

In particular for the patient data, we have two sub-categories: the physical characteristics and the general health conditions. In the first sub-category we identify the patient age and weight, and the anthropometric measurements of the patient human body while he/she is standing and sitting on a chair (such as total height, lower limbs lengths, etc.). In the second sub-category we take a note of the amputee general health conditions: level of activity, pathologies, need of safe walking, dinamicity in deambulation and ground adaptation. While for the stump characteristics, we have two other sub-categories: the anthropometric and the physiological characteristics. In the first sub-category we acquire different measurements of the stump, with and without liner (such as the total length, the

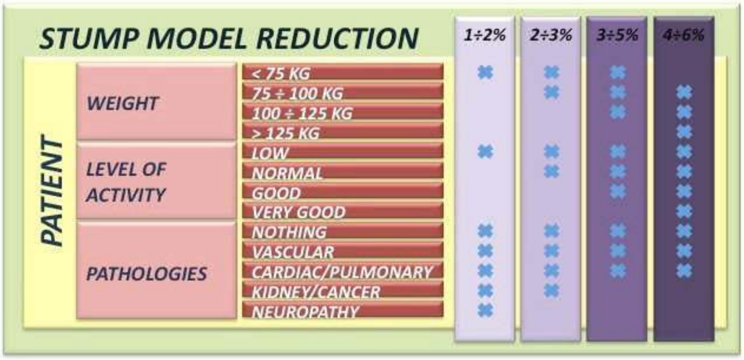
trochanter height, etc.) In the second sub-category we identify all the data about the amputation, such as the typology (transfemoral or transtibial), the stability of the stump, the morphological shape, the localization of all the bone protuberances of the residual limb, the sensibility of the skin and so on.
All this information entered in the system substitute the paper form used in the traditional process to collect the patient case history and are used to guide the technician in an appropriate socket realization following the same rules applied during the traditional process.

5 PRELIMINARY MODELLING

The aim of this phase is to generate a preliminary geometric model of the socket on which the technician will apply afterward other specific modifications to reach the final socket shape. It is constituted by a sequence of operations executed in automatic or semi-automatic way on the base of the patient characteristics, collected in the previous phase. After having imported the stump digital model composed by skin, muscles and bones, three main operations are carried out: stump model scaling, generation of socket reference surface and socket top optimization. In the following we briefly describe mentioned procedures.

5.1 Stump Model Scaling

In the traditional process the first operation applied on the stump positive plaster cast is the rasping procedure to reduce the stump volume. This is done since the socket, manufactured directly on the positive model, has to be perfectly close-fitting on the patient's residual limb. In particular the technician first identifies on the plaster cast the same reference circumferences previously measured on the patient's residual limb, and then starts to file harmoniously the plaster until these circumferences are reduced of the desired percentages. From the analysis of the technician work, we have identified the percentage values for this operation. Figure 9 shows a part of the table to choice the most appropriate percentages in relation to the patient characteristic: once it is defined the weight, the level of activity and the pathologies of an amputee, the technician decides which is the most correct range.



STUMP MODEL REDUCTION

PATIENT		1÷2%	2÷3%	3÷5%	4÷6%
WEIGHT	< 75 KG	✖	✖	✖	
	75 ÷ 100 KG		✖	✖	✖
	100 ÷ 125 KG			✖	✖
	> 125 KG				✖
LEVEL OF ACTIVITY	LOW	✖	✖	✖	✖
	NORMAL		✖	✖	✖
	GOOD			✖	✖
	VERY GOOD				✖
PATHOLOGIES	NOTHING	✖	✖	✖	✖
	VASCULAR	✖	✖	✖	✖
	CARDIAC/PULMONARY	✖	✖	✖	✖
	KIDNEY/CANCER	✖	✖		
	NEUROPATHY	✖			

Fig. 9: Table for stump model reduction according to patient characteristics.

The range of percentage varies from 1% to 6%. It is not uniform on the stump, but it starts with 1% at 4 cm over the stump top, and it increases gradually going up until the stump upper part. For example for a tonic stump and a patient very active, the reduction is low since the muscles are strong (e.g. for a young amputee, dynamic and without particular disease, the reduction starts from 1% until to 2%).
For this procedure the system first identifies the socket top, calculating the lowest point of the geometric model. Then, starting from this point, the system selects 4 reference circumferences at a distance of 4 cm from each other. For each of the 4 sections it is calculated the middle point and then the distance of each circumference point is scaled by the appropriate percentage. All the other sections situated between these 4 reference ones are scaled by interpolated values, in relation to their position on model. Figure 10 portrays this procedure: the system shows a mask with the proposed percentage

values for the 4 reference circumferences; the user can accept these values or modify them, and then the system automatically scales the model.

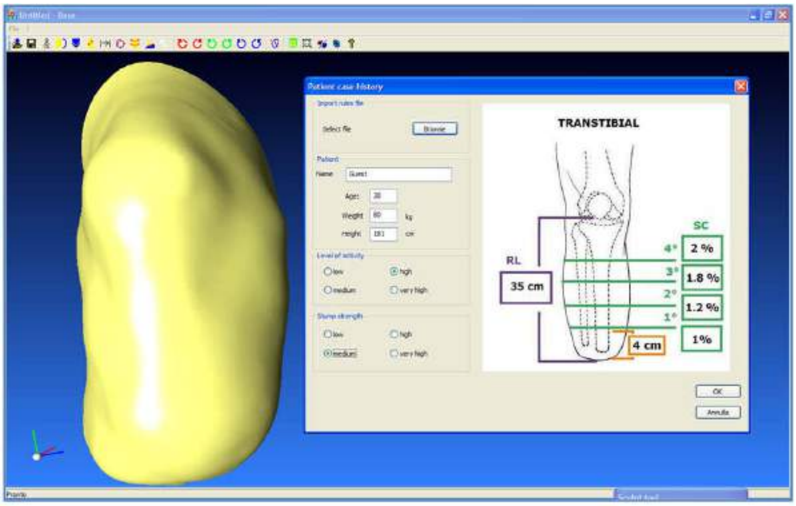


Fig. 10: Example of suggested values for the stump model scaling.

5.2 Generation of Socket Reference Surface

Once scaled the model, the system automatically realizes a reference socket surface creating an offset with constant distance from the previously modified stump geometry. Figure 11 shows an example of the generated offset surface. This surface constitutes the socket internal surface and will represent the starting point for the customized modelling.

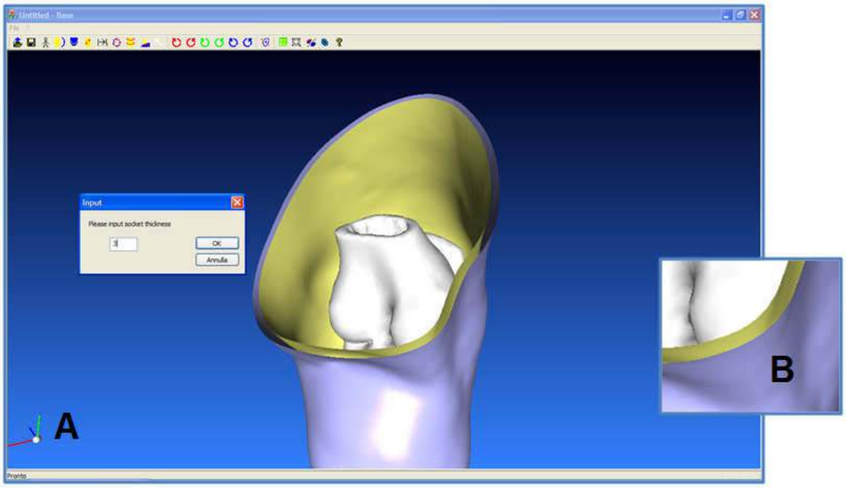


Fig. 11: Example of the suggested offset distance (A) and a detail of the generated offset surface (B).

5.3 Socket Top Optimization

An important procedure applied in the traditional process is to make round the low extremity of the positive plaster cast. Since normally the stump top has an irregular shape due to bone protuberances and scars, the orthopaedic technician creates a smooth and rounded area around the cast top, so that the model has a more functional shape with a view to wear the liner. This step is automatically executed from the system, which modifies the socket surface but not the stump model. Figure 12 portrays the socket top before the optimization (A), after the optimization (B) and an internal view of the stump inside the optimized socket (C). This operation can be also set up manually indicating the starting point for the rounding.

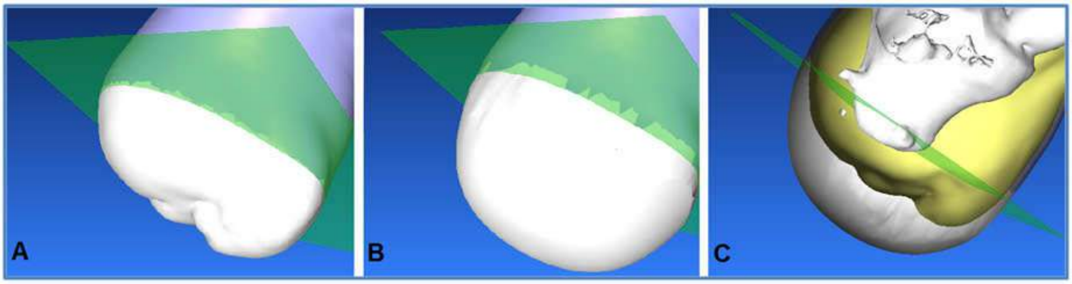


Fig. 12: Example of automatic socket top before the optimization (A), after (B) and the optimized socket with the internal stump (C).

After these preliminary operations, the model is ready for a more detailed socket modelling phase.

6 CUSTOMIZED MODELLING

This is the most important and critical phase of the whole process. Here the socket model is shaped directly on the stump digital model to be perfectly customized on each specific patient anatomy.
In the traditional process the technician first identifies with markers the areas on the positive model which have to be modified (see the general scheme of these areas for a transtibial amputee in Figure 13), and then starts to modify these zones adding or removing plaster.
In particular, we have divided these areas in two categories:

a) *Load zones*, where there are not bony protuberances or tendons and it is necessary to constrict the socket closer to the limb and therefore to create a pressure to sustain the body weight;

b) *Off-load zones*, where there are bony protuberances or tendons and the socket does not have to press the limb and in the meantime not to be much wide since it could cause other physical problems.

Normally the thickness of the added plaster varies from 1 to 8 mm in correlation to the patient stump tonicity. Figure 14 shows the scheme for the choice of the most appropriate plaster additions according to the level of stump tonicity, which has been derived from the technician's implicit knowledge.
For these procedures we have implemented two different tools: *Marker tool* and *Sculpt tool*. These tools simulate respectively the traditional operations of:

a) *Marker tool*: highlighting the critical zones with pencils and adding/removing different coloured plaster in these zones;

b) *Sculpt tool*: adding plaster by a slice or removing plaster by a rasp.

Besides Marker tool allows the user to apply the modifications in automatic way, since it is the system itself suggesting the most appropriate levels of addition or removing plaster. While with Sculpt the user can freely manipulate the model and decides the level of modification. In the following we will briefly describe the mentioned tools.

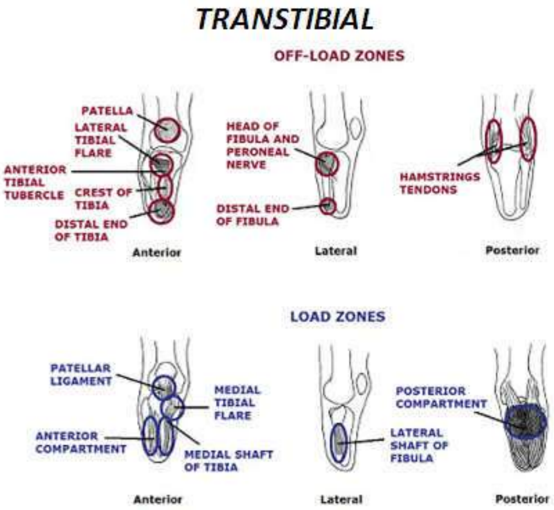


Fig. 13: General scheme of the load and off-load zones for transtibial stumps.

Fig. 14: Reference values for the choice of the plaster additions.

6.1 Deformation Tools

In the Socket Modelling Assistant the areas on which the technician has to work are suggested by the system and they can be highlighted using coloured pencils: these operations are allowed from the *Marker tool*. Figure 15 shows the automatic highlighting of the critical zones with different colours (left) and the window with the suggested areas (right). Once determined the zones, the system automatically modifies them on the base of the patient weight and muscles tonicity, as previously cited.

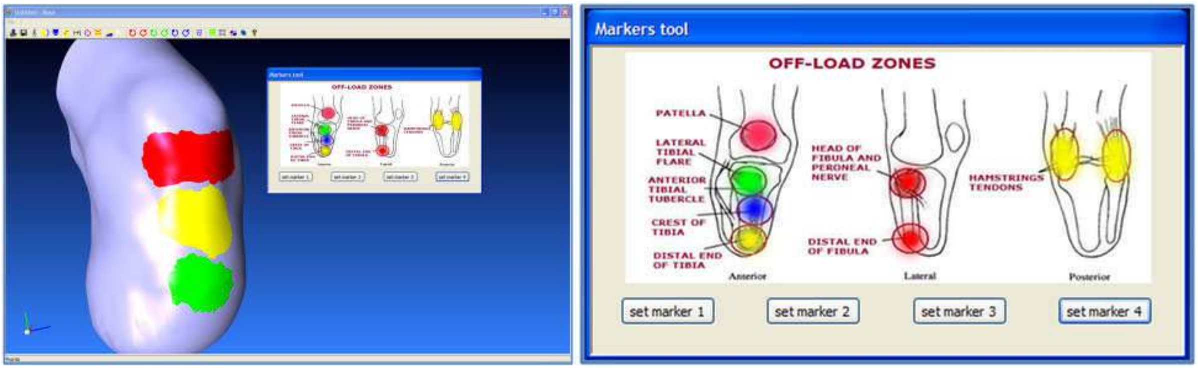


Fig. 15: Example of Marker Tool functionalities: highlighting the critical zones (left) and a window with the suggested areas (right).

The other tool to apply or removing material in a semi-automatic and interactive way is *Sculpt tool*. Sculpt tool is a virtual utensil which can slide on the socket surface, and can push and pull this surface, simulating the action of adding or removing plaster. The dimension of the cursor working area can be modified manually by the user. Figure 16 shows how this tool works: there is a mask which allows the user to choose between push or pull operation, the force applied from the cursor, and the dimension of the cursor itself. It is very similar to the real tools used by technicians in the traditional process to manipulate the plaster cast.

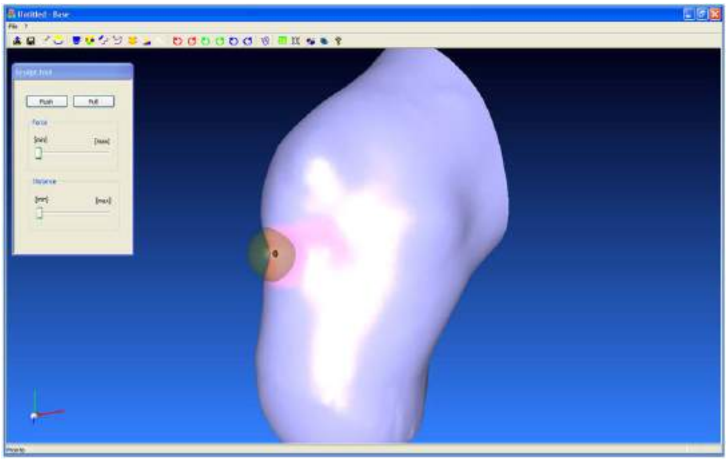


Fig. 16: Example sculpt tool functionalities.

The user can move the cursor everywhere on the virtual socket surface: the correct coordinate where to position the cursor is identified by the system through an intersection test between all the geometry polygonal faces and a line perpendicular to the surface, whose point of departure is the mouse arrow. The 3D point on which the line crosses a polygonal face coincides with the sphere centre of Sculpt tool. The virtual socket faces are organised in an Octree hierarchical space to optimize the intersection tests.

In the deformation phase first a test is performed to check which faces are inside the range of the sphere cursor; then the average of the internal faces normal vectors is calculated. Finally the internal faces vertexes are moved along the average normal vector, of a length inversely proportional to the distance from the sphere centre. This displacement can be positive or negative, in correlation to the different modalities “push” (vertexes moved inwards) or “pull” (vertexes moved outwards).

Once the technician has finished modifying the critical zones, the socket model is ready for the finalization procedures.

7 FINALIZATION MODELLING

In the traditional process, after all the operations applied on the positive plaster cast, the technician creates directly on this model the socket. After the customized modelling, the socket model has to be finalized moulding the upper edge and giving a final thickness to the model. For the last operations there is available a tool named *Surface tool*.

This one allows the user to obtain really smooth and harmonious deformations, since it permits to act on the single surface control points of the model. It can work on different sections of the model, both horizontal and vertical. Moving the control points, the surface is modified in a homogenous way and it is also possible to scale the surface in the different sections. It is also present a function which avoids that the control points can penetrate inside the socket shape, while it is allowed to enlarge it outwards. With this tool the user can model the socket upper edge. Figure 17 illustrates how Surface tool works where the user can choose to act on the surface (left) or on horizontal and vertical sections (right). This tool permits also to measure the socket dimensions.

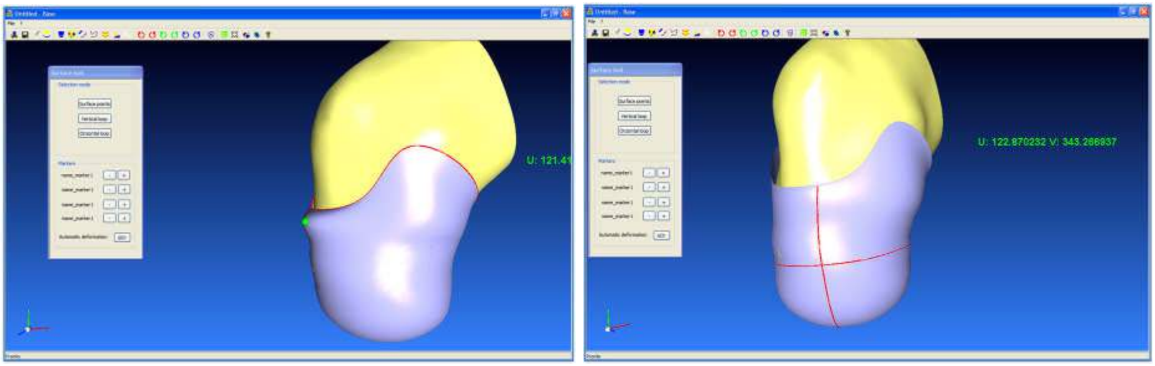


Fig. 17: Example of Surface tool functionalities: moving the surface control points (left) and acting and measuring different sections (right).

The operation of socket thickening is automatically executed by the system creating a surface offset outwards. This generated offset surface represents the socket external surface and the offset distance is the final socket thickness. Such as in the traditional process, the distance value is decided in relation to the patient weight: more is the weight, more is the socket thickness. Usually it goes from 2 mm until 6 mm. The formula which is normally applied to calculate this thickness is the following:

$$\textit{Socket thickness [mm]} = \textit{Patient weight [kg]}/20 \quad (7.1)$$

This equation is an empirical formula which has been derived from qualified orthopaedic technicians' experience.

Figure 18 shows the final socket model with the generated offset external surface.

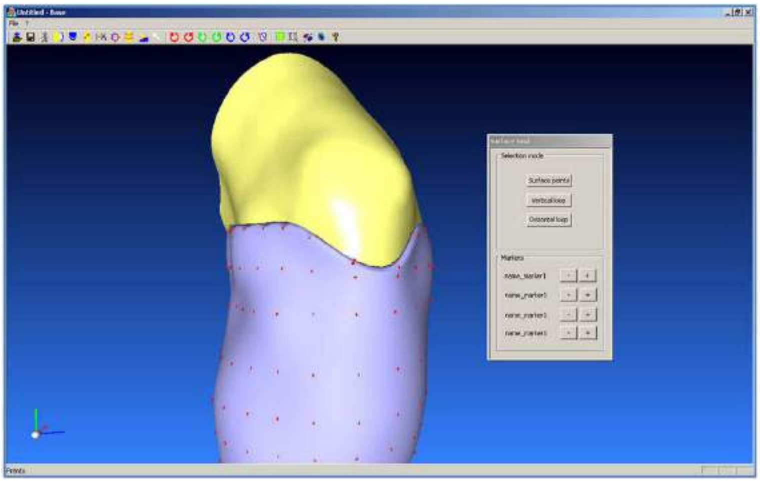


Fig. 18: Example of a definitive socket model.

At this point the geometric model of the socket together with the stump one can be exported into a FE system to analyse the interaction between the stump and the socket. For this last and strategic point, in previous projects we have already experimented the use of FEM/FEA tools to simulate the behaviour of prosthetic components [6]. Results obtained were encouraging and we have planned to go further fully integrating the modelling and simulation tools.

8 CONCLUSIONS

In this paper we have presented a tool named Virtual Socket Laboratory-VSL where the socket virtual prototype is created directly on the digital model of patient residual limb, following rules and procedures, which simulate the real activities performed in an orthopaedic laboratory. It guides the orthopaedic technicians during each step of the modelling process in automatic or semi-automatic way on the base of the specific domain knowledge. The prototype has been preliminary experimented using data related to a transtibial amputee but we have planned to carry out a wider campaign in collaboration with the technical staff of an Italian orthopaedic laboratory. At present we have acquired the digital model of four patient stumps, three transtibial and one transfemoral.

Future developments will concern:

- Test the prototype realizing the 3D model of both transtibial and transfemoral sockets;
- Fully integrate within VSL a FEM tool to analyze the socket-stump interaction and allowing the technician to optimize the product;
- Define, as done for socket modelling, a kind of knowledge-based simulation strategy to study the behaviour of the socket under different conditions;
- Evaluate results comparing the 3D socket model obtained with the new approach with the model of handmade socket.

For the last issue we have planned to acquire with reverse engineering techniques both the stump of the patient and his handmade socket.

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