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A Computer Assisted Methodology to Improve Prosthesis Development Process

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Abstract
This paper refers to the implementation of a product development process based on the use of virtual model of the human body to design specific custom-fit products, such as a prosthesis socket. It considers the integration of ICT tools coming from reverse engineering and medical imaging for the acquisition of patient's morphology and bony-muscular structure, virtual prototyping to model the limb and the socket, physics-based simulation to reproduce the interaction between the socket and stump and rapid prototyping tools for the product physical realization. Problems related to the implementation of each design step are described as well as results of the paradigm experimentation. The work has been developed within the framework of the DESPRO Project funded by Italian Research Ministry.

Keywords:
Custom-fit product, Physics based simulation, reverse engineering, prosthesis development process

1 INTRODUCTION

Nowadays there are many IT tools supporting design activity. Many of them are "general purpose", i.e., not finalized to some specific product. Typical examples are: CAD systems used to realize digital prototypes, FEA and Multibody systems useful for functional simulations, and PDM systems for data management.

A fundamental characteristic of the systems described is the specificity of the task they can face. The 3D CAD tools and related modelling techniques have reached maturity and they are mainly used when the geometry and the structure of the product are well defined. The systems for the functional analysis, such as FEA and multibody ones are rather used essentially during the design detailing phase. Anyway, in these last years, a great care has been focused on custom-fit products which often have a close interaction with parts of the human body.

In this field some tools are available and /or under development; but they are targeted to a particular kind of product [1-4] and they can support only few specific phases of the product development process (PDP).

In this paper we refer to the development process of a specific custom-fit product, a prosthetic socket.

With regard to this sample product, CAD/CAM prosthetic systems (www.biosculptor.com, www.rodin4d.com, www.ossur.com, www.tracerCAD.com) replicate some steps of the traditional process followed by the orthopaedic technicians to realize prosthesis, in particular the socket, and some of them are used only by the company which produces them to develop inside prosthetic components.

Typically, once the residual limb has been measured (manually or with a digitizer), they allow to capture and modify the geometry/shape of the positive model in correlation to the patient's morphology (not directly the socket) and, then, the following creation of the model guided by a CAM module, on 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. They don't foresee, therefore, integrated structural or multibody analysis. Another problem is the incapacity to create models which take care not only of the external shape, but also of the characteristics of the materials which constitute an object and influence its behaviour. For example try to think about the possibility to model a socket on a stump model made of bones with high mechanical characteristics with muscles and soft tissues, highly deformable.

For this last strategic point, in literature, it is possible to find many publications which describe applications based on two different approaches: finite element models [5-6] and particle-based models [7].

In particular, there are various experiences with regard to the use of FEM/FEA tools for the simulation of the behaviour of prosthetic components [5-6, 8-10]. The described researches use different models for the materials (linear and not linear [9-10]), simulating different situations: contact between residual limb and socket under quasi-static load, distribution of the pressure, etc. From the described results, it seems that the approach based on finite element models gets to better results compared to the particle-based one. However, it is necessary to develop some strategies which allow the designer to guide the definition and the execution of the simulations integrating CAE tools for structural analysis.

As mentioned, in literature, we can find various researches on ICT tools to support some single steps of the process; however, there is not a validation of a complete process based on digital data and tools. This highlights the need of new design methodologies that take into account materials used for the socket, the stump structure (i.e., bones, muscles and skin) and manage their mutual interactions.

In the following, we propose a new design paradigm based on the use of virtual models of human body to design a prosthesis socket. Problems related to the implementation of each design step are described as well as results of the paradigm experimentation. The work has been developed within the framework of the DESPRO (DESign PROsthesis) Project funded by Italian Research Ministry.

2 NEW DESIGN PARADIGM

The new design paradigm is completely based on computer-aided tools and on the modelling and simulation of the two interfacing parts (human body and socket).

Our main goal is to identify the fundamental phases of socket development process and verify the adequacy and limits of current ICT tools and technologies in an integrated environment.

In such a context, different issues related to the human body should be considered, e.g., the acquisition of stump morphology, generation of a complete virtual model that includes both the external shape (skin) and the geometry of internal parts (muscles and bones) and mechanical characterisation of the stump to be able to simulate correctly the socket-stump interaction.

The design process has been thought to implement best practices used by orthopaedic technicians and finalised to ensure high-level products independently of the competencies of the domain expert that manufactures the socket. It integrates following tools (Figure 1):

- reverse engineering tools for the automatic (or semi-automatic) acquisition of patient's morphology and bony-muscular structure (in our case the residual limb);
- a modeler allowing the designer to represent both the human body's parts and the socket as composed by different materials;
- an environment for physics-based simulation to reproduce the real behaviour of socket-stump system and to verify the product functionalities;
- Rapid prototyping tools for the realization of physical prototypes to test and validate the virtual product and to identify adjustments.

Thus, the process that brings to the final design of the socket is made up of several steps according both to the specific CAE tools adopted and to the reached partial results. The first is a reverse engineering phase, in which the real geometry of the stump and the internal bones is reconstructed in a CAD software. Once modeled the residual limb and the socket, the functional simulation is performed in order to obtain the internal surface of socket that prevents pressure peaks during the donning and the standing phase of the patient. Final phase is the realization of physical prototypes using RP technologies.

In the following we describe each design steps, related problems and results obtained. The proposed design paradigm has been experimented both for trans-tibial and trans-femoral amputees.

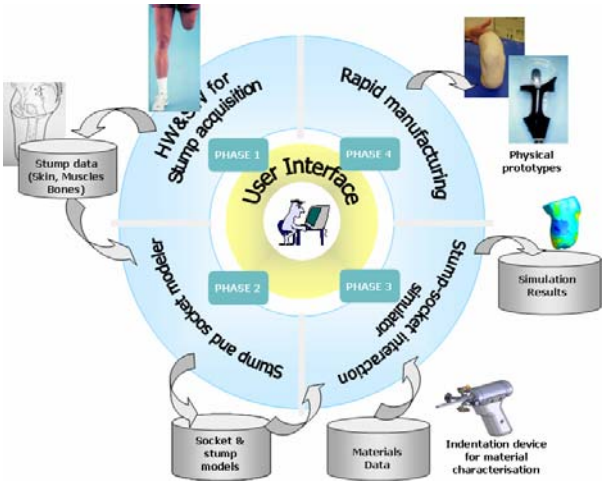

Figure 1: The new design paradigm.

3 PATIENT'S MORPHOLOGY ACQUISITION

This step concerns the acquisition of the body's part morphology, necessary for the following phases related to modelling and functional simulation. We adopted different equipments and RE techniques to obtain a stump digital model that includes both external shape and inner parts (muscles and bones), as shown in Figure 2. This permitted also, during modelling phase, to verify which of them is more suitable for our purposes.

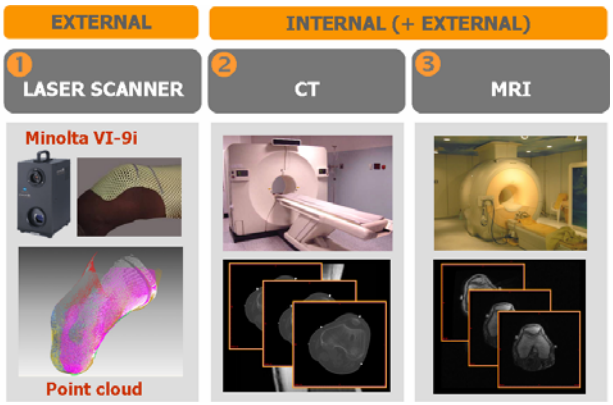

Figure 2: RE equipments and techniques for morphology acquisition.

A non-contact laser scanner (Minolta Vivid VI-9iTM) has been adopted to acquire the external shape of the stump. We also acquired the geometry of the related positive plaster cast to compare the stump external shape with the socket internal surface and determine critical zones.

Computer Tomography (CT) and Magnetic Resonance Imaging (MRI) have been used for the internal structure, respectively for bones and soft tissues and muscles.

Two main problems have been faced: patient's posture and alignment of data acquired with the three techniques at different times.

To replicate posture, a support device has been realised to maintain lower limb position adopted for manual measurements and a plastic mask has been disposed over the patient's stump (Figure 3a). For the second problem, markers have been used to identify anthropometric standard points (Figure 3b).

The acquisition has been carried out for four patients.

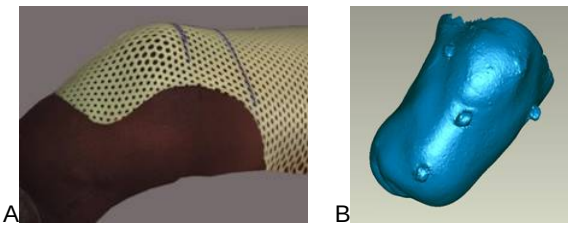

Figure 3: A) Plastic mask, B) Digital model with markers.

4 MODELLING

This step concerns the creation of the digital model for the patient's anatomical part and for the socket.

4.1 Stump digital model

Two geometric models have been reconstructed for patient's stump: one tasselled (STL) and another based on NURB surfaces.

The geometric model of the skin have been derived from laser points clouds since it ensures to reach a high quality in morphological details necessary for a detailed simulation of stump-socket interactions.

For the internal parts both CT and MRI data have been used. The three different models have been integrated aligning them into the same reference global system and using as reference the markers used during acquisition phase. Figure 4 portrays one of the reconstructed stump digital models.

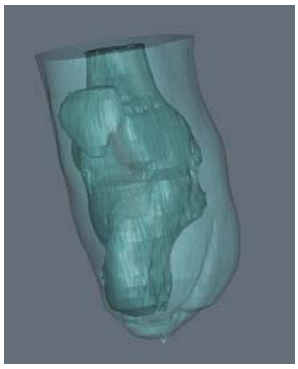

Figure 4: Residual limb's digital model.

4.2 Socket model

The basic idea is to generate, first, a conceptual parametrical model of the socket to simulate/verify its functionality like wearibility and comfort around the digital model of the interested human body part (in this case the residual limb), and, then, generate the detailed on.

The idea behind is to derive 2D sections from the 3D model of the residual limb, similarly to what done manually by the technicians, and, then, generate the 3D conceptual model using virtual prototyping tools with addition of some standard features (e.g., in case of a tran-stibial prosthesis, an opening for knee joint with a patellar support is added, etc.), as shown in Figure 5.

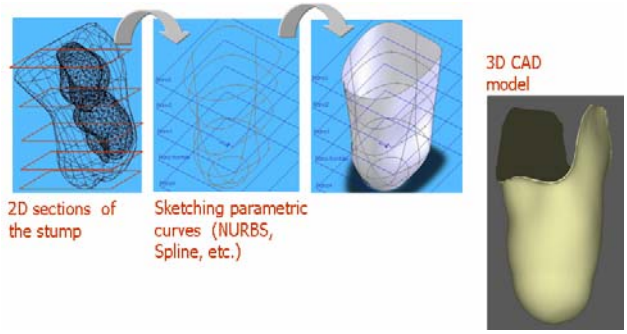

Figure 5: Generation of socket model.

This activity is particularly critical because it is highly knowledge-driven and requires the acquisition of the technician skill. To validate the new design process, we designed the socket model starting from the points of clouds acquired for the positive plaster cast. Twice are the objectives: first compare the stump and socket model in order to identify main differences and, then, provide reference data to evaluate simulation results.

5 PHYSICS-BASED SIMULATION

The aim of the simulation phase is to optimize the shape of the socket according to fitting and wearability criteria. Figure 6 shows the procedure adopted.

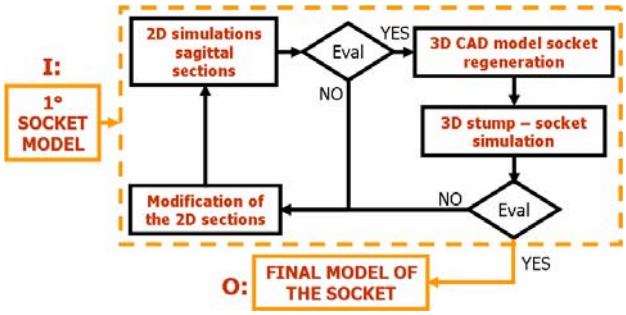

Figure 6: Simulation procedure.

A two steps simulation approach has been considered. The first is based on 2D elements and analyses meaningful sections of the stump and the socket. The 2D models are related to the significant cross sections of the limb. In this way the designer may better understand the interaction between the socket and the limb and he/she can modify the 3D model of the socket starting from the 2D curves. When the 2D simulations furnish good results, the second more complex simulation based on 3D models can start. It permits to verify the fitting and the wearibility of the whole 3D model of the socket. If these verifications are satisfied, final model of the socket is reached. Otherwise, other modifications to the 3D geometrical model of the socket are planned and a new cycle of 2D and 3D simulations is performed.

We initially planned to use both FE and particle-based methods (Figure 7) to analyse two different aspects: the wearability (donning simulation) and patient's motion (gait simulation). However, more important efforts have been reserved to the first method because it permits to obtain better results from quantitative point of view. In FE simulations we investigated 2D and 3D models, implicit and explicit codes.

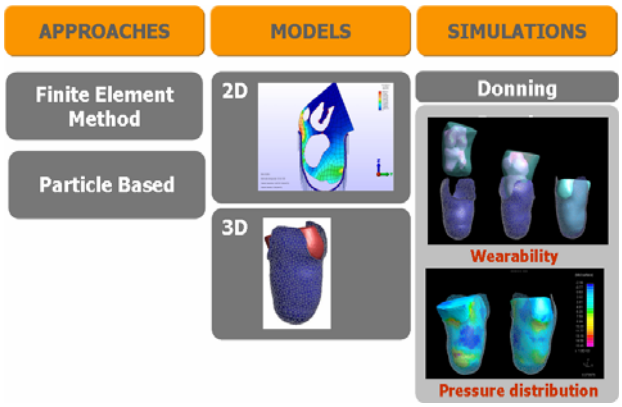

Figure 7: Simulation phase.

At present, we have focused the attention on the donning simulation, by which the designer can verify if the shape

of the socket allows the wearibility that is the main criterion guiding the design process. In this way the presence of dangerous undercuts, which can produce stresses and large deformations of the soft tissue, can be easily identified. The fitting is evaluated by:

- the contact pressure at the interface;
- the sliding, evaluated as relative motion between the socket surface and the residual limb during the gait.

The FE models of the stump and internal surface of the prosthetic socket have been defined as follows.

First, the material model of the soft tissue representing the real biomechanical behavior has to be defined. To perform this task, the external surface of the patient residual limb has been ideally divided into several parts having more or less the same thickness of soft tissue beneath, according to diagnostic images acquired. The material model to be defined is a bulk model: the layer subdivision of soft tissue among skin, fat and muscles, is not considered since the average behavior under compression forces is sufficient to simulate the biomechanical interface among socket and limb. This approach allows characterizing the mechanical properties of soft tissues in different locations of residual limb. In this way a local material model, one for each part, can be defined according to the real stiffness distribution of soft tissues around the bones of residual limb.

In order to extract a stress-strain curve for each patch, a portable indentor has been designed and realized (Figure 8). It is made up by an optical device and a force measurement device. The optical part is composed by a cross laser and two cameras each one mounted parallel to an arm of the cross. The other part of the tool is composed by a load cell connected with a rounded tip which has the function to press the soft tissues of the limb.

Figure 8: The portable indentor device.

During the indentation experiment, cameras take some pictures at a prearranged time step, and a signal conditioner connected to the load cell and synchronized with cameras, registers force values. With image processing techniques the displacement of the point under load and the deformed shape of the limb along two orthogonal directions are extracted (Figure 9). To obtain the material model parameters of the soft tissue a finite element model is built and the indentation test is simulated. Given the great difference between bone and soft tissue stiffness, in this first model, bone parts are considered as completely rigid. The virtual model of the limb has been divided into several volumes according to the indentation points, since a different material model, one for each patch of limb, is needed. The finite element model of the limb has been built and a generic material model (anisotropic and non-linear material) with initial plausible values of its parameters is assigned to each sub volume. The load curves extracted by the indentation test are applied to each virtual volume, and a first FEM simulation has been performed. With the results of this simulation a parametric optimization cycle is set-up, by integrating an optimizer tool and a FEM explicit solver: all the parameters defining the material model are considered as design variable of the optimization, instead the displacements in the load application point and in few selected nodes around it have been considered as goals.

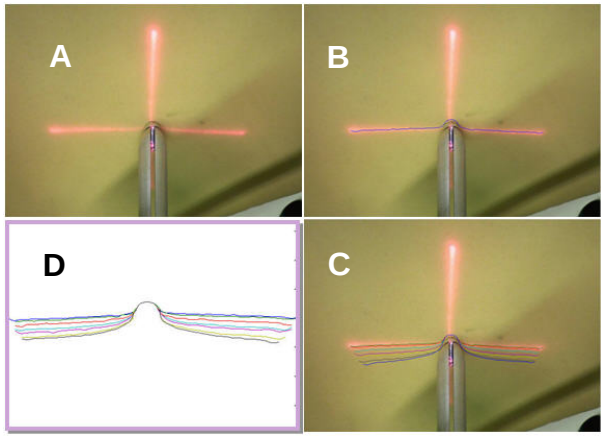

Figure 9: A), B) and C) images of different indentation steps; D) the deformed shapes.

The authors are, also, evaluating the impact the muscular tone of residual limb may have on comfort and stability requirements during the gait cycle. Such analysis will suggest the opportunity to adopt more complex soft material models which take into account residual muscular activity during the simulations.

For the FE socket model, a linear elastic material with Young's modulus equal to 1.5 GPa has been considered. To carry out the simulations, the FE explicit code LS-DYNA rev. 9.70 has been adopted. The use of the explicit solution strategy allows managing simulation problems that are characterized by large deformations and hard contact conditions in a suitable way. The explicit solver allows to use contact models that do not require to define the contact surfaces; indeed this solution strategy is able to deal with problems where the contact surfaces are a priori unknown such as in the case of the donning simulation phase where, due to the large deformations of the soft tissue and the irregular geometry of the stump, the contact surface changes a lot during the simulation. Moreover, in terms of computational efforts, the explicit code is more efficient and faster than the implicit one for such a kind of problems. Figure 10 shows the pressure distribution obtained by a 3D simulation of the fitting between the socket and the stump under the body weight loads using a 3D mesh and the explicit solver LS-DYNA.

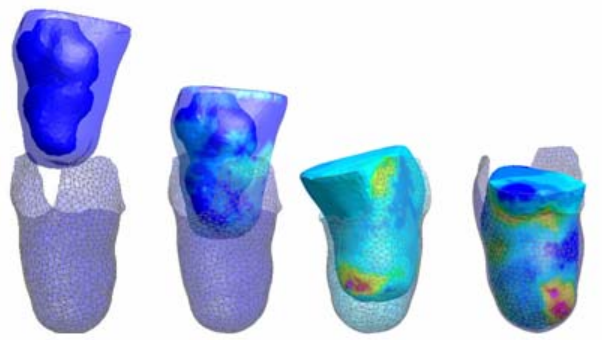

Figure 10: Wearibility simulation.

6 RAPID PROTOTYPING

During this phase the physical prototype of the socket is produced using RP technologies that get as input the digital model generated and verified during previous activities. The generation process consisted in the following steps:

- Generation of the triangle mesh (STL file): once finished the simulation activities, the digital model of the socket has been described as a triangle mesh and saved using the .stl file format. In fact this is the best representation of the model suitable for Rapid Prototyping activities.
- Verification of the triangle mesh: depending from the modeling software used, sometimes the result of the triangle mesh generation contains some errors that could prevent a correct prototype generation. For this reason, a check is required and it is performed using software packages like Magics developed by Materialise.
- Generation of a master prototype using SLA (stereolitography) RP technology. The RP equipment named SLA3500 by 3DSystem has been used to build an epoxy resin model that is used afterwards as the master for the generation of a polyurethane mould. Figure 11 portrays the epoxy resin model resulting from this step, still inside the building chamber of the SLA equipment.

Figure 11: Epoxy resin prototype still inside the SLA equipment.

- Generation of a polyurethane mould using a vacuum casting machine. Once generated the epoxy resin model, the KLM Vacuum Casting Machine V 1000 equipment uses it to generate a block of polyurethane that completely embeds it. This process is performed in a vacuum chamber to avoid the presence of blisters in the polyurethane. Figure 9 shows the polyurethane block inside the vacuum casting machine. At the end of the building process, the block is split to obtain the punch and the die of the final mould (Figure 12). Between them, there is the SLA prototype, painted for aesthetic reason.
- Selection of the material best fitting the functional requirements of the socket. The database containing the characteristics of different materials is now searched to select the best one to assure the manufacture, the wearibility and the comfort of the socket. The parameters to take care about are a lot; by the way one of the most important is the Shore value because it represents the hardness of soft, flexible materials (Shore A) or hard materials (Shore D).
- Generation of the final prototype(s). In this case, three materials with different Shore values are put into the polyurethane mould to generate three final prototypes. Materials, ordered by ascending hardness, are: AXON PX761 (Shore A = 60), AXON UR3558 (Shore A1 = 95), and AXON PX205 (Shore D1 = 70). This time it is not necessary to paint them because the polyurethane used is already of the desired color.

Figure 13 shows the realised prototypes: the punch and the die of the polyurethane mould in the background, with the painted epoxy resin prototype in the middle; in the foreground, the three final prototypes ordered by ascending hardness, left to right, with different orientations.

Figure 12: The polyurethane block inside the vacuum casting equipment at the end of the building process.

Figure 13: Socket prototype.

At present the prototypes are under experimentation with the patient to validate design and simulation results.

7 CONCLUSIONS

The experience acquired highlighted how custom-fit products can have a high qualitative improvement from the implementation of innovative computer-aided tools which integrate all necessary functionalities to carry out the various activities within a unique framework.

The research project identified the fundamental phases of socket development process and verified the adequacy and limits of current ICT tools and technologies. The proposed approach has demonstrated a not negligible impact on the patient life quality especially from a psychological point of view. The use of virtual prototyping tools allows avoiding patients several tests that may be very bothering and speed-up the product development process.

However, the designer still relies exclusively on his/her know-how and on standard technical solutions. On these bases, we envisage the need of a development process for custom-fit products centred on the virtual model of the involved human body part and of an environment that assists the whole design process integrating all the necessary tools and realising a collaborative-based approach where each activity is directly supported by the knowledge management of the specific domain.

Our future activities concern the development of a framework which pays attention to global process and not anymore to the single activity, allowing the management of the full development process in one integrated environment. This framework should allow the management of the experts' knowledge to guarantee a high level quality of the final product. This will permit to move from products based on the adaptation of a standard solution and to products based on "ad hoc" solutions and then highly customised.

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