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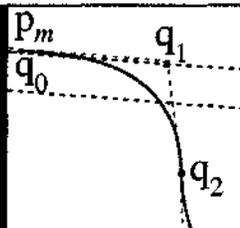
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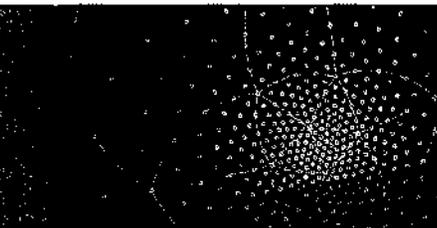
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DESPRO Project: a computer assisted methodology for prosthesis development

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ABSTRACT

The design of custom-fit products, especially those with a tight interface with the human body, cannot be carried out using methods and tools developed for other industrial fields (i.e. mechanical field), for mass production or for modular products, but it is necessary to realize "ad hoc" methodologies, because of the wide variety of morphologic and anatomical situations to deal with. The work presented in this paper refers to the implementation of a design paradigm for a specific custom-fit product, a prosthesis socket (interface between the residual limb and the mechanical part of the prosthesis), through the integration of advanced ICT tools coming from the reverse engineering, the physicsbased modelling and simulation, and the rapid prototyping fields. The paper describes problems related to the implementation of each step within a real socket development process. The work has been developed in the framework of an Italian PRIN Project (Research Project of National Interest) named DESPRO (Integration of Innovative Methodologies to DESign and Develop Custom-fit Products: Application and validation for a Socket of a Lower Limb PROsthesis) funded by Italian Research Ministry.

1. Introduction

Nowadays several industries are moving towards configurable or custom-fit products. In the former case, a general common architecture is defined and the choice of specific options (depending on the industrial sector) permits to generate a new product variant; in the latter case, most of goods consists in products or devices that have to interface with human body. They have been designed and customised according to the human shape. Hence, custom-fit products, especially those with a tight interface with the human body, cannot be completely designed using

methods and tools developed for other industrial fields, but it is necessary to realize "ad hoc" methodologies.

The work presented in this paper refers to this context with the aim of verifying the implementation of a design paradigm for a specific customfit product, a prosthesis component, through the integration of advanced ICT tools, allowing the evolution from a handmade production to a computer assisted realisation of highly customised products. In particular, we consider the case of the socket (interface between the residual limb and the mechanical part of the prosthesis) both for transfemoral or transtibial amputee since it requires a high level of customisation.

The following benefits can be achieved following this approach:

- A reduction of product development times. A patient has to wait for 3-5 working days before having his customized socket, without considering the rehabilitation phase. Domain experts estimated a reduction up to 60%, this means that a socket could be delivered in 1-2 working days.
- Physiological and social impacts. "Design the right product first" will improve both the psychological impact and the health of patients, especially for the considered sector, where most of them are aged people with vascular diseases. Another important aspect concerns the reduction of the skilled personnel of approximately 50%, increasing the feasibility of this kind of products at lower prices in countries where there is no skilled people, e.g., in post war areas such as Bosnia, Kosovo, Iran, and Afghanistan.
- Cost reduction. This aspect, depending on the custom-fit product considered may interest both the final user and the producer or only the producer, such as for the considered case.

The work has been developed within the framework of an Italian PRIN Project (Research Project of National Interest) named DESPRO (Integration of Innovative Methodologies to DESIGN and Develop Custom-fit Products: Application and validation for a Socket of a Lower Limb PROsthesis) funded by Italian Research Ministry. The consortium consists of four universities, University of Bergamo, Florence, Udine, and Polytechnic of Milan with

the collaboration of an Italian prosthesis manufacturer named Centro Protesi INAIL, Budrio (BO).

2. Socket development process

The socket (Figure 1) is the most important component of prosthesis since the quality and the patient' comfort rely on it.

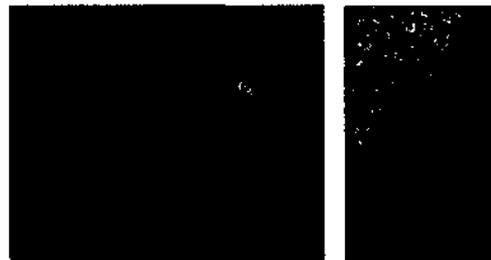


Figure 1. Some example of sockets

The socket is manufactured starting from a plaster cast or measurements with a CAD/CAM system [1]; however in Italy, most of Italian laboratories producing prostheses are SMEs and the socket is almost handmade. Figure 2 shows the main activities to design and manufacture a socket through an IDEF0 diagram.

ICT tools available for this kind of products are not able to manage all the product development stages, from design to manufacture. 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.

3. The new development process

The new paradigm is totally based on computer aided tools and consists of four steps, organically connected each others, where following tools are integrated (Figure 3):

- *Reverse engineering* tools for the automatic (or semi-automatic) acquisition of patient's morphology and bony-muscular structure (in our case the residual limb) both under static and dynamic conditions;
- A *physics-based modeler* allowing the designer to represent both the human body's parts and the socket as composed by different materials (inner parts modeling);

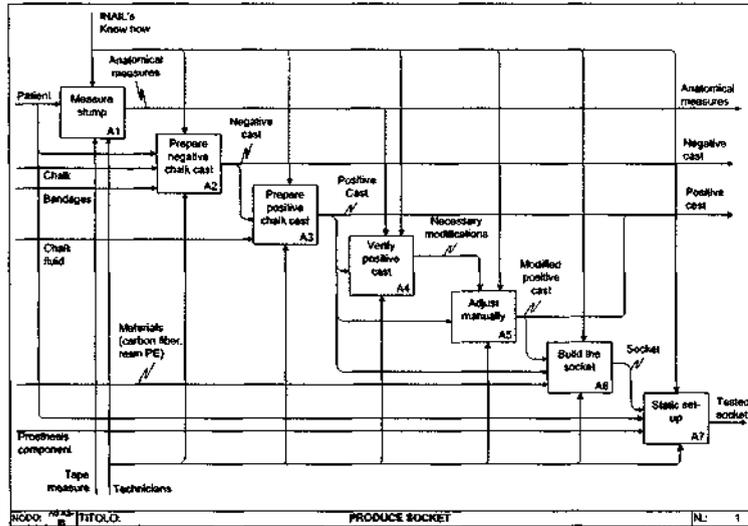


Figure 2. IDEF0 diagram of the socket design and manufacturing process

- an environment for *physics-based* simulation to reproduce the real behaviour of socketstump 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.

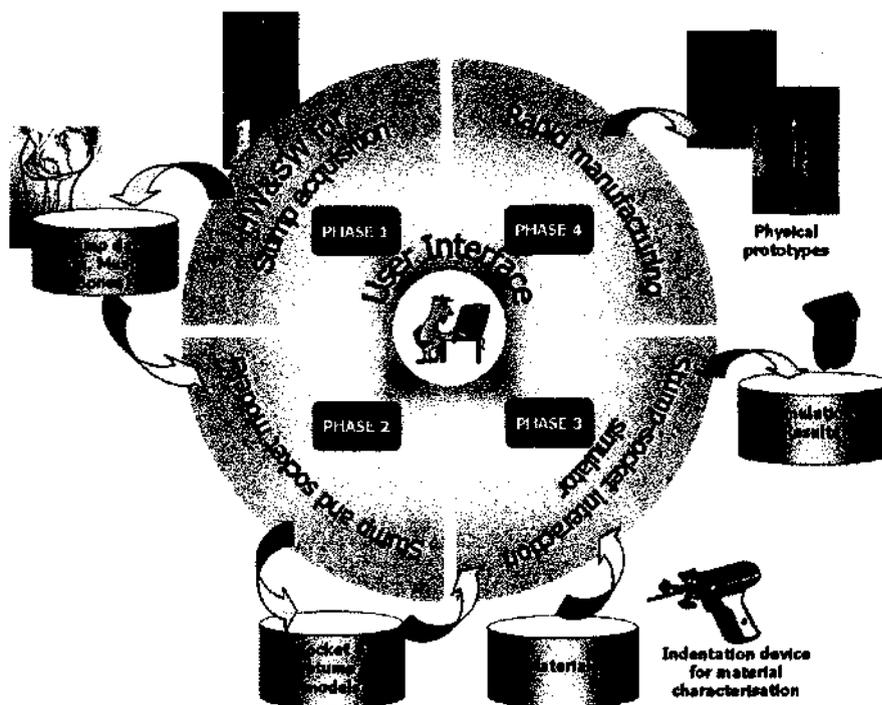


Figure 3. System Architecture

In the following, we describe the preliminary results of the projects.

4. Preliminary Results

4.1. Acquisition of the stump geometry

We adopted reverse engineering equipment, specifically a non-contact laser scanner for the external shape of the stump and medical imaging, Computer Tomography (CT) and Magnetic Resonance Imaging (MRI) for the internal structure, respectively for bones and soft tissues and muscles [2, 3].

Figure 4 shows the point clouds (A) and CT acquisition (B and a CT images (C) with markers) acquired for a "transtibial amputee".

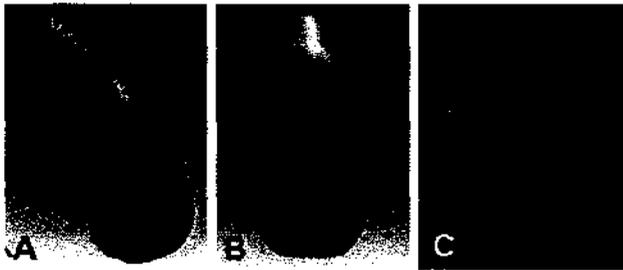


Figure 4. Acquisition of stump's external and internal parts

We also acquired the shape of a positive plaster cast manufactured by an orthopaedic technician to compare the stump external shape with the socket internal surface and determine critical zones [3].

4.2. Stump and socket modelling

One of the project goals is to develop a methodology to physically model objects as composed by different materials. In fact, commercial CAD systems as well as CAD/CAE tools for prosthetic applications (e.g., TracerCAD and Ossur CAD) [1] are not able to generate interactively models describing the inner parts of the product (bones and muscles) taking into account their mechanical properties.

At this stage of the project, we have generated a complete digital model of the stump including skin and bone structure (Figure 5) by integration data acquired through the three mentioned technologies [3].

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.

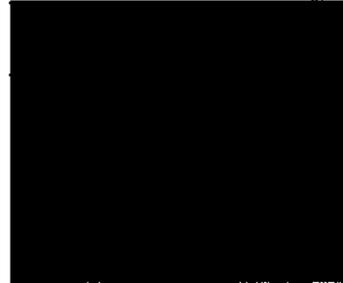


Figure 5. Stump digital model

The 3D socket design can be carried out starting from significant 2D sections in correspondence of significant planes, such as the sagittal or frontal plane of the stump. 2D socket design could come in different ways. For example, some longitudinal or transversal sections of the stump could be considered and, starting from them, some local deformations (derived from orthopaedic technicians' expertise) could drive to the generation of the sections of the counterpart: the socket. These sections could be used to generate the internal skin surface of the socket and then, applying a proper thickness (depending on patient's weight), the 3D model.

4.3. Stump-socket simulation

Modelling and simulation of the interaction socket-stump during the socket design process can be strategic; however this task is very hard to accomplish since biological soft tissue exhibits a strong nonlinear mechanical behaviour and they may undergo large deformations during the gait load cycle. In the last years, many researches have been performed to obtain models able to simulate the interaction between soft tissues and hard materials [4-8].

We have scheduled two types of simulations: the so-called donning simulation and gait simulation. By the donning simulation the designer can verify if the shape of the socket allows the wearability by the user, while the gait simulation allows the characterisation of the biomechanical behaviour of the socket-limb interface during the walking of the patient. We first dealt with

loning simulation. In order to verify the functionality of the socket, the fitting between the socket surface and the stump is the criterion that guides the design process. The fitting is evaluated by the contact pressure at the interface and by the sliding, evaluated as relative motion between the socket surface and the residual limb during the gait. The stresses in the socket and its stiffness are also evaluated in order to verify the compliance with the structural specifications.

To carry out the simulation process, we intend to use both FE and particle-based methods [9-11]. We first put the efforts on the first method because it permits to obtain better results from quantitative point of view. In FE simulations we are investigating 2D and 3D models, implicit and explicit codes and different types of material models. Whether we use 2D or 3D meshes, fitting and wearability simulations requires the analyses of complex contact problems; we intend to evaluate the performances of implicit and explicit solvers related to this problem. Figure 6 illustrates a preliminary simulation of wearability realised by using a 3D mesh and the explicit solver LS-DYNA; in this case, the bucket sort-searching algorithm is used as contact model between the socket and the limb.

4.3 Socket rapid prototyping

During this activity the physical prototype of the socket is produced using RP technologies that get as input the model of the socket generated and verified during previous activities. This means that RP technologies should be able to manage materials as those ones used for the generation of the definitive socket produced with the traditional processes. At present, these issues are under investigation and will be analy-

sed in detail during the next stages of the research [12-13].

4. Conclusions

This paper presents the preliminary results of DESPRO Project related to the experimentation of a new design paradigm for a prosthesis component, the socket. The new development process is based on the integration of different ICT technologies, from reverse engineering to physics-based modelling and simulation and rapid prototyping. Main problems for each step of the design process have been analysed and adopted solutions have been described. The results obtained encourage us to proceed even if some issues are still open and require further efforts.

In particular, future research activities will be concentrated on 3D socket modelling, optimal simulations, stump material characterisation and rapid prototyping. Finally, the feasibility and usefulness of simulations using "virtual human" will be considered and to estimate the effects of prostheses modifications.

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Figure 6. Wearability simulation

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