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A computer-assisted methodology to innovate the development process of prosthesis socket

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Abstract: In this paper we propose a computer-assisted methodology to improve prosthesis development process. We consider the case of the socket (interface between the residual limb and the mechanical part of the prosthesis) both for trans-femoral or trans-tibial amputee since it requires a high level of customisation. The new paradigm forecasts the integration of the following techniques: 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 real movement of the patient and the interaction between the socket and stump and, finally, rapid prototyping tools for the physical realization of the product. The paper describes problems related to the implementation of each step within a real socket development process; in particular, first results regarding the reconstruction of the stump virtual model and physics-based simulation will be presented and discussed.

Key words: Product Customisation, Virtual prototyping, Reverse Engineering, Rapid manufacturing, Physically-based modelling and simulation

1- Introduction

Today computer-based methodologies and tools make easier the design of 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) allows generating a new product variant; in the latter case, most of goods consists of products or devices that have an interface with human body. These have to be 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 (i.e., mechanical field) for mass production or for modular products, 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 custom-fit product, a prosthesis component, through the integration of advanced ICT tools, allowing the evolution from an hand-made production to a computer assisted realisation of highly customised products.

The efforts have been focused to demonstrate the feasibility of the practical implementation of the proposed approach and to highlight the aspects to be improved.

In this research we make reference to a component of lower-limb prosthesis, precisely the socket (the interface between the residual limb and the mechanical part of the prosthesis) since it requires a high level of personalisation. 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 **DES**ign and Develop Custom-fit Products: Application and validation for a Socket of a Lower Limb **PRO**sthesis) 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- State of the art

2.1 – Socket development process

In Europe, USA, Japan, and China, there are several companies that produce standard components for external

prostheses (arm and leg). Some examples are Ottobock (D), Medi (D), Blatchford (UK), Orthoeurope (UK), Proteor (France), Proteval (France) Ossur (Iceland) Alps South Corporation (USA), College Park (USA), USMC (USA), Teh Lin (China), and Nabco (Japan). Foot, knees and the other modular parts of the prosthesis are purchased by catalogues and are standard for a class of weight and height of the amputee; besides, the socket (Figure 1) is not standardized and has to be customized for every patient. It contains and protects the stump allowing the patient to transmit the load to lower parts. Therefore, the socket plays the fundamental role both in the comfort and in the functionality of the prosthesis.



Figure 1: Example of socket for trans-femoral prosthesis.

A socket has to be manufactured in the correct way both from anatomical and biomechanical point of view because each movement between stump and socket can hugely reduce the prosthesis control causing unsafe and pain during walking. The design and manufacturing of high-quality sockets must fulfill the following principles: accurate measurement of the stump geometry, perfect close-fitting of the prosthesis to the stump,

good response to forces and mechanical stress, safety, and each single area of the socket must have a tight connection to the stump anatomy without affecting blood circulation. The socket is manufactured starting from a plaster-cast or measurements with a CAD/CAM system; however in Italy, most of laboratories producing prostheses are SMEs and the socket is almost hand-made. The As-Is production process consists of the following main phases:

- manual measurement of the stump from under patella to fibula apex for transtibial and from greater trochanter to femoral apex for transfemoral;
- realization of the negative plaster-cast directly on the patient's stump using chalk and bandages exerting pressures to ensure the correct load points of the stump in the socket;
- production of positive plaster model;
- comparison of the positive cast measurements (acquired as done for the patient's stump) with those taken on the patient in order to verify the cast model accuracy and if necessary manual adjustment of the plaster model;
- thermoforming of the styrene or polyurethane liner on the plaster model to manufacture the inner shape of the socket;
- resin lamination with a carbon fibre leaf for the socket embodiment.

Figure 2 shows in detail the IDEF diagram of the design and manufacturing process.

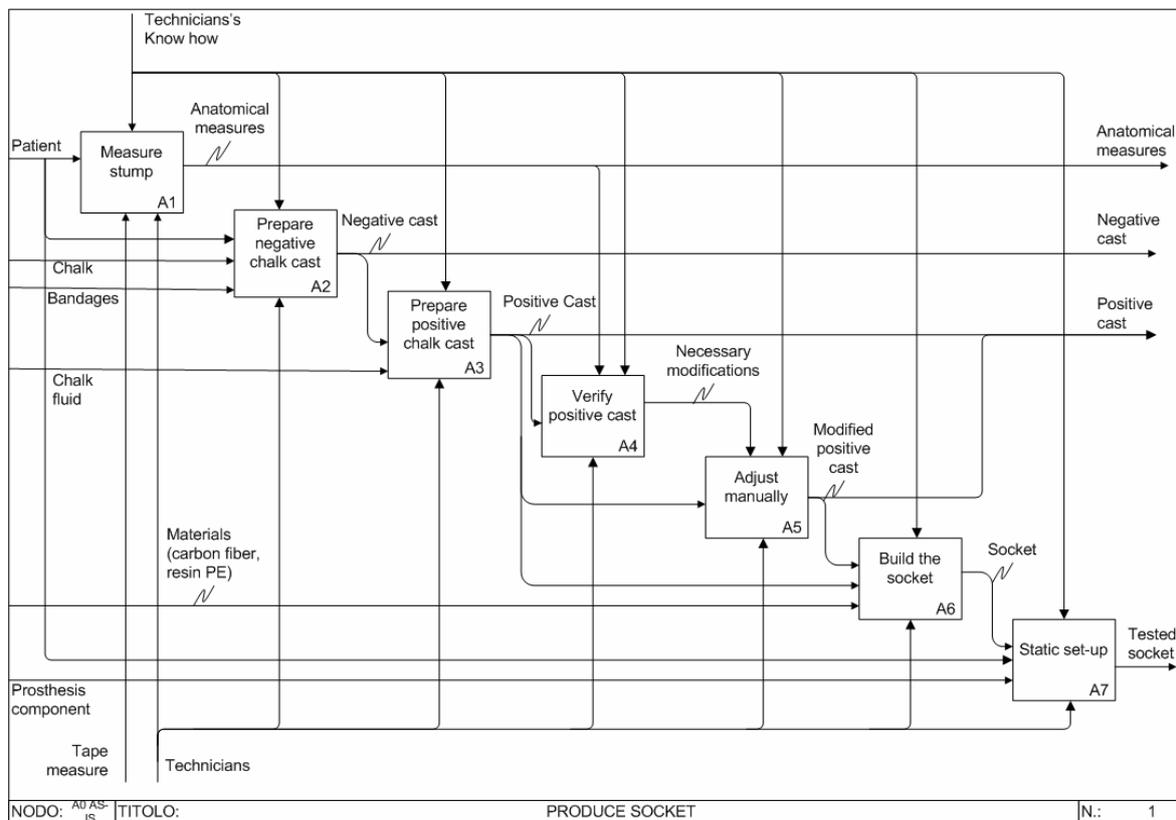


Figure 2: IDEF diagram of the socket design and manufacturing process.

2.2 – ICT Tools and methodologies

Virtual prototyping, reverse engineering, rapid prototyping, and physics-based simulation are methodologies that can

improve and innovate the design process ensuring products customisation. In the following we briefly present the state of the art of mentioned technologies for socket development process.

Actually the acquisition of stump geometry is mainly carried out manually and several measurements protocol have been developed [1,2]. However, since ten years ago several non-contact reverse engineering techniques and medical imaging have been tested. First techniques for digitalizing the 3D geometry of an amputated leg were based on the acquisition of bidimensional silhouettes [3], but more recently it has been proposed the adoption of MRI (Magnetic Resonance) and CT (tomography) in order to build a model as a set of cross-sectional images, by distinguishing bones, soft tissue and skin of the residual limb [4-7]. With the aim of providing a greater support to the design of prosthesis sockets, further efforts have been dedicated to the measurement by Reverse Engineering techniques of the soft tissues deformations under external loads. Besides, it is still open the problem of the integration of Reverse Engineering systems with modelling and simulation techniques in order to allow the representation of the mechanical behaviour of the limb/prosthesis system under static and dynamic loads.

Concerning socket and stump virtual prototyping, different CAD/CAM systems are available on the market, but only few of them are specifically targeted to prosthesis design (e.g., TracerCAD - www.tracerCAD.com, Ossur CAD - www.ossur.com). They permit to model the external shape of the stump and/or socket as composed by homogenous material and are not able to model objects made by different materials (e.g., for the stump: skin, tissue, bones...).

Another important issue related to functional surface of the socket is the interaction between socket and the residual limb. 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. Two main approaches have been adopted: the Particle-based modelling and Finite Element Method.

In [8] the authors present a method able to simulate the muscle deformations in real-time using a linear mass-spring system. In [9] a soft tissue simulator for aesthetic surgical operations is presented. This system uses a fast tetrahedral mass-spring model to calculate soft tissue deformation due to the interaction with the bones in a short time interval. In [10] a linear mass-spring model has been described to simulate the interaction between the surgical tools and the human soft tissue during suturing operations. As stated, all these kinds of models have been largely adopted only for real-time simulation and visualization purposes.

Also, Finite Element Method (FEM) has been largely adopted to simulate the prosthetic socket – residual limb interaction. In [11, 12] the effects of the inertial loads and contact conditions on the interface between prosthetic socket and residual limb of an amputee during the gait, have been studied. The pressure distribution at the socket-limb interface has been determined by means of a 3D finite element model based on the geometry

of the residual limb, the internal bones and the liner; the soft tissues have been modelled as linear elastic. In [13] the authors have developed a FE model composed of a socket, liner and residual limb by which to simulate the socket interface behaviour under quasi-static loading conditions. The load boundary conditions have been derived by measuring the ground reaction forces during the gait. All the soft tissues have been modelled as linear elastic. As described in the mentioned researches, FEM may be a powerful tool in order to simulate the socket-limb interactions with respect to the Particle-based approach. However, at present, the success of the FEM as a prosthetic socket design tool has been strongly limited by the linear elastic approximation used to simulate the soft tissue behaviour. Better results may be obtained using a nonlinear elastic approximation such as summarized in [14, 15]. Here the authors have proved that the James – Simpson – Green nonlinear viscoelastic material model, one of the simplest formulation of the elastomer material models (such as the rubber), allows simulating the compressive behaviour of the residual limb bulk soft tissues of trans-tibial amputees.

Finally, the added-value in using RP consists in the fact that it doesn't show the limitations or drawbacks of the classical approaches, based on NC-milling machines. For RP, the geometrical complexity of the digital models is not a problem; the same is for internal cavities, free-form surfaces and so on. These features are intrinsically present when dealing with medical data, anatomical structures, etc. The main contexts where RP plays a valuable role are maxillo-facial surgery [16], orthopaedic surgery [17], dental surgery, plastic and reconstructive surgery [18], vascular surgery and others.

Countless are the applications of RP in the medical field, specifically regarding prosthesis development. These last ones have been considered for the production of the stump positive plaster cast and for socket manufacturing [19-21]. Different RP technologies have been evaluated to establish the impact on the design process as far as concerns test evaluation, costs and time reduction. However, some problems still open, such as materials and RP processes able to deal with graded materials that are under investigation within the CUSTOM-FIT Integrated project funded by UE.

3- The new design process

As previously described, the manufacture of a socket is almost a hand made activity carried out by skilled technicians, and CAD/CAM tools for this kind of products are not able to manage all the product development stages, from design to manufacture.

Figure 3 shows the proposed development process to overcome the limits previously described. This approach is totally based on computer aided tools, designed to implement best practices used by orthopaedic technicians and finalised to ensure high-level products independently of the competencies of the domain expert that produces the socket. It consists of four steps, organically connected each others, where following tools are integrated:

- 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 modeller allowing the designer to represent a product as composed by different materials (inner parts modelling);

- 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.

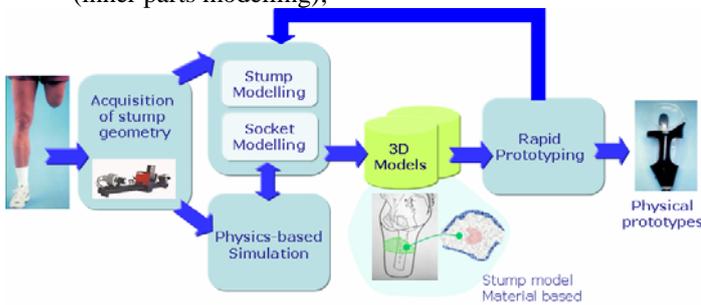


Figure 3: The design process and related tools.

Figure 4 shows the design process using the IDEF formalism. In this way, activities, controls, tools, inputs and outputs are fully defined and explicitly treated.

What follows is the description of the four phases of the innovative process and preliminary results of experimentation carried out until now.

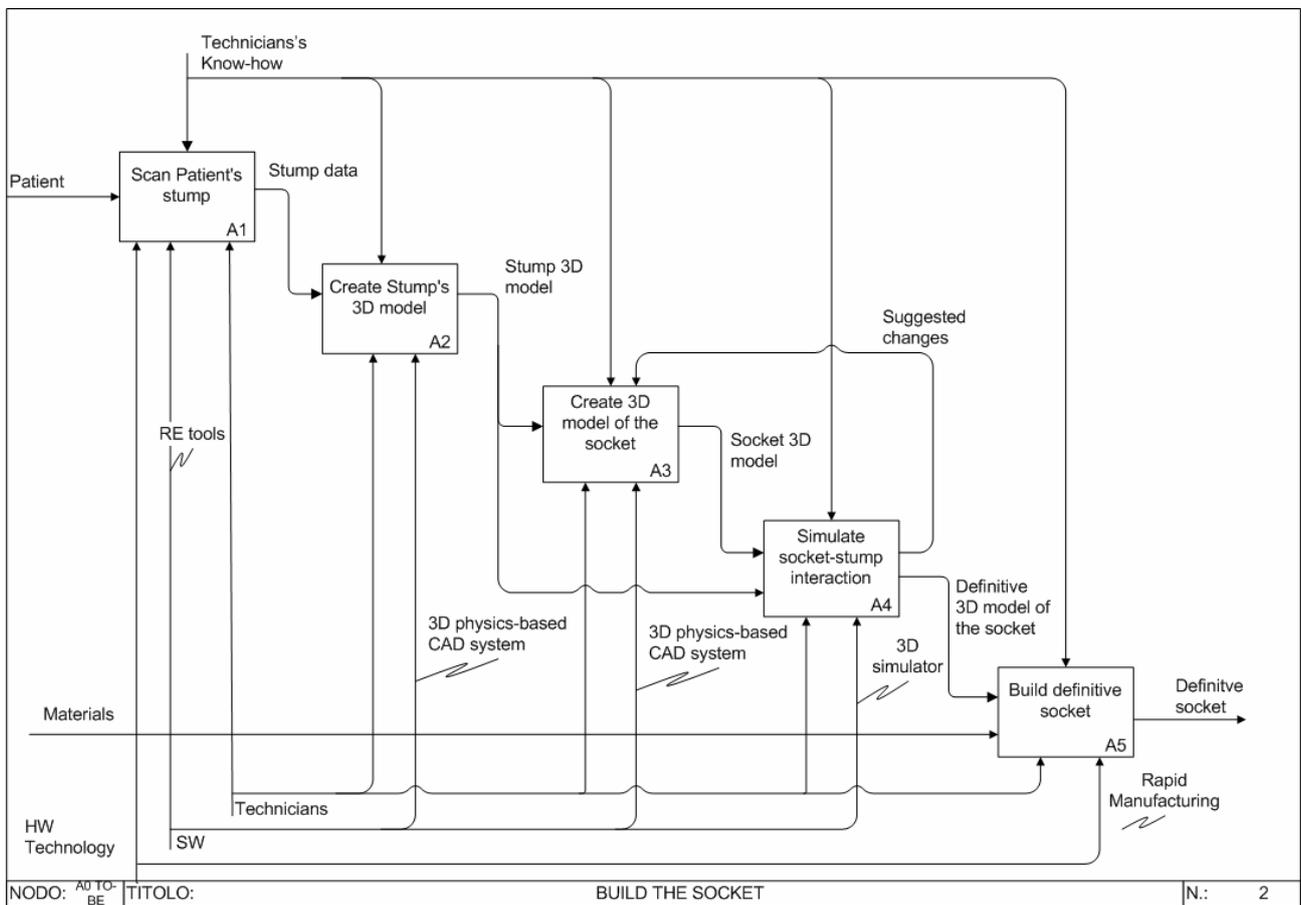


Figure 4: New design process.

3.1 – Stump shape acquisition

The aim of this activity is the acquisition of stump geometry to be used for the reconstruction of stump digital model and the following socket model. Both reverse engineering and medical imaging techniques have been adopted to obtain a model that includes both stump external shape and its inner parts [22]. Specifically a non contact laser scanner (Minolta Vivid VI-91™) has been adopted to acquire the external shape of the stump and of a positive plaster cast manufactured by an orthopaedic technician. The last one has been considered to make a comparison between the stump external shape and 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.

During acquisition, patient's posture has been determined using a support device that permitted to maintain lower limb position adopted for manual measurements. In addition markers have been used to identify anthropometric standard points.

Figure 5 shows the point clouds acquired for a trans-tibial (A), a trans-femoral amputee (B) and a CT images (C) with markers.

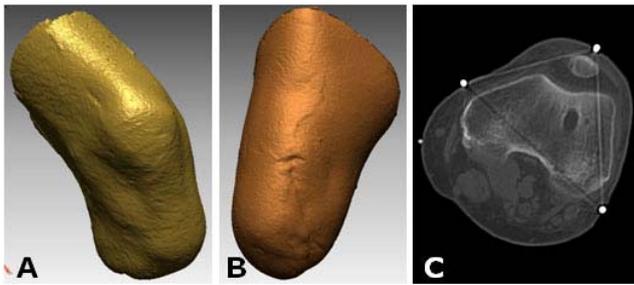


Figure 5: Acquisition of stump external and internal shape.

3.2 – Stump modelling and socket design

Data acquired for the stump have been processed and elaborated to generate a complete digital model including skin and bone structure. To this end we integrated the data acquired through the three mentioned technologies.

Two types of geometric model have been reconstructed: 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. CT and MRI could be considered quite similar from the shape reconstruction point of view. They are based on different technologies (X-ray and magnetic resonance of particles respectively) but both have as output a data volume consisting in a set of images, strictly ordered, and representing anatomical sections. Starting from this data, the 3D reconstruction of the anatomical structures is quite straightforward.

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 6 shows the complete model.

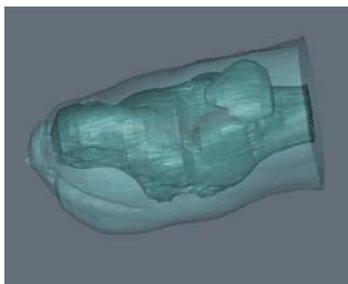


Figure 6: Stump virtual model.

As explained in §2.1, the shape of positive plaster cast depends on technician manipulation that models the negative cast around the patient's stump exerting pressures in order to ensure the correct load points; therefore the stump morphology under static condition does not correspond to its morphology when wearing the socket. In order to detect the differences and critical areas between the two configurations the stump virtual model with that one derived from positive plaster cast scanning have been compared. Figure 7 portrays the sagittal section of volume variations between the two models which corresponds to the zones where the technicians assure no loads on the stump (critical bone zones), exert pressure to guarantee socket

adherence (popliteal area) and manipulate to reduce and compact volume (fleshy zones at the bottom of the socket).

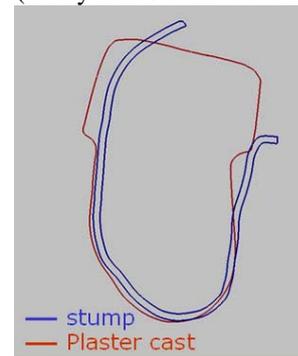


Figure 7: Stump virtual model and plaster cast – Sagittal section.

For further details see [23].

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 previous considerations) could drive to the generation of the sections of the counterpart: the socket. Then, as usual, these sections could be used to generate the internal skin surface of the socket. But in this way because of the local reasoning, the result could present poor shape homogeneity or congruence. To avoid this, the statistical approach could come in help. A digital model, built up by joining the features gathered from collections of specimen, could be considered for parametrization and the result will be for sure shape-homogeneous and congruent.

Finally, the 2D sections and/or 3D models could be fatherly refined on the basis of results coming from physics-based simulations.

3.3 – Stump and Socket simulation

During this activity designers and orthopaedic technicians use virtual simulations to optimize the socket design. Two types of simulations are scheduled: 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. In this way the presence of dangerous undercuts which can produce stresses and large deformations of the soft tissue, can be easily identified. The gait simulation allows the characterisation of the biomechanical behaviour of the socket-limb interface during the walking of the patient. The time-dependent loads acting during the gait are applied to the physics-based models of the socket and of the stump. Such a kind of data may be obtained by experimental tests or, at least, via literature.

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;
- 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. According to the results of the simulations, the designer and orthopaedic technicians perform the optimization of the socket shape until the mentioned requirements are reached. This task require a lot of iterations so it may be speed up using the shape optimization tools those are able to perform an automatic and iterative variation of the physics-based model of the socket according to the requirement objectives.

To carry out the previously described simulations, we intend to use both FE and particle-based methods. However, more important efforts are reserved to 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.

A two steps simulation approach is provided for in the project; as in the geometric modelling phase, first 2D models of the socket – limb interaction are used and then 3D ones. 2D models are related to the significant cross sections of the limb, those ones that contain the curves used to define 3D socket geometric model. 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 wearability 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.

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 8 illustrate 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. Figure 9 illustrates the pressure distribution obtained in a fitting preliminary simulation.

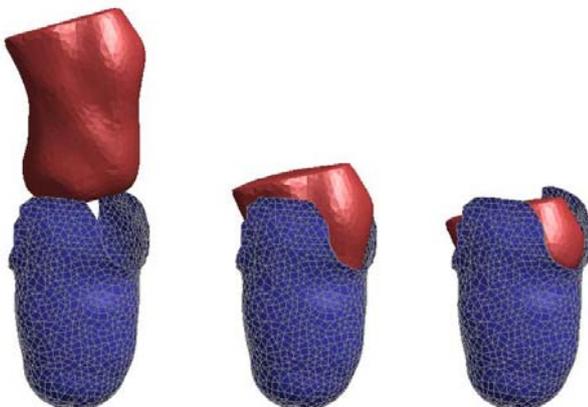


Figure 8: Wearability simulation.

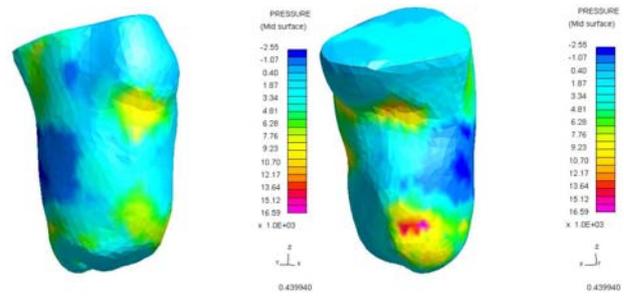


Figure 9: Pressure distribution.

In the simulations described, the models of the materials (tissues, bones and sockets) play a fundamental role. For the tests documented in Figures 8 and 9, only linear models have been used; for the bones, one with Young's modulus equal to 10 GPa, for the socket, a second linear elastic material with Young's modulus equal to 1.5 GPa, and, for the soft tissues, a third linear model with Young's modulus equal to 0.2 GPa according to [12].

In further developments, we intend to evaluate more proper nonlinear models of materials for highly deformable tissues; for example, hyperelastic and viscoelastic models. The parameters of these models can be determined from experimental tests, for example performing in-vivo indentation tests in different locations of the limb. Figure 10 shows the indentation system device that has been designed in order to perform these tests.

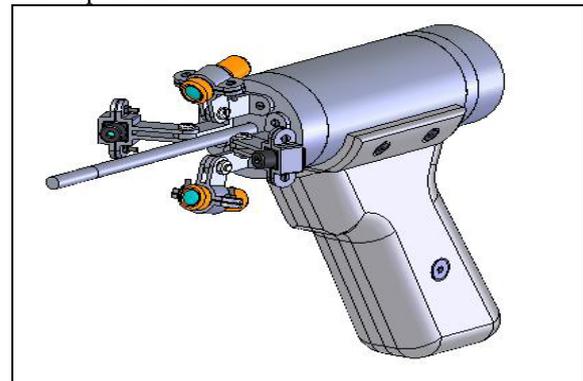


Figure 10: Indentor device.

3.4 – 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 analysed in detail.

4- Conclusions

This paper presents a design paradigm for a prosthesis component, the socket, based on the integration of different ICT technologies, from reverse engineering to physics-based simulation and rapid prototyping. Main issues and problems related to the implementation of each step within a real

socket development process have been generally discussed. Problems related to stump measurement and modeling have been completely identified; results from acquisition and modelling of the stump and of positive plaster cast provided useful guidelines for socket modelling and physics-based simulation. Methodologies and preliminary results about simulation task have been analyzed and described.

Future research activities will be concentrated in particular on 3D socket modelling, optimal simulations, stump material characterisation and rapid prototyping.

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