Physically Based Modelling and Simulation to Innovate Socket Design

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ABSTRACT

This paper introduces a virtual laboratory to design prosthetic socket, which integrates a 3D CAD module, named Socket Modelling Assistant (SMA), specifically developed to create the socket digital model, and a CAE system to analyze the stump-socket interaction. Software tool, named Virtual Socket Lab (VSL), is part of a knowledge-based framework to design lower limb prosthesis centered on digital models of the patient or of his/her anatomical districts. The focus of this paper is on the definition of an automatic simulation procedure to study the stump-socket interaction and validate socket design. We first introduce the new design framework and main features of VSL. Then, we present a state of art on FE models adopted for residual lower-limb and prosthetic socket during last two decades highlighting key issues. Finally, the identified procedure and the integration strategy within SMA are described as well as preliminary results of the experimentation.

Keywords: socket, socket-stump interaction, physics-based modelling and simulation.
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1 INTRODUCTION

Prosthesis development process is mainly carried out manually and heavily relies on the orthopedic technician's skill and his/her experience. Components, such as foot, knee and tube, are selected from commercial catalogues according to patient's characteristics; while the socket is realized around the patient's stump and has to be carefully manufactured to guarantee high quality prosthesis. In fact, the socket represents the most critical component from which depends the whole prosthesis functionality. Two are the key issues: the patient's morphology and technicians' expertise that guides the whole design process.

In such a context, we are developing an innovative framework, centered on digital models of the patient or of his/her anatomical parts, which integrates a set of "assistants" to guide the technicians during each design task providing specific knowledge and rules (e.g., dimensioning or selection rules for standard parts). The framework, implemented using a commercial KBE system (Ruledesigner® Configurator) is not a simple interface among different software tools but an environment, which manages the operations sequence and pilots the appropriate tools for the realization of the specific task, ensuring a high level of usability and interaction among the system and potential end-users. It includes (Fig. 1.): a commercial 3D CAD system to generate the 3D parametric models of the standard parts and the final prosthesis assembly, the Virtual Socket Lab (VSL) developed in house to design the socket and a Virtual Testing Lab to realize a complete amputee's digital model, execute prosthesis set up and evaluate its functionality simulating postures and movements. The framework guides the technician during the 3D modelling phase and selection of standard and custom-fit components of the prosthesis on the base of the digital model of the anatomical district, the patient's characteristics (e.g., anthropometric data) and the prosthesis use (e.g., daily use or sport activities).

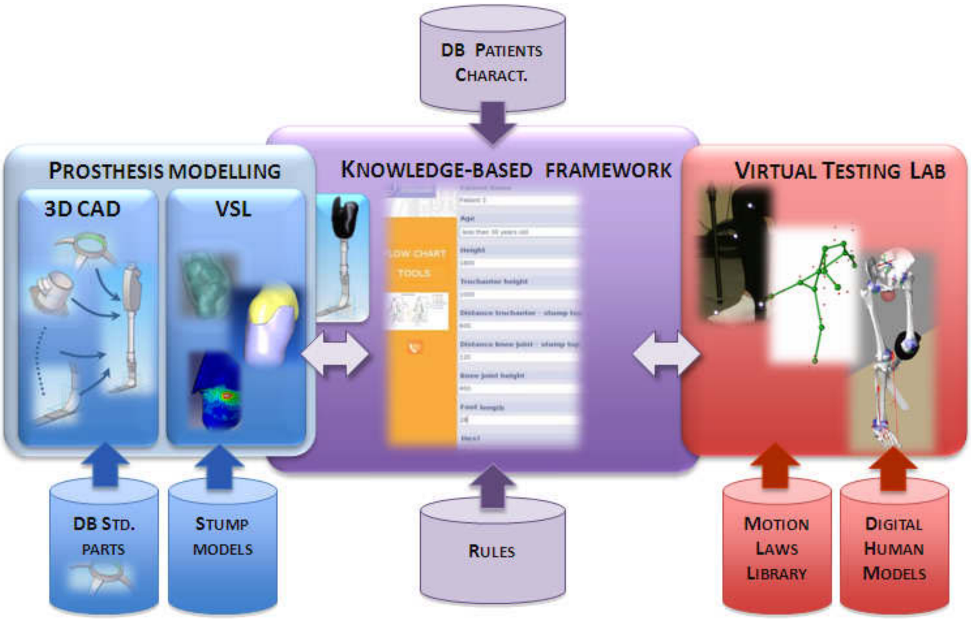


Fig. 1: High-level architecture of the framework.

In this paper, we present the Virtual Socket Lab focusing the attention on the validation step. In fact, our aim has been to define and implement an automatic simulation procedure to study the stump-socket interaction and validate socket design and functionality.

In literature and on the market, we can find prosthetic systems [1-5] or design process that integrates CAD and FEA tools [6-7]; however, they do not provide any support or guidance to the designer. The basic idea of our approach has been to provide an environment where the orthopedic technician can create directly 3D socket model onto the stump digital model, and apply design rules and modifications in automatic and/or assisted way, coherently with the traditional procedures.

We first describe main features of VSL and the state of art on FE models adopted for residual lower-limb and prosthetic socket during last two decades highlighting key issues. Then, the identified procedure and the integration strategy within SMA are described as well as preliminary results of the experimentation.

2 VIRTUAL SOCKET LAB

The Virtual Socket Lab permits to design socket both for trantibial and transfemoral amputees. It integrates a 3D CAD module, named Socket Modelling Assistant (SMA), specifically developed to generate the socket digital model and a CAE system to analyze the stump-socket interaction (Fig. 2.). SMA guides the technician during each step of the socket design process on the base of the patient's characteristics and according to experts' knowledge and design rules embedded in the system (see [8] for further details).

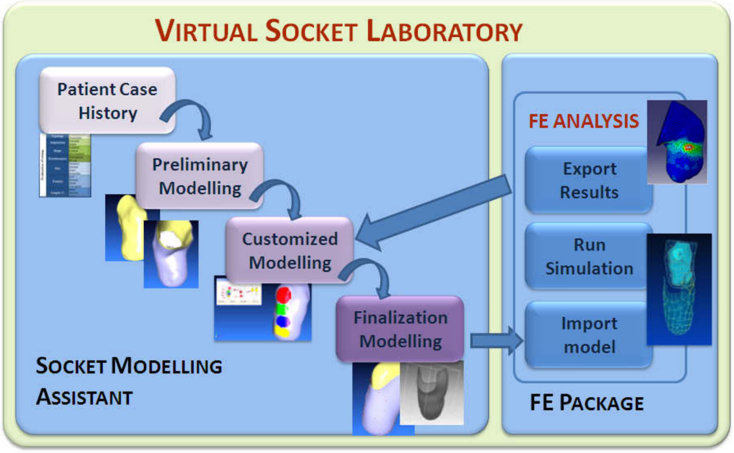


Fig. 2: Virtual socket Lab.

The process to model the socket can be divided into 5 steps (Fig. 2.): Patient's case history, Preliminary modelling, Customized modelling, Finalization modelling and FE analysis. First four steps are carried out within the Socket Modelling Assistant; the last one is automatically executed using a commercial FE package.

First step consists of importing the patient stump digital model from the specific database, acquiring values of patient's parameters, and setting the knee position and the areas to be manipulated. The second phase, preliminary modelling, aims at generating an initial geometric model onto which the technician applies specific modifications to reach the final socket shape. Main operations (stump model scaling, generation of socket reference surface and socket top optimization) are carried out almost completely in automatic way according to patient's characteristics. The customized modelling is the most important and critical phase of the whole process. Here, the socket model is shaped directly on the stump model to be perfectly customized for the specific patient's anatomy. The system makes available an interactive deformation tool, named Sculpt tool, which permits to emulate the traditional operations of adding and removing chalk material when the technician manipulates the positive plaster cast. Based on patient's data and zones highlighted in the first step, the system suggests the most appropriate levels of plaster addition or removal, and accordingly applies the modification to the reference shape. In the finalization modelling, the designer shapes the socket upper edge in semi-automatic way and the system suggests the socket thickness according to an empirical formula based on the patient's weight. Once the first 3D socket model is generated, the FE analysis is automatically executed in order to verify contact pressure and then optimise the socket shape. FEA results, imported in SMA, are analysed and socket geometry is modified until the optimal shape is reached.

3 STATE OF THE ART & SIMULATION PROCEDURE

Finite element modeling and analysis have been already adopted to simulate the socket-stump interaction, and over the past two decades, several researches have been performed [9-13]. Most of them have considered transtibial socket, only few transfemoral one.

Our main objective has been to integrate within the Virtual Socket Laboratory a procedure allowing the prosthetic to automatically run the simulation and analyze stump-socket interaction in order to optimize socket shape. Among the various FE solvers commonly used in this field, we adopted Abaqus package V 6.9 (Dassault Systemes S.A.).

First, we have identified key issues that should be considered in order to implement an automatic procedure. They are acquisition and definition of the stump and socket geometry, mesh generation, material characterization, boundary conditions and analysis steps. In the next sections for each issue, we summarize related state of the art and the solution we have implemented.

3.1 Geometric Models Acquisition and Meshing

The external shape of the residual limb, the internal bones, the socket and the liner, if considered, are fundamental to create the FE model, which reflects the real geometry of the stump and permits to compute the pressure distribution on limb surface. In fact, it is commonly accepted that the meaningful parameter to evaluate the socket functionality is the contact pressure between residual limb and socket during patient's movement.
Geometry acquisition and the correct alignments can improve the quality of the simulation and the convergence of results.

Zheng et al. [11] analyzed possible methods for geometric and biological assessment for residual limb tissues, while Silver-Thorn et al. [14] identified qualities and limitations for each common technique from laser scanner to Magnetic Resonance Imaging. Colombo et al. [7] proposed a methodology to generate a 3D detailed model of the stump integrating data acquired with Magnetic Resonance Imaging (MRI), Computed Tomography (CT) and laser scanning.

For the acquisition of the stump morphology, we have selected MRI since it is the less invasive technique for the patient and permits to obtain a geometric model with reasonable accuracy. At present, the 3D models of the soft tissues and bones are generated using the commercial software Mimics and, then, imported into the Socket Modelling Assistant to create the 3D socket model according to rules derived from prosthetics' practice.

Generated models are imported and assembled into Abaqus using iges format: soft tissues and bones as 3D deformable solids while the socket as 3D deformable shell, because socket thickness is significantly smaller than the other two dimensions.

The bony structure, the soft tissues and the socket are previously aligned using SMA. In our approach, bones and soft tissues are merged to create a unique part (the stump) without geometric discontinuity, despite the different parts that compose it, and taking into account the real distribution of rigidity. This solution allows us to simplify the real problem and consider the residual limb as a continuum characterized by two models of different materials. It also prevents to specify the type of interaction existing between bones and muscles.

In order to automate the procedure we have adopted a free auto meshing technique. To select the seed value we have performed a sensitive analysis, since the size of the seed mesh influences simulation times (Tab. 1.) and the conformity requirements of tetrahedral and triangular elements (Tab. 2.) in the residual limb and the socket. We have used explicit elements, which increase their size in the internal regions, and, precisely, 3-noded triangular (S3R) elements for the socket and 4-node tetrahedral (C3D4) for the stump. In our test-case, the whole FE model has 5323 nodes and 23460 elements. Simulations have been performed using a workstation with Intel Xeon processor at 2.53 GHz and 12.0 GB of DDR3 RAM at 1333MHz.

Fig. 3. shows the pressure map for donning simulation using a seed equal to 9.6, 8, and 6.4 mm. Increasing the mesh detail, the pressure rises in the critical area; however, the values are lower of 50 kPa than standard model. This means that a model with a seed equal to 8 mm, used as benchmark, simulates with sufficient accuracy the interaction between socket and stump, without increasing dramatically analysis time.

Seed mesh	*9.6*	*8 (standard)*	*6.4*
Time	1:05	1:28	4:02

Tab. 1: Simulation time for the entire process [h: min].

Seed mesh	*9.6*	*8 (standard)*	*6.4*	*3.2*	*Variable Seed*
Distorted elements	14	9	6	3	138

Tab. 2: Number of nonconforming items in the mesh.

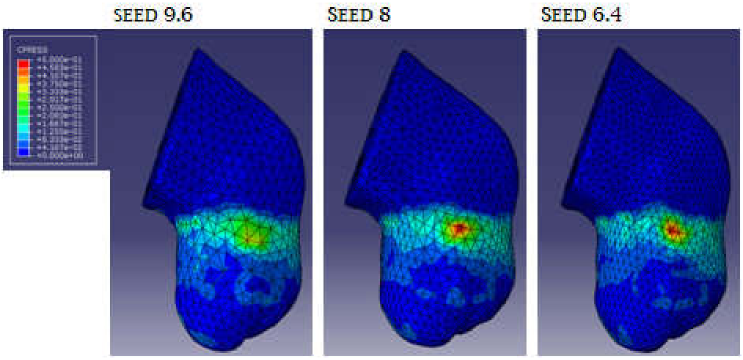


Fig. 3: Donning simulation with seed equal to 9.6, 8, and 6.4 mm.

3.2 Material Properties

Different parts (bones, soft tissue, socket and eventually liner) included in the FE model have to be characterized with different mechanical properties. In literature, they are sometimes estimated by *in vivo* indentation test [15]. In general, analyzed models properties were assumed to be linear, homogeneous and isotropic.

Lee and Zhang [16], Sanders and Daly [17], Silver-Thorn and Childerss [18] considered bony structure as rigid or fixed; while Goh et al. [6], Jia et al. [19-20], Lee et al. [21], Wu et al. [22] assumed a fixed socket. For the bone structure common values of Young's modulus E are 10000 or 15000 MPa with a Poisson's ratio ν equal to 0.3; for the socket, E is usually considered equal to 15000 MPa and ν from 0.3 to 0.39.

Young's modulus for soft tissue is around 0.2 MPa, while Poisson's ratio is 0.45 or 0.49 [6, 7, 17-22]; only Zachariah and Sanders [23] assumed E equal to 0.965 MPa. Lin et al. [24] and Zhang and Roberts [25] considered a more refined model for soft tissues subdividing them into specific regions, such as patellar tendon and popliteal depression; while Faustini et al. [26] increased to 25% soft tissues Young's modulus where the pre-stresses were the highest.

During the last years, to get a better approximation of soft tissue behavior, nonlinear elastic and also nonlinear viscoelastic approximations have been adopted [27, 28]. This increases the complexity of the FE model and requires additional computational time.

For our purposes, we have assumed the mechanical properties of the material for bones, residual limb and socket to be linear, homogeneous and isotropic. Tab. 3. summarizes values derived from aforementioned literature.

To reduce the computational costs, without losing essential information about the interface pressure, we have considered bones and socket as rigid bodies. The Young's modulus of bone and socket is five orders of magnitude greater than soft tissue ones. This difference suggests that a deformation of these parts can be neglected (Lee and Zhang [16]).

Regarding soft tissue, we have also experimented a hyperelastic model, with the potential energy of deformation expressed by a second order polynomial [29]. The pressure distribution is similar but with a decrease of pressure values. However, the hyperelastic model leads to a considerable increase of simulation times by almost 400%. The simulation requires 5 hours and 32 minutes to complete the analysis.

Material	*Density [Kg/dm³]*	*Young's modulus [MPa]*	*Poisson's ratio*
Bones	2	10000	0.3
Soft tissue	1.48	0.2	0.49
Socket	7.8	15000	0.3

Tab. 3: Mechanical properties for linear behavior characterization.

3.3 Constraints

Interaction between stump and socket can be modeled as a contact problem at different level of complexity, considering or not friction.

3.3.1 Contact Problem

Zachariah and Sanders [23] compared an automated contact interface model with a gap element model. They found out that automated contact methods have a good behavior, in particular, when the initial position of the limb in the socket is not known a priori. Lee et al. [21], using the same computational model, considered the prosthetic socket and residual limb as two deformable bodies in contact with different shapes and implemented the simulation of the pre-stresses produced by donning the stump into the socket. Wu et al. [22] adopted the surface-to-surface contact element since it is better than the traditional point-to point contact pairs. Colombo et al. [7] adopted an explicit FE code (LS-DYNA rev. 9.70) that allows managing adequately simulation problems characterized by large deformations and difficult contact conditions. The choice of an explicit solver allows the use of models that don't require the definition of contact surfaces.

In our procedure, we simulate the contact conditions between the residual limb and prosthesis with an automated surface-to-surface contact as Wu et al. [22].

3.3.2 Friction/slip Conditions between the socket and the Stump

In this case, friction means considering the friction coefficient between the skin and different materials, assessing the shear stress and the slipping at the materials interface and estimating the shear stress contribution during load transfer.

First models considered the stump fully connected to the socket as one body; in this case each part assumes different mechanical properties [18]. Others considered the stump and the socket as two separate bodies with the same surface shape [23].

The magnitude of friction coefficient depends on the condition of the skin. It does not appear to be significantly influenced by age or gender, and varies considerably in different district regions [30].

Zhang and Roberts [25], to simulate the friction/slip condition between the liner and skin, used interface elements to connect them; however, this lead to a poor match between the clinical data collected and simulations, underestimating the pressures.

Lee et al. [21] assumed that the static and kinetic coefficients of friction were the same and allowed the slippage only when the shear stress exceeded the critical shear stress. During sliding, if the shear stress decreases and is lower than the critical shear stress value, sliding ends. For all the materials tested by Zhang and Mak [31], the average coefficient of friction is equal to 0.46±0.15: silicone has the highest (0.61 ±0.21) while nylon has the lowest (0.37±0.09).

According to Lee et al. [21], we adopted the same model characteristics. It has been defined the inner surface of the socket and the outer surface of the stump respectively as the master and slave surfaces. Both surfaces are potentially in contact or separated. According to the master-slave contact formulation and hard contact relationship used in Abaqus, donning and adjustment steps are friction-free, while during loading the friction coefficient is equal to 0.46 (Zhang and Mak [31]).

3.4 Boundary Conditions and Analysis Steps

FE analysis requires quantifying and specifying numerically the location of the external forces acting on the structure. Loads can be expressed in terms of strength and as stump movement. The static load is equivalent to consider only the body weight. When deambulation is simulated, the load fluctuates over time and can be quasi-static or quasi-dynamic depending whether inertia forces are considered or not. Usually, load is applied to the knee joint center, which is concentrated in a single node in the bone structure, or in the distal-end of the socket if the bone structure is fixed. The loads magnitude is estimated according to body weight or through experimental measurements that require the survey of ground reaction forces and joint angles.

In initial models, loads application was done in a single step because they did not consider friction at the interface and the socket had the same stump shape. In this case, the simulation started with the prosthetic socket already donned. Sanders et al. [17] and Silver-Thorn and Childress [18, 32] applied loads and moments to the top of the socket; while Zhang et al. [25, 33] used a socket whose inner surface did not coincide with the external stump surface and considered the analysis divided into two steps, reflecting the two different phases of soft tissue deformation.

Usually the constraints are applied to the socket edge. Sanders et al. [17] assumed the bone and the knee joint to be zero displacement surfaces, Silver-Thorn and Childress [18] fixed the bones, Zhang et al. [25, 33] assumed the socket as rigid, Goh at al. [6], Lee and Zhang [16], Lee et al. [21] and Wu et al. [22] considered the outer socket surface or the outer liner surface, which has the same inner socket shape, as fixed and rigid.

The geometry of FE model, consequently the directions of forces and moments, determines considerably analysis results: the change of the stump posture affects the accuracy of interface forecast [34].

We decided to perform simulation in three phases corresponding to the deformation stages of soft tissues. The first step replicates the donning of residual limb into the socket and imposes a pre-stress on the stump. Since we do not know these adaptive movements a priori and for computational costs, the donning simulation is performed by fixing the residual limb and moving the socket. Boundary conditions have been defined as shown in Fig. 4(a).. Socket translation stops according to the length of the residual limb. The stump displacements, due to the wearing configuration, cause the pre-stress on the residual limb.

Then, the adjustment phase follows to achieve a better repositioning of the socket around the stump and to obtain maximum comfort. Here, the socket is free to translate and rotate in different directions with the exception of the vertical one, which is kept locked until the load application in order to prevent elastic recoil due to fit. During these two steps no external load is applied.

In the third and final step, the constant static load, equal to the amputee’s weight, is applied to the centre of mass of the socket and has vertical direction to simulate single support stance (Fig. 4(b).).

Socket translation and the static load are not applied immediately, but gradually during the analysis steps to avoid rapid acceleration and high inertia to the masses.

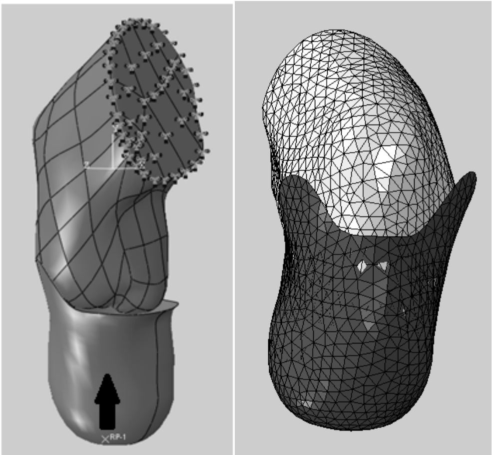


Fig. 4: FE models for residual limb and prosthetic socket: (a) direction of load and boundaries applied, and (b) final configuration.

3.5 Evaluation Parameters

The main task of the prosthetic socket is to distribute loads over desired regions of the residual limb (Fig. 5.) acting on the difference between stump and socket. Through an iterative process of adjustments, the socket shape is modified and optimized by prosthetic technician to eliminate undercuts, minimize weight and, especially, distribute loads in the appropriate way. The interface pressures should not exceed pain threshold in order to be tolerated for a certain time period.

Wu et al. [22] and Lee et al. [35] took over and compared the pain threshold, the minimum pressure that induces pain, and pain tolerance, the maximum tolerable pressure without feeling discomfort, in different regions of the residual limb through the indentation test, as shown in Tab. 4..

Lee et al. [35] demonstrated that these two parameters depend on the age and detection area, but are independent of the skin thickness. In addition, adjustments of some areas (e.g., patella tendon and popliteal area) have a significant affects on the pressure in other stump's regions [18, 33].

The validation of the finite element model can be made comparing the stresses expected with those empirically measured [25, 34-42].

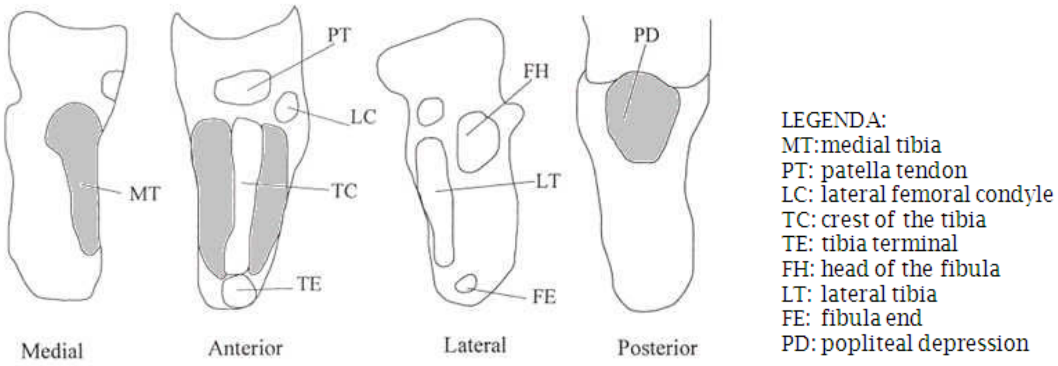


Fig. 5: Critical areas of transtibial residual limb (In gray the load areas) [25].

Pressure (kPa)	*Fibula's head*	*Medial condyle*	*Popliteal depression*	*Distal area*	*Tendon patellar*
Pain threshold	599.6±82.6	555.2±132.2	503.2±134.2	396.3±154.5	919.6±161.7
Pain tolerance	789.8±143.0	651.0±111.1	866.6±77.3	547.6±109.1	1158.3±203.2

Tab. 4: Pressure pain threshold and pain tolerance in different stump's regions [22].

4 IMPLEMENTATION

As said, our main goal has been to realize a virtual laboratory where it is possible to optimize socket shape according to patient's morphology. For this purpose, we have developed a FE simulation module with Python language. It implements the procedure described in Section 3 and integrates SMA with the commercial FE solver, Abaqus.

Abaqus can be used in two modes: through Abaqus CAE-Graphical User Interface (GUI) or Abaqus Scripting Interface. We considered the second tool since it allows bypassing the ABAQUS/CAE GUI and communicating directly with the kernel using a script or rather a file containing ABAQUS Scripting Interface commands. This permits to execute a series of "jobs" without manual intervention. The ABAQUS Scripting Interface is an extension of the object-oriented language called Python and uses the syntax and operators required by Abaqus. Embedding in the script all the commands to import the geometries and to define the FE model, it is possible to perform automatically the simulation in Abaqus, launched directly from the Socket Modelling Assistant (SMA).

Fig. 6. shows the logic sequence of the operations performed by the script and interactions between SMA and Abaqus.

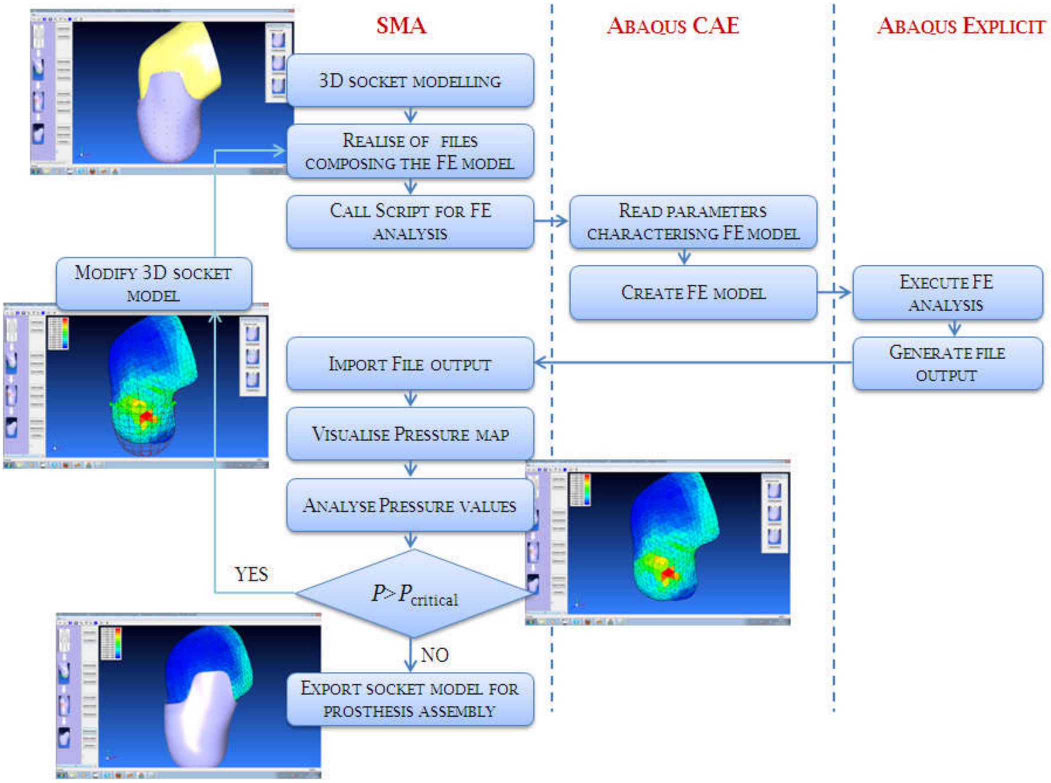


Fig. 6: Logic scheme of SMA-Abaqus integration.

The simulation procedure should be performed only in automatic way, i.e., the prosthetic cannot modify simulation parameters; however, if necessary, the system permits to set some parameters such as material properties. Three main players can be identified:

- The end-user (the prosthetic): his/her role consists in launching the simulation, and evaluating results. Pressure values are compared with pressure tolerance thresholds (Tab. 4.) and, if necessary, the 3D socket model is modified in automatic way or interactively using ad hoc tools made available by SMA. These deformation tools permit to modify socket geometry simulating the traditional operation performed by the technicians to create “load” or “off load” areas.
- Socket Modelling Assistant: it takes the control of the analysis. It creates the files in .iges format containing the stump and 3D socket geometry, launches the simulation, acquires and visualizes the results. On the base of pressure rules, SMA can suggest critical areas to be modified.
- Abaqus: its role is that of a calculus slave. It executes the FE simulation and sends results, when required, to SMA.

In the following, we present preliminary results of VSL experimentation.

5 PRELIMINARY EXPERIMENTATION AND RESULTS

We have considered as test case a unilateral transtibial male amputee, 40 years old, 180 cm tall and 80 Kg weight and tested the automatic procedure accordingly. For the experiments, we have used a workstation whose technical characteristics are summarized in Tab. 5..

Processor	Intel Xeon W3505 at 2.53 GHz
Memory RAM	12.0 GB DDR3 at 1333MHz
Graphics support	Nvidia Quadro FX 580
Operating system	Windows 7 Ultimate 64 bit

Tab. 5: Workstation technical specification.

Once acquired patient's characteristics, we imported the digital model of the stump (acquired in previous research works [7]) within the Socket Modelling Assistant onto which we have created the socket virtual model guided by the system and following steps described in §2 (Fig. 7.). Patient's characteristics are particularly important since most of operations strictly depend on them, such as the modification of critical areas ("load" and "off load" zones). The system automatically runs the simulation and visualizes the results (Fig. 8.). Pressure values are associated to a color scale from blue to red, covering a range of fixed values ranging from 0 to 500 kPa. The areas that exceed the maximum are colored in gray. The limit value of 500 kPa represents the average pain threshold derived from literature. Evaluation has been be made by analyzing critical regions shown in Fig. 5.; since they are the lower limb areas typically manipulated by the technicians to reach an optimal shape of the socket.

Fig. 9. shows some steps of the donning simulation; while Fig. 10. portrays the pressure distribution on the stump after the simulation of donning and loading phases. The pressure distribution is uniform and consistent, with the exception of the medial tibia region (523 kPa). During the loading phase the medial tibia area increases pressure to 615 kPa and there is excessively deformation close to stump fixed boundary that leads pressure value to 1121 kPa.

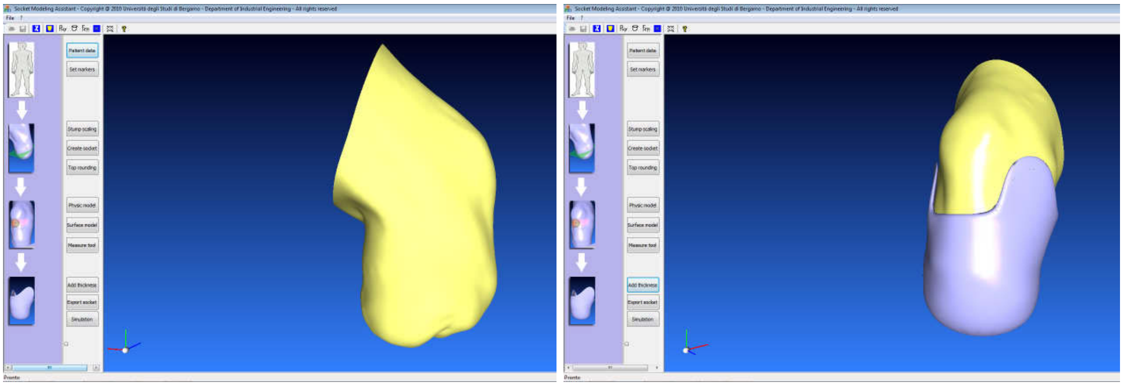


Fig. 7: Virtual model: (a) stump, and (b) socket.

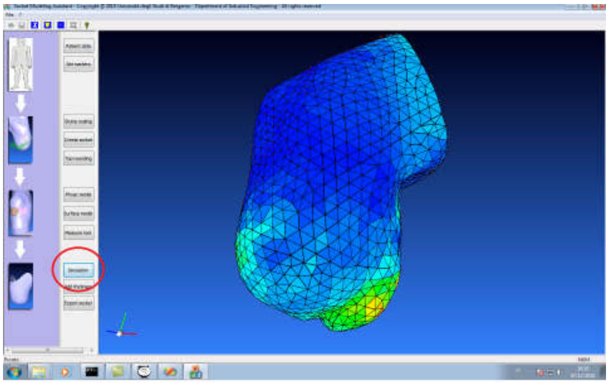


Fig. 8: Simulation results visualized in SMA.

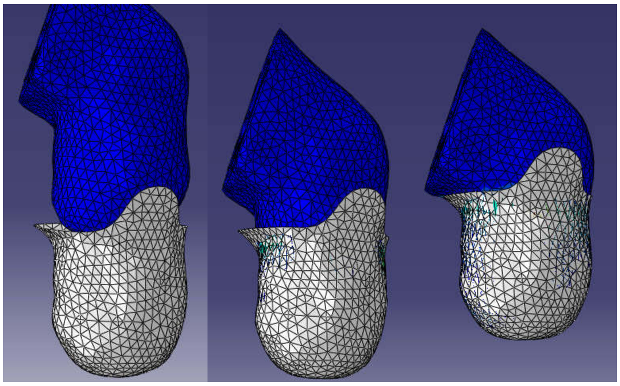
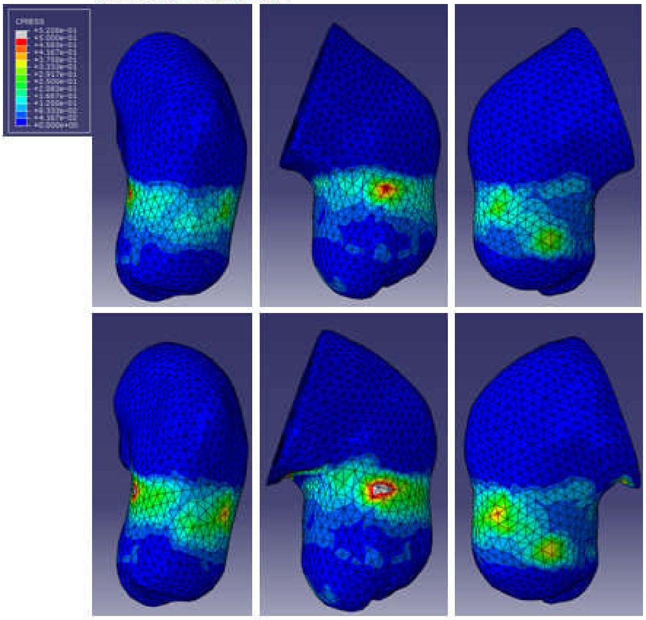


Fig. 9: Donning simulation.

DONNING SIMULATION



LOADING SIMULATION

Fig. 10: Donning and loading simulation: front and side views.

To decrease the pressure in the medial tibia area (a “load” region), the geometric model of the socket has been modified and re-executed the simulation. Fig. 11. shows the Sculpt tool to modify socket shape making it less tight in the medial tibial area and new pressure distribution where the pressure values are below the threshold.

Finally, as final test, we have considered the introduction of the silicone liner interposed between the residual limb and the socket since it allows a better redistribution of the pressure. The liner was characterized as a linear elastic isotropic material (density 2 Kg/dm^3, Young’s modulus 0.5 MPa and Poisson’s ratio 0.45) with constant thickness of 4 mm (Lin et al. [24]).

Although it’s just a coarse model, the results about liner shaped as skin on the socket surface are satisfactory and interesting; there is a general decrease pressure value , detected mainly in the medial tibia, which sees the peak pressure switching from 523 kPa (reference model) to 425 kPa (Fig. 12.).

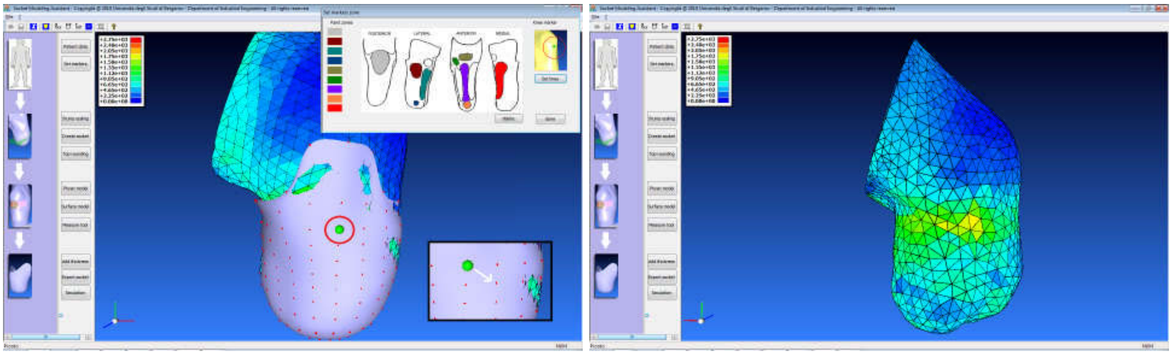


Fig. 11: (a) Socket shape modification and (b) new pressure distribution.

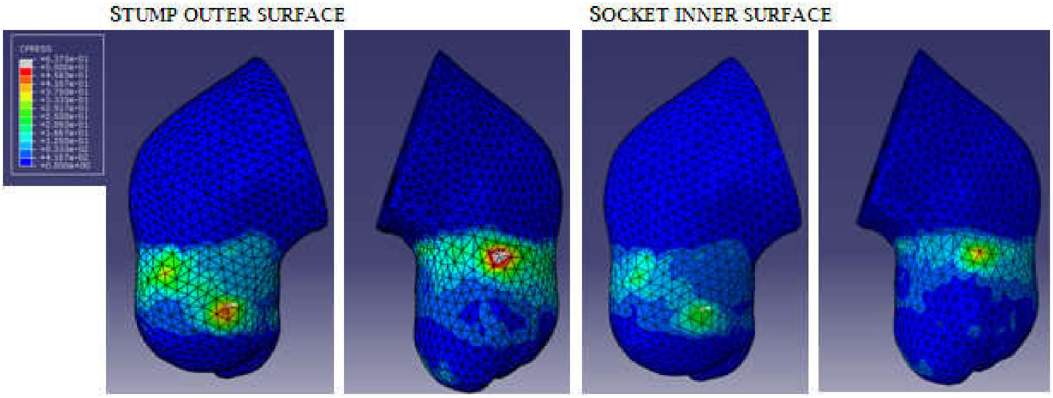


Fig. 12: Donning simulation with liner.

6 CONCLUSIONS

In this paper we have described a Virtual Socket Laboratory to design prosthesis socket. In particular, we have put the attention on the simulation of stump-socket interaction. From the analysis of state of the art, we have derived a simulation procedure that has been implemented within the Socket Modelling Assistant integrating a commercial CAE system.

The procedure and the integration have been experimented for a transtibial amputee. Preliminary results have been considered encouraging; however further tests and system refinements have been envisaged. First, we will acquire stump geometry with patient's postures as much as possible similar to those one when wearing the prosthesis. Then, we have planned to validate the procedure also for transfemoral amputees. Finally, an experimental campaign will be set to better characterise material properties with indentation tests and to acquire real pressure values in the critical areas of the considered human district.

To conclude, the new socket design tool could improve the prosthesis development process, simplifying and speeding up the technician tasks. It should permit to reduce number of prototypes and lower the psychological impact on the life of the patient; in fact a computer aided approach allows carrying out in a virtual way several tests of the traditional socket development process that are very bothering for amputees.

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