Virtual patient to assess prosthetic devices

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Abstract

In this paper we propose a digital model of the patient around which the prosthetic devices, in particular for lower limb, can be designed. The patient’s model is defined at different level of details, depending on the task to be accomplished. Three main tools are used to create the biomechanical model: a general-purpose human modeling system, medical images of the residual limb (obtained for example from Magnetic Resonance Imaging-MRI) and an ad hoc SW module for the automatic reconstruction of the residual limb model.

To create the patient’s virtual human we adopted LifeMOD™, a biomechanical simulation package based on MSC ADAMS solver. Starting from a default virtual human, it is possible to generate a customized model modifying anthropometric data. We considered two reference avatars, one for transfemoral amputee and another one for transtibial amputee, which have to be customized for each specific patient. To characterize the amputee’s avatar following data are necessary: (1) patient’s anthropometric data and (2) digital model of the lower limb. This means that the biomechanical model of the amputee is realized in two steps: the first concerns avatar’s dimensioning and the latter residual limb linking.

The patient avatar can be used both to design some specific components of the prosthesis and to virtually test it. Some examples will be shown in the paper as well as results reached so far.

Keywords: Digital Patient, Prosthetic device, Numerical simulation

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1. Introduction

During last years, Digital Human Modeling-DHM is becoming more and more popular thanks to its broad applicability within the product development process.

Depending on the target application, different models of the human body, or of its parts, with different levels of details can be considered. Ergonomics analyses of a product need a raw human skeleton able to replicate the human movements without any need of detailed anatomical information. Biomedical applications on the contrary require a precise description of anatomical district under investigation, including internal parts, such as muscles, bones or even blood vessels and nervous apparatus.

The research activities on modeling of a complete human body does not have an end in the near future, since the complexity of each apparatus of the body and, even more, the interactions among different apparatuses are still far to be captured in a model or a set of models. In the field related to the present research activity, i.e., the design and test of lower limb prosthesis in a virtual environment, the human avatar is considered having different level of details. The residual limb is described with accurate details of the external surface, the skin, and of the residual bone geometry. The rest of the body is modeled with a lower degree of precision because only the gait needs to be simulated.

Actually, artificial prosthesis for lower limb amputee is a product typically designed and highly customized according to patient’s morphology. The adoption of a digital model to represent the amputee is in line with the current research trend focused on multi-scale human modeling as a tool for a wide variety of applications from ergonomics to work safety and health (Coveney et al. 2011; McFarlane et al. 2011).

In the followings, we introduce the digital model adopted to represent the amputee; then, we show its role to virtually test the artificial prosthesis. Final remarks conclude the paper.

2. Modeling of the virtual patient

The virtual amputee constitutes the backbone of a new software platform to virtually design artificial prosthesis (Colombo et al. 2013). The patient’s model is defined at different level of details For example, the design of the socket (i.e., the most

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critical component of the whole prosthesis) requires a detailed model of the residual limb (skin, bones and muscles) around which the socket is modeled.

Three main tools are used to create the patient's model: a general-purpose human modeling system, medical images of the residual limb (in our case, Magnetic Resonance Imaging-MRI images) and a hoc SW module for the automatic reconstruction of the residual limb.

To create the amputee's model following data are necessary: (1) the patient's anthropometric data to customize the human model and (2) the digital model of the lower limb to replace the leg.

Therefore, the biomechanical model is realized in two steps: avatar's dimensioning and residual limb linking, as described in detail in the following sections.

2.1. Patient's reference model

To create and simulate the patient's avatar we used LifeMOD™, a biomechanical simulation package based on MSC ADAMS solver. It allows creating a detailed model of human body using rigid links connected through joints to simulate the skeleton, and flexible elements to represent muscles, tendons and ligaments.

Starting from the default virtual human, we defined two reference avatars: one for transtibial amputee (patient with amputation below knee, Figure 1a) and another one for transfemoral amputee (patient with amputation above knee, Figure 1b) that must be customized for the specific patient.

2.2. Residual limb model

The residual limb model is fundamental to design the prosthesis, in particular the socket, and to simulate gait.

To acquire the residual limb morphology, we decided to use Magnetic Resonance Imaging, since it is the less invasive for the patient and commonly used in considered field (Faustini et al. 2006; Lee et al. 2004).

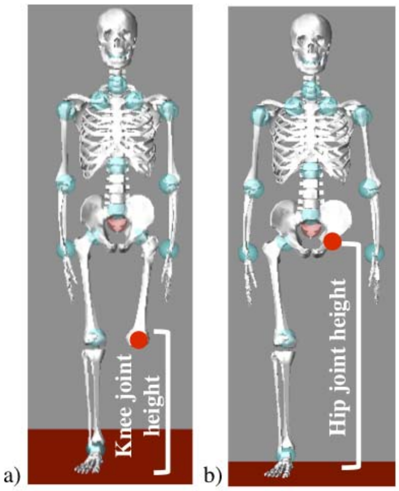
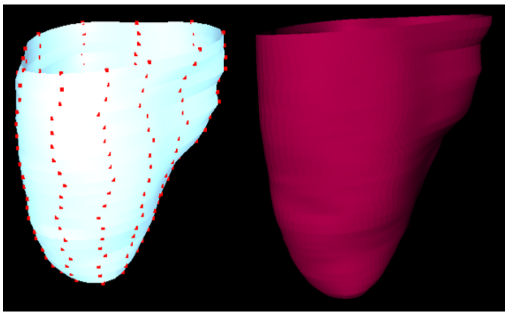


Figure 1: a) Transtibial and b) Transfemoral reference models.

The 3D reconstruction can be manually performed using commercial (e.g., Mimics) or open sources systems (e.g., 3D Slicer) we can find in the scientific literature. However, the final users of the before-mentioned design platform are orthopedic technicians without specific competences and skills on computer-aided tools (e.g. tools for medical image processing); therefore, we decided to implement a software module that automatically reconstructs the three-dimensional model of the stump without requiring human intervention and starting for the MRI volume.

The software module has been implemented using C++ languages, NURBS++ library, VTK library for polygonal conversion, and OpenCascade library for IGES exporting.

The reconstruction procedure is composed by three different phases: image pre-processing, voxel segmentation, 3D models generation. In the first one, the MRI images are pre-processed in order to reduce noise and digital artifacts. Initially, we tested a classic Gaussian smoothing but, in our case, this kind of filter did not preserve edge very well. Thus, we implemented noise reduction with a 3D anisotropic diffusion filter (Perona and Malik, 1990). This noise reduction fits our purpose since it can also work in three dimensions and we can apply the filter to the whole 3D matrix of voxels. The second phase consists in segmenting the voxels belonging to the bone and those to the external surface and in discarding the other ones. The final output is two clusters of voxels representing the geometry of bone and of the external surface from which we can derive the soft tissue. In the last phase, the procedure, starting from the voxels cluster of bones and soft tissues, creates the 3D geometric models. This operation is carried out using NURBS surfaces. The control points of the NURBS are placed on the external perimeter of the cluster to define the correct shape. Then, the module can export a standard IGES or an STL file after triangulating the NURBS surface. Figure 2 and 3 show respectively the NURBS and tessellated models of the external surface and of the bone considering as reference a set of MRI images acquired for a transfemoral amputee.



a) b)

Figure 2: a) NURBS and b) tessellated model of the external surface

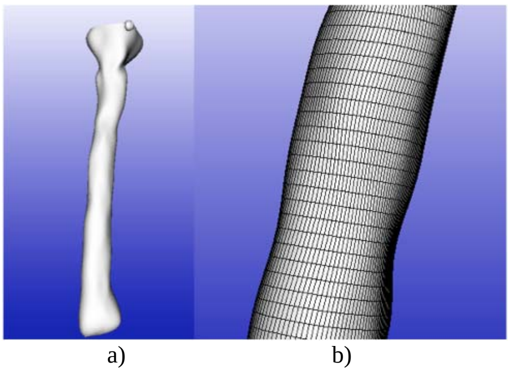


Figure 3: a) NURBS and b) tessellated model of the bone

2.3. Customized patient's avatar

Anthropometric data are necessary to customize the reference model for the specific patient. We distinguish between general data (e.g., weight, height, shoulder height) to properly size the avatar and residual limb measures to position and link the residual limb and the prosthesis to the avatar (e.g., knee joint for transtibial or hip joint for transfemoral, Figure 1).

Once entered or automatically acquired the necessary data, LifeMOD™ automatically applies the first level of customization to the virtual amputee generating skeleton, joints and soft tissues on the basis of anthropometric measures.

The following phase consists in importing and linking to the avatar the residual limb to replace the leg. This operation is performed in two steps:

- The bone segment is first linked to the virtual hip (transfemoral) or to the knee (transtibial) using, respectively, the hip joint and the knee joint height.
- Then, the residual limb soft tissues are accordingly positioned.

As an example, Figure 4a shows the virtual avatar of a transfemoral amputee, 50 years old, 175 cm tall.

2.4. Patients avatar wearing the prosthesis

As mentioned, the aim of the project is to use the digital patient to virtually assess medical devices and, in particular, artificial legs. This means that digital amputee has to wear the digital prosthesis. To this end, we have created the 3D prosthesis model using the software platform we have specifically developed for lower limb prosthesis (for further details see Colombo et al. 2013) and linked to the human model. The 3D prosthesis is imported using IGES or Parasolid format and the correct positioning of each part is obtained taking into account the prosthesis height and foot rotation respect to the vertical line. In particular, the socket alignment respect to soft tissues is guaranteed using the same coordinate system adopted inside the modeling environment; while, the prosthetic foot is aligned symmetrically to the other one.

Figure 4b portrays an above knee amputee's avatar wearing the prosthesis.

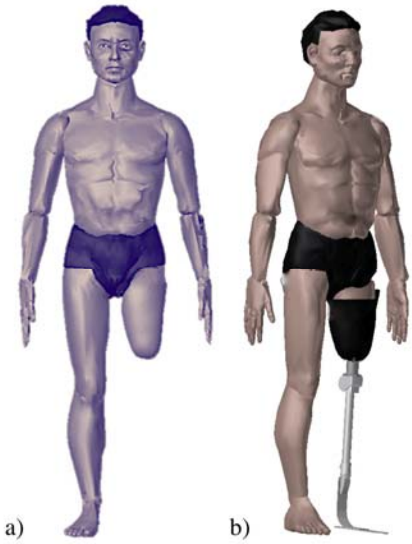


Figure 4: a) Customized transfemoral avatar and b) avatar wearing the prosthesis

3. Simulation of the virtual patient's gait

The overall goal is to provide an environment where the orthopedic technicians can test the prosthesis replicating the traditional procedures. For this purpose, we are collaborating with the technical staff of a qualified orthopedic laboratory since they can provide the domain knowledge about prosthesis development process.

The underlying ideas are: (1) to study the interaction between socket and residual limb during gait and (2) to analyze the patient's gait deviations.

To prove the validity of our approach, we simulated the digital patient's gait using LifeMOD and we implemented a Finite Element Analysis model to analysis the stump-socket interaction.

Patient's walking has been simulated using motion laws deduced from experimental data acquired with a marker less mocap equipment, based on four Sony-eye webcams (Colombo, Regazzoni and Rizzi 2013). The motion law is described by *motion agents* that drive the skeleton joints and teach to patient's avatar how to move. Once position and orientation of each avatar's links are known and traced, LifeMOD proceeds with the inverse dynamics simulation to get internal forces, torques and ground reactions. We tested the procedure considering as case study a unilateral transfemoral male amputee, 50 years old, 176 cm tall and 78 kg weight and the patient was asked to walk as naturally as possible on a straight path.

3.1. Socket-residual limb interaction: preliminary results

In this case the aim of the simulation is to evaluate forces transmitted on the residual limb-socket-prosthesis system during walking, and in particular, loads acting on the socket. We focused the attention on the first step of the patient's walking, when s/he starts to walk, because it's the most challenging in terms of involved forces. We consider the patient's avatar during loading step in three different stance phases: initial loading response, midstance, and terminal stance. Specifically, to avoid convergence problems in FE analysis, we neglect the first and last frames of the stance phase where the load values are lower than 25% of the magnitude peak. Figure 5a shows the filtered numerical result of the three force components, and the magnitude over the first stance phase.

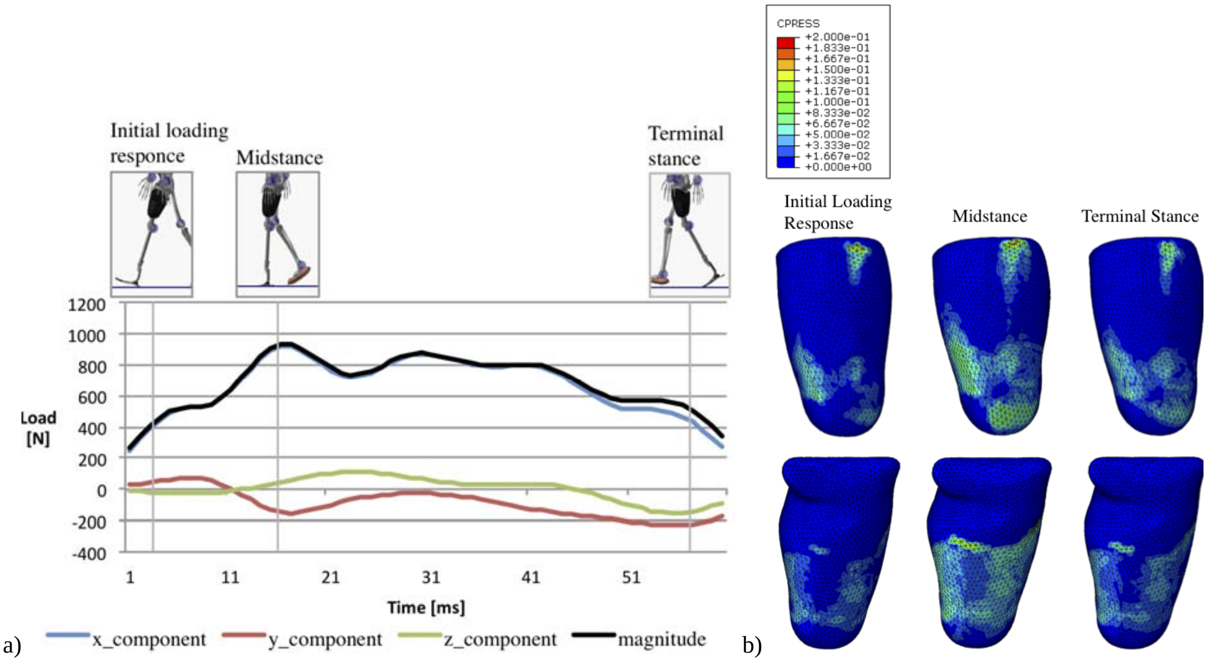


Figure 5: a) Load components acting on the socket during stance phase and b) Pressure distribution on stump surface during loading step in three different stance phases

Among the various FE solvers commonly used in this field, we adopted Abaqus package V 6.9 (Dassault Systemes S.A.). We first identified a model using the Abaqus/CAE; then, we generalized the commands to obtain a script that automatically implements the FE model and executes the analysis applying the loads computed during the avatar's gait simulation. The socket is imported as 3D shell, while bony structure and soft tissues as 3D solids. Bones and soft tissues are merged to form a single part, the stump, without geometric discontinuity but characterized by two different materials. We used 3-noded triangular (S3R) elements for the socket and 4-node tetrahedral (C3D4) for the residual limb, with growing size in the internal regions. The seed values have been chosen performing a sensitive analysis. Concerning material properties, we considered a linear, homogeneous and isotropic model to limit the computational time. Mechanical properties of materials are derived from literature (Goh et al. 2005). We considered the socket and the bony structures as rigid bodies without losing crucial information about the pressure interface.

Before simulating the stance phase using the loads achieved from gait analysis, we performed two phases corresponding to the deformation stages of soft tissues. In the final step, the forces, computed by gait simulation, are applied as load to the centre of mass of the socket to simulate the single stance over the phase from initial loading response to terminal stance.

Boundary conditions and loads have been defined according to the simulation step. To model the interaction between stump and socket, we adopted the automated surface-to-surface contact element since it is better than the traditional point-to-point contact pairs, as reported in a previous study (Wu et al. 2003). 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 0.4 as documented in (Zhang and Mak 1999).

Figure 5b portrays the pressure distribution over the stump surface during loading step in three different stance phases. Pressure values are associated to a color scale, from blue to red, covering a range of fixed values from 0 to 200 kPa; the areas that exceed the maximum are colored in gray. The pressure distribution is homogeneous, except for the greater trochanter area, which seems to be overstressed. During the loading step the pressure distribution increases, as it should be, without exceeding 100 kPa in most areas of the residual limb. Similar data can be found in literature, as described in a previous study (Hong 2006). However, our goal was to verify the feasibility of our approach. Even if preliminary results have been considered interesting by the prosthetist, we need to perform further activities to fully validate our approach and the FE models.

3.2. Gait deviations analysis

The goal is to extrapolate geometric or dynamic parameters for each body segment or joint in any time frame of the gait simulation and to identify gait deviations. Gait deviations are defined according to the Atlas Limb of Prosthesis (Berger 1990) for lower limb prosthesis. To this end, we have defined a map connecting each deviation in the amputees' gait with the only parameters sensible to the said deviation and with a range of referring values. Once that the direct simulation of the gait has been simulated with LifeMOD, we are able to plot all the geometric and dynamic parameters of each joint or body segment in any time frame.

We found out that it is possible to cut the number of variables to a limited set, often only one, that clearly identify the particular gait problem. For example, for circumduction deviation, even if the entire body is involved, we can determine its presence only by means of the hip frontal angle. Actually, by measuring the angle of the hip in the frontal plane during swing we are able to identify this problem. The analysis of the entire classification of deviations (Berger 2013) has led to a set of parameters comprehending not only geometric but also dynamic dimensions and time.

For our case study, main deviations are related to lateral trunk bending, swing-phase whips and terminal impact (Berger 2013). The lateral bending of the trunk is the main deviation and it is clearly identified by the gait analysis (Figure 6). Actually, the patient, after four years of good use, was going to change the socket of his prosthesis. This happened because, due to a patient's loss of weight and muscular mass, the socket was no tight enough to work properly. As a consequence the quality of the gait decreased causing lower back pain and an intolerable friction between socket and residual limb.

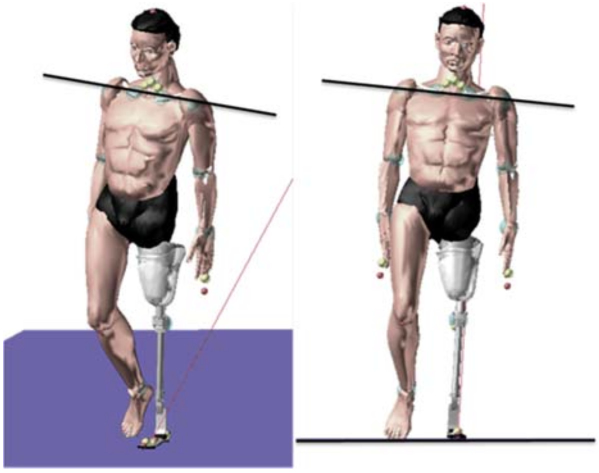


Figure 6: Digital model of the amputee patient in LifeMod environment showing a high lateral bending of the trunk

The results of the gait deviation test have been analyzed together with orthopedic technicians who appreciated the approach used as well as the first outcomes with the patient.

4. Discussion

Regarding the virtual patient, the modeling procedure by means of LifeMOD has been considered adequate. The module for the automatic reconstruction of the residual limb geometric model has been primarily tested for transfemoral amputees and we compared the results with models reconstructed using a commercial package and following a hand-made procedure. The results have been considered satisfactory even if the model of the bone is less accurate. In any case, the model can be automatically reconstructed without human intervention and geometrical models are suitable for socket design and finite element analysis.

We have planned to improve the reconstruction of the bone. The segmentation graph algorithm loses some voxels belonging to the bone, due to high difference of voxel intensity. New features, such as texture characteristics, will be introduced during clustering. Furthermore, a shape analysis of the temporary cluster created during the segmentation will be performed to drive the segmentation toward the correct final clusters shape.

The use of the amputee's avatar wearing the prosthesis to evaluate the socket-residual limb interaction has been considered valuable; the simulation results could offer precious information to characterize the pressure distribution on the stump under different walking conditions and improve quality and comfort of the prosthetic socket. Next step concerns the validation of the FE model. In literature we can find two main approaches: the first consists in comparing the computed pressure values with those measured with pressure transducers, the latter in assessing the virtual soft tissue deformation with the real ones acquired by MRI during fitting or loading phase. We have planned to adopt the first approach. In addition, we are considering non-linear characterization of soft tissues.

Regarding the virtual detection of gait deviation, this study constitutes the starting point for two further activities that will complete the virtual testing phase. First, the motion tracking of a considerable number of amputee patients will be exploited for the building of a database of motion laws. These last ones will constitute the basis for the predictive simulation of virtual gait. Then, the gait deviations analysis will permit to link a set of rules to change the set-up of the virtual prosthesis in a closed loop until the desired performances are reached.

5. Conclusions

In this paper, we presented the virtual model of an amputee to assess the design of lower limb prosthesis.

Simulating with good accuracy the real behavior of the amputee’s avatar standing and walking on the new prosthesis is a challenging goal. To this end, we have considered two different simulation tools: the first one to study the interaction between socket and residual limb during gait and the second one to analyze the patient’s gait deviations. Combining these numerical analyses, it is possible to investigate the causes of gait deviations and suggest remedies, both related to the prosthesis setup and the socket modeling.

We have identified a procedure to characterize a patient’s avatar wearing the prosthesis and to simulate the prosthesis behavior by means of a virtual patient. We verified the feasibility of our approach with a transfemoral case study and preliminary results have been considered encouraging and promising. Further developments are necessary both to validate the FE model and develop a library of laws of motion for the predictive simulation of the patient’s gait. Moreover, it will be necessary to make easy the use of numerical analysis also by people, like prosthetist, without specific competences on computer-aided tools. In this context, the collaboration with the orthopedic technicians to validate the simulation procedure is crucial to acquiring their knowledge, extrapolate rules and validate the results.

Finally, the use of a virtual patient could improve the prosthesis developing process. It should permit to reduce the psychological impact on the life of the patient since a computer aided approach allows carrying out in a virtual way several tests of the traditional socket development process that are very bothering for the amputees.

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