A Digital Patient for Prosthesis Design

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1 Introduction

Lower limb prosthesis are designed and manufactured almost completely in a manual way, deeply relying on experience and manual skills of orthopaedic technicians. Both below knee (transtibial - TT) and above knee prostheses (transfemoral - TF) are realised with the state of the art components in order to obtain the maximum comfort and usability for the amputees. Most of components (e.g., foot and knee) are standards and selectable from catalogues, except the socket that has to be manufactured on the basis of the specific anatomy of the patient. In such a context, our aim is to develop a design framework centred on the patient's digital model and on the technician' knowledge. To reach the goal of replacing the manual process with a virtual one several issues have to be considered and addressed: the capture and formalization of process knowledge of orthopaedic technicians, the acquisition of patient's information and digital data also by means of diagnostic instruments, the development of integrated solution to design and test standard and custom-fit components and the use of digital human techniques to simulate the way the prosthesis will behave during walking. In the following we first introduce the digital model we adopted to represent the amputee and, then, the new design framework as well as its main features.

2 Digital Amputee and Patient characteristics

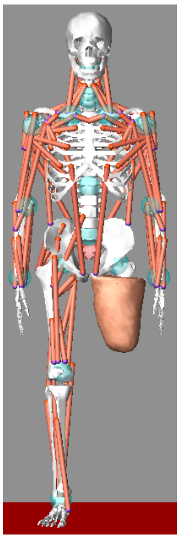
To create the virtual amputee we use LifeMOD, a biomechanical simulation tool based on MSC ADAMS solver. It permits to create a detailed biomechanical model of a human body using rigid links connected through joints to simulate the skeleton and flexible elements to represent soft tissues (muscle tissue, tendons and ligaments). Following data are needed: the patient's anthropometric measures and the digital model of the lower limb. The digital amputee will be used to design the socket around the detailed model of the residual limb and to validate the whole prosthesis simulating postures and movements. In addition the digital patient is enriched with amputee's characteristic (e.g., general health conditions, residual limb status, anthropometric data); they represent the key elements that guide the entire prosthesis development process, from standard component selection to socket shaping. Figure 1 portrays the avatar of the amputee and the list of considered characteristics.

The residual limb model is generated from MRI acquisition and a module for automatic reconstruction is under development. The final target of the reconstruction stage is to obtain the 3D model of stump (skin, muscles and bones) to be used for socket modelling. The module exploits some artificial intelligence techniques, such as unsupervised clustering and graph cut segmentation, to obtain a collection of curves and then to create loft surfaces. Later on, these surfaces are converted into a suitable format to be imported within the socket modelling platform.

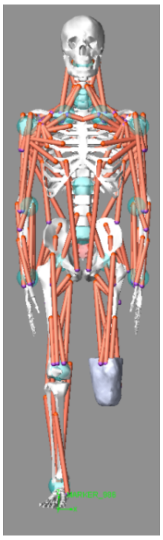
3 Design Platform

The proposed design platform provides the technicians with a set of tools to design, configure and test the prosthesis in a virtual environment. On the basis of the analysis of the traditional product and process knowledge required for lower limb prosthesis manufacturing, we reengineered the prosthesis design process and developed a knowledge-based design framework, which assists the technicians step by step providing for each activity specific knowledge and rules (e.g. dimensioning and selection rules for standard parts, socket shape deformation/manipulation).

Figure 2 shows the high-level architecture of the proposed framework where we can distinguish two main environments: the Prosthesis Modeling Lab and the Virtual Testing Lab-VTL.



a)



b)

	Parameter
Patient Evaluation	Gender [Male or Female]
	Age [years]
	Patient force
	Life-Style [K1, K2, K3, K4]
	Pathologies [Yes or No]
Stump Evaluation	Amputation type [TF or TT]
	Amputation Side [Left, Right or Both]
	Stump stability [Yes or No]
	Shape [cylindrical, conical, not-standard]
	Bone protub. [widespread, on top]
	Skin conditions [sensitive, normal, scars, scratches]
	Tonicity [low, normal, good, very good]
Anthropometric Measures	Height [mm]
	Foot lenght [mm]
	Weight [kg]
	Residual limb length [mm]
	Knee height [mm]
	Thigh length [mm]

c)

Figure 1: Amputee's avatar: a) transfemoral; b) transtibial; c) patient's characteristics

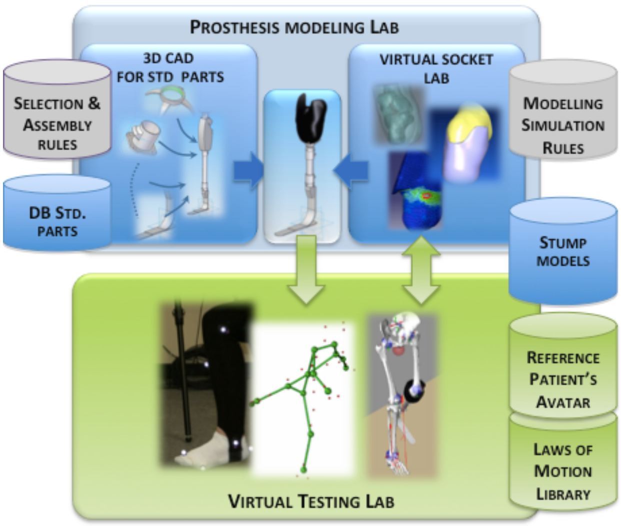


Figure 2: Design framework for prosthesis design

The *Prosthesis modelling lab* permits to generate the 3D assembly of the whole prosthesis, crucial to virtually study prosthesis set-up and patient's walking. It guides the technician during the 3D modelling phase and selection of standard and custom-fit components of the prosthesis on the basis of the digital mock up of the anatomical district, the patient characteristics (e.g., anthropometric data) and the level of usage of the prosthesis. It comprises:

- *A Virtual Socket Laboratory*-VSL developed to create the 3D model of the socket. This step uses an ad hoc socket modeller, named Socket Modelling Assistant (SMA) [6], integrated with FE tools to study the stump-socket interaction. Using SMA, the technician can model the socket using virtual tools that emulate the traditional procedures for socket manufacturing.

Once the first 3D socket model is generated, the FE analysis is automatically executed in order to determine the contact pressure with the residual limb and then optimise the socket shape. The Socket Modelling Assistant is developed with C++ language, VTK library (Visualization ToolKit) for 3D visualization and MFC (Microsoft Foundation Classes) for the graphical user interface. In order to carry out FE analysis in an effective way, SMA has been integrated with a FE commercial package, Abaqus, exploiting the Abaqus Scripting Interface (an extension of Python language) for data exchange.

- A commercial 3D CAD system (SolidEdge) to configure the prosthesis, generate the 3D models of the standard parts and the final assembly. The dimensions of the components have been taken from real ones and from data available in commercial catalogues. Since our purpose is to correctly assemble and check a virtual prosthesis, and perform a virtual gait analysis, CAD models have been properly simplified: we considered the characteristics that affect static and dynamic behaviour, such as weight and joints position, and not the actual shape and appearance of components. For the extrapolation of guidelines to select the standard components, we have studied the indications given in commercial catalogues by the most important prosthetic providers, and the rules adopted by technicians on the basis of their personal expertise. Thus, we have elaborated a procedure and electronic sheets to choose automatically the appropriate components for each kind of amputee and accordingly size them.

The *Virtual Testing Lab*-VTL permits, once created the amputee's avatar wearing the prosthesis, to set up and evaluate prosthesis functionality simulating postures and movements. The underlying idea is to develop a library of laws of motion specialized for amputees wearing the prosthesis. To this end, it is necessary to acquire patients' movement and posture during typical daily-activities.

At present, the approach has been tested using a markerless motion capture system to acquire the motion laws of the patient's joint and simulate posture and movement with LifeMOD™. Six cameras and a workstation for data triangulation compose the system. It does not require the patient wearing markers, since it is based on image and silhouette analysis. In this environment, the patient has to perform typical daily-activities, such as walking, sitting, going on a step, and so on. Obviously precision of the tracking data is crucial and we are testing the quality of a webcam-based solution. We are dealing with some issues, such as some imprecision in the ankle movement.

Figure 3 shows a transfemoral amputee and the simulation of amputee walking on a floor and going up a step.

Modelling and simulation tests were performed on workstations with the following technical characteristics: Intel Xeon W3505 2.53 GHz processor, 12.0 GB DDR3 1333 Mhz RAM, Nvidia Quadro FX580 graphic unit, Windows 7 Ultimate 64 bit operating system.

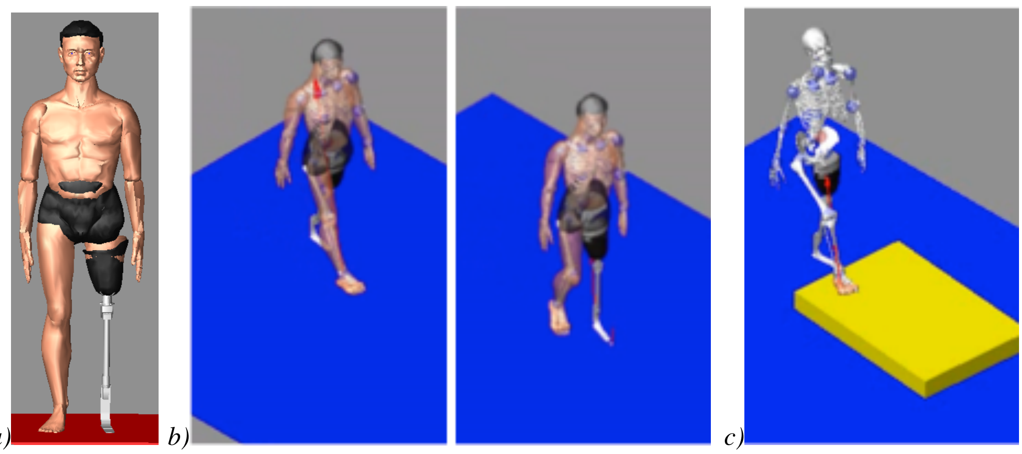

a) b) c)

Figure 3: a) transfemoral avatar; b) walking on a floor; c) going up a step

4 Conclusions

The system has been experimented as far as concerns the modelling phase while only preliminary results have been obtained for the virtual testing lab. Modelling approach and tools have been tested with the technical staff of an orthopaedic laboratory. Modelling tools were appreciated by the technicians for their ease of use and the configurations suggested by the system correspond to those obtained following traditional procedures, with the advantage that different configurations can be generated and compared more easily.

Concerning the Virtual Testing lab, preliminary results are promising; however further enhancements and system refinements have been envisaged. For instance, we are going to plan a campaign to acquire motion laws of joints during daily activities accordingly to the patient's life-style. Then, a set of simulation tests will be performed to verify the performances of the framework and implemented procedures.

We feel confident about the extension of the framework to other kind of prostheses, primarily for those types in which a patient specific modelling is required, starting from 3D anatomical models. We could adapt the MRI 3D reconstruction, modelling and FE analysis stages. Conversely the Virtual Testing Lab is very focused on the analysis of amputee movements, even if we can customize the LIFEmod virtual avatar according to the specific problem, such as upper limbs amputees.