3D DIGITAL MODELS RECONSTRUCTION: RESIDUAL LIMB ANALYSIS TO IMPROVE PROSTHESIS DESIGN

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ABSTRACT

The paper introduces some important aspects of an innovative methodology which authors are developing, based on digital data and computer tools to optimize lower limb socket prosthesis design. Socket customization is essential in order to obtain the best adaptability for the patient's body, guaranteeing a high functional degree, comfort, durability and prevention of medical complication. Until now, lower limb prostheses have been designed and manufactured with handicraft methods, depending on the skills of the orthopaedic technician. Our research aims at introducing the use of computer aided methodologies and tools in this context, where they are not commonly and intensively used. The methodology consists of the reconstruction of stump digital model, the simulations on the digital model for obtaining the stump deformed shape, the design of the socket over stump deformed shape and socket manufacturing. Finally, the last step consists of the evaluation of the socket comfort perceived by the amputee and the analysis of the functionality of the prosthetic components by means of the gait analysis. The methodology has been tested on four patients with a trans-tibial amputation as an experiment.

1 INTRODUCTION

The successful design and fitting of a prosthetic socket results in the effective transfer of forces from the socket to the residual limb, such as the amputee can maintain daily activities without damaging tissue or experiencing pain: in fact, the most common reason for residual limb pain is due to an intolerable pressure applied to the stump. So uncomfortable socket may cause many clinical problems, such as dermatitis or skin lesions, due to the friction against the prosthetic components; the altered biomechanics induces a postural disequilibrium with progressive decrease of quality of life. In the last years the increasing involving in sports related activities strongly enhanced the request of the best custom-made prosthesis.

In order to improve the prosthetic socket design and fitting, it is necessary a comprehensive understanding of the pressure distribution at the socket–limb interface and of the residual limb strength to withstand pressure. In current practice, technicians have to rely on their clinical experience in prosthetic socket design and manufacturing, because socket fit assessment can only be valuated after prosthesis manufacturing and fitting: if the comfort is insufficient, the socket should be re-designed, requiring extra time and costs. Moreover, the residual limb general features, such as geometry, size, and load bearing tolerance, vary from person to person. In addition, socket shape obtained manually by technicians is not an exact replica of the residual limb: it includes some appropriate rectification to optimize stresses at leg interface. More quantitative and objective information about residual limb modification, its load tolerance and the bio-mechanical interaction at the stump-socket interface is required in the prosthesis fitting process. Consequently, that would provide a satisfactory socket design, a reduction of time-consumption or unnecessary complications for the amputees, which may greatly affect their daily activities.

The residual lower limb is subject to continuous morphological changes (Nawijn 2005), both at short and long term; these changes require a new socket realization when any significant variation occurs. On residual limb prosthesis, studies have detailed residual limb analysis with imaging technologies, such as CT (Smith 2001), MRI (Buis 2006) (Douglas 1998) and ultrasound system (Douglas 2002). Some studies investigate the interface pressure between the residual limb and the prosthetic socket, analyzing and outlining a variety of sensors and transducers (Sanders 1997; Neumann 2005; Sellen 2003) or applying Finite Element Analysis tools to simulate pressure distribution and to define material properties assumptions (Ming 2000; Lee 2004; Lee 2006).
The paper presents an innovative methodology based on digital data and computer tools for the optimization of lower limb socket prosthesis design. The methodology has been tested experimentally on four patients with amputated limb below the knee; the patients were three men and a woman, aged between 25 to 40 years old, with a stump length of approximately 10 cm below the tibiae plate.

2 SOCKET DESIGN METHODOLOGY

2.1 Traditional socket manufacturing

The traditional socket manufacturing has different steps: after taking some reference measurements of the stump (Fig.1), the orthopaedic technician manually moulds some chalk bandages on the stump, pressing on the landmarks which correspond to stump loaded parts inside the socket (Fig.2), like the under patella zone and popliteal fossa. The chalk negative cast is used to obtain a positive model, which is modified when necessary and used to produce the socket.


Fig.1 Measurement of stump with liner


Fig.2 Chalk negative cast


Fig.3 Positive cast

When the positive cast is ready, if the measures are different from those of the reference ones, the orthopaedic technician files the model until the measures coincide: this last model is used to make socket by lamination. Specific attention (Fig.3) is due to the definition of the stump most critic zones, like the tibia apex and other bone prominences (cyan zones), which are maintained without compression to avoid residual limb pressure against the socket.

2.2 Proposed methodology

The proposed methodology for socket design is based on the following main activities (Fig.4).
We acquire the stump by different technologies: Reverse Engineering (RE) technologies, specifically, a non contact laser scanner system, for the limb external surface acquisition; medical imaging technique, such as Computer Tomography (CT), and Magnetic Resonance Imaging (MRI), used for complete residual limb acquisition, divided into components (bone structure and dermis).
Firstly, we consider the problem of the reconstruction of stump digital model; it requires a measurement phase and a following CAD modelling task. Secondly, simulations on the digital

model are necessary to obtain the stump deformed shape, corresponding as much as possible to the shape the stump assumes during motion or during manipulations performed by the orthopaedic technician: we analyze stump behaviour and modifications comparing data from traditional socket manufacturing and gait analysis tests. The subsequent steps concern the design of the socket over stump deformed shape and socket manufacturing by using Rapid Prototyping (RP) techniques.

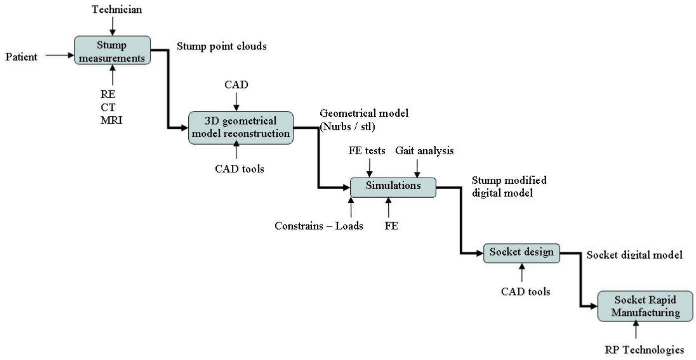

Fig.4 Socket design flow-chart

Finally, the last step consists of the evaluation of the socket comfort perceived by the amputee and the analysis of the functionality of the prosthetic components by means of the gait analysis.

In fact, the stump geometric model is used for physics-based simulations, detailed socket design with CAD tools and for producing the socket directly with some Rapid Manufacturing technique.

3 STUMP RECONSTRUCTION

The first step of our research was the reconstruction of the stump digital model, acquired both by laser scanning (limb external surface) and CT/MRI medical imaging (complete residual limb with bone structure and dermis). During this phase, we considered all problems related to 3D geometric reconstruction: the patient and stump positioning for the different acquisitions, markers definition on the stump to identify landmarks, alignment strategies for the different digital models in order to define a protocol procedure with the requested accuracy for socket production. Particular attention was paid to points which define the biomechanics and should afflict the virtual model accuracy.

The second step consists of comparing the digital model and the one obtained by the orthopaedic technician. The obtained results demonstrate that this practice, which provides both 3D digital data and RGB textures, allows us:

- to acquire the morphology of the stump in less invasive way for the patient;
- to have textured digital models, which permit an easy evaluation of the assessments and/or alteration suffered by limb for the normal post-surgical course and for skin abrasions and blisters, during everyday life;
- to detect the variations of shape and volume, due to incorrect pressures at the limb-socket interface, highlighting also the possible changes depending on the posture.

3.1 Laser scanning

For what concerns the patient’s posture during the acquisition phase, we defined a configuration which reproduces the lower limb position during manual measurements for chalk manufacturing, making a supporting device which maintains the residual leg with an angle of nearly 30° between femoral bone and tibiae, while the patient is lying on a bed totally relaxed. In order to guarantee repeatability of the acquisition set-up, and to have some more fixed parameters for limb configuration, we use markers for identifying anthropometric standard points that indicate zones with fewer variations of shape and volume opposed to the other stump parts. We use lead shot markers for laser scanning and CT (Fig. 5), and vitamin E tablets in the MRI.

We use a typical RE system, the laser scanner Minolta Vi-9i, equipped with a middle lens, having f = 1.4 mm. In this specific application we used the following settings:

- in order to limit the acquisition time as much as possible and to avoid muscular contractions, a single stripe light is scanned, applying only a filter for noise reduction and edge control (Fig.6);
- the depth of view is about 850 mm (±100 mm) to keep measurements in the standard instrument field and guarantee laser acquisition accuracy. The 3D digital models were reconstructed with a good precision, obtaining the standard deviation of the model alignments of about 1mm (± 0,2 mm): we accept this tolerance according to socket's operability.

Fig. 5 Stump with markers

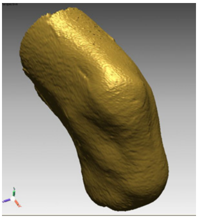

Fig.6 Laser digital model with noise

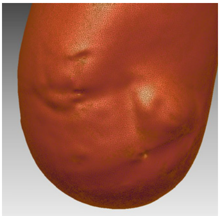

Fig.7 Mesh detail (253200 triangles)

The difficulties of the 3D digital reconstruction were mainly related to stump deformability, due to muscular contractions occurring during the acquisition and to skin artefacts resulting from the amputation surgery: they were corrected verifying in each case that the mesh deviation remains within the fixed tolerance limits. For markers set we used a Davis' protocol (Davis 1991) which was changed according to lower limb amputation: femoral epicondyles, patella plate and the tibia apex define the stump measures. In addition, other reference points were considered, projecting the principal points into the sagittal and frontal planes, in order to create a grid for scans alignment. Similarly, we decimated the mesh to keep the digital model as light as possible (Fig. 7).

3.2 Medical Imaging

Bones are reconstructed from both CT and MRI: in fact, MRI imaging cannot be used when the patient has inner metallic support applied to bones after amputation, and CT is more diffused on territory. Moreover, the orthopaedic surgeons consider CT scans more useful than MRI ones to define the bone morphology; the computed assisted orthopaedic surgery as well as the design of last generation of hip and knee prosthesis were developed on CT scans. The newest CT software permit an accurate three-dimensional bone reconstruction with a slice thickness of 5 mm providing a minimum X-ray exposure. For these reasons we adopted CT to reconstruct the geometry of the bony structure through medical images conducted on the residual limb with axial cross-sectional images. We let to RMI a role of controlling the precision of soft tissues' reconstruction obtained with CT scans.

CT acquisition has been performed using the PICKER PQ 5000 by Philips-Marconi Medical System, at the Radiology Division of the Orthopaedic Institute "Gaetano Pini" in Milan. The DICOM standard format for the 2D images has the following parameters: bitmap dimension 512x512 pixel, 16 bit, pixel size=0.3/0.5mm, DFOV of 20x20 cm. The bony structures and the soft tissue boundaries are identified within the images and segmented using MIMICS v9.01(Materialise, Leuven, Belgium). The resulting digital models had good quality in the 3D bone reconstruction, while the external surface had less definition referred to anatomic characteristics, such as cicatrix and abrasions which have great importance in the socket-limb interaction (Fig.8).

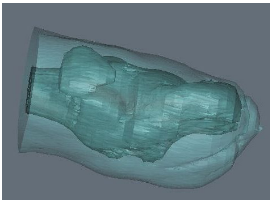

Fig.8 Test2- CT skin/bone model

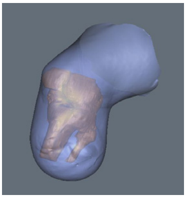

Fig.9 Test1 – MRI skin/bones model

As far as CT acquisitions are concerned, we adopted the same limb support employed during laser acquisition, in order to keep the residual limb fixed in the delivered position; this support was easily integrated into the standard CT acquisition equipment tools.
For MRI we used a GE Medical Systems, 1,5 Tesla Signa Excite, at the Centro Diagnostico Italiano, in Milan. We set the following test parameters values: slices of 20x20 cm, 256x256 pixel, pixel size= 0.78/0.82mm, obtained using a sequence with Repetition Time= 38/50, Echo Time=1,5/1,6, Flip Angle= 30°. Some problems occurred using our supporting device, whose integration with the MRI apparatus used for lower limb scanning was difficult; the magnetic knee bore has a diameter of only Φ =40cm and requires horizontal leg positioning, while our system needs a little more volume in order to be fully performing. MRI slices were affected by noise, which needed a pre-processing filtering to improve definition, causing a loose in detail quality; the reconstructed digital model has been recognized quite similar to the laser model, with a less accurate and detailed surface (Fig.9).

3.3 3D digital model

We noticed that the 3D digital model reconstructed with a laser scanning RE system presents a better correspondence to the real skin surface: it shows all the “abnormalities” due to amputation, stump conditions and socket possible interactions. We use this model as reference for the complete 3D reconstructed model. To obtain the 3D digital integrated stump together with the external surface and the inner bone structure, we align the different model into the same reference global system, using the software Geomagic Studio 7.0 to check the differences. We obtain good models positioning (Fig.10), especially in the anterior limb part, corresponding to the tibiae, while variations are located in residual limb apex, where soft tissues are.

4 STUMP – CAST ANALYSIS

In order to evaluate the obtained model as a first virtual cast for designing the socket, we compared this model with the digital one obtained through RE of the positive plaster cast made by the orthopaedic technician (Fig11). The aim is highlighting possible differences and critical zones whose deformations strictly depend on technician’s manipulation. We consider a positive plaster cast obtained from the limb wearing a Thermoliner™ Cushion EDFR, 6 mm thickness, by Alps™, and the 3D digital model, whose volume was increased of a surface offset having the same thickness. The comparison shows the following:
a. The digital models correspond in the bones critical zones, such as the tibia prominences , with both tibia crest and its inferior extremity (Fig.11: green area). These are the zones where orthopaedic technician assure no loads on stump, to avoid problems on bones/socket interface; the plaster cast profile (red line) remains outside the stump.
b. Significant differences between plaster cast and the stump were located at:

- the popliteal zone (Fig.11: red area) where the orthopaedic technician exerts pressure on stump, to guarantee the maximum socket adherence, to create a closing zone which enables socket movement and avoids stump contact with the socket bottom;
- the fleshy parts on the bottom of the stump (Fig.11: cyan area) that the orthopaedic technician manipulates to reduce and compact volume.

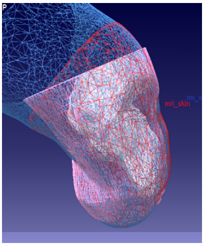

Fig.10 Models into global reference system

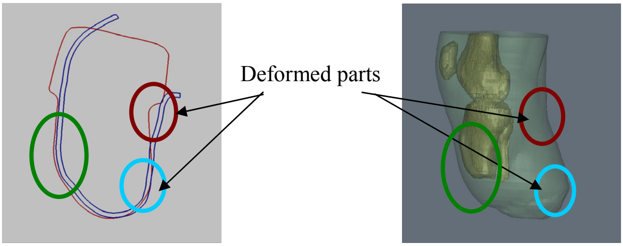

Fig.11 Sagittal section on limb (blue) and plaster cast (red):
a. sectioned, b. 3D limb with bones

5 PROSTHESIS FITTING EVALUATION

The orthopaedic technician can evaluate both socket and prosthesis good performance by considering: the comfort perception and prosthetic aid acceptance from the amputee subject (Menard 1989), stump conditions, to verify that the loads areas are respected and that there are no suffering in the critical zones (bony prominences) and finally the walk functional evaluation through Gait analysis, to confirm the prosthetic components correct alignment (Czerniecki 1996, Gitter 1996) and the prosthesis correct manufacture. In our research we performed the gait analysis in two steps: the first step concerns the gait of amputee with a traditional-made polyethylene thermoformed socket in order to fixing the reference level to compare performances of future socket manufactured with the new methodology. The prosthetic foot we used was TRIAS® by OttoBock. We performed our test in the MBMC Lab, Laboratory of Movement and Motor Control at Politecnico of Milan; the laboratory is equipped with the Smart Motion Capture System, and a Kistler piezoelectric force plate and the used protocol was SAFLO (Frigo 1998)with adaptation to prosthesis.

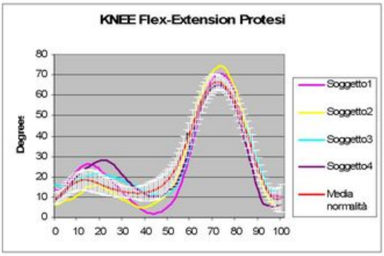

Fig.16 Knee Flexion-extension prosthetic limb

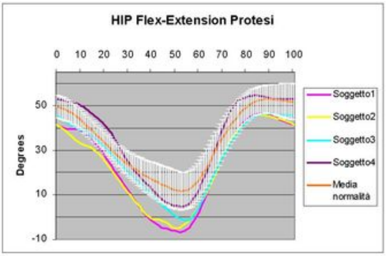

Fig.17 Hip Flexion-extension prosthetic limb

For our activity, we considered the movement of hip and knee joints (17,18,19) (Verni, Bateni 2002, Macfarlane 1991) to evaluate traditional socket fitting: the diagram four amputee subject results, one redline as normal subject average and white normal range. Considering knee joint diagram the four subjects lines were included in the normal range, except the subject 4 which introduces a greater flexion at moment of load acceptance as compensatory strategy : in fact the ankle moment diagram presents two spikes. Considering hip joint diagram, three subject introduced a greater extension at toe-off to compensate a smaller prosthetic ankle propulsive push, compared to sound limb ankle. The next step will be the gait analysis of patients wearing the new methodology-made socket and with the same prosthetic components, to compare the different diagrams for the same interesting joints referred to the two sockets.

6 SIMULATIONS

Further activities concern the definition of interactions which generate volume modifications on the residual limb. We consider the following activities:

a. the measurement of the technician's manipulation forces, using a liner with sensor-equipment, registered during the plaster cast acquisition;

b. the acquisition and measurement of stresses between socket and stump, and stump deformations, using sensors and markers, during gait analysis, to define the deformed shape and the applied loads on the digital model.

This 3D integrated digital model allows us to manipulate a high quality digital model for prosthesis socket design, while at the same time reducing errors of current measurement operations and traditional pre-casting process. Tests will be performed to verify the patient comfort and walking functionality, wearing both the traditional made socket and the one manufactured from the 3D final digital model.

7 CONCLUSIONS

The paper presented a methodology to customize prosthesis socket where all phases are "computer aided" and all data involved in the process are digital. The paper, in particular, discussed specific problems related to the geometric model of the stump. Firstly, we analyzed three different technologies to reconstruct the geometric model, in particular RE based on laser scanning to acquire external geometry of the stump, and CT and MRI for the inner parts. Secondly, we compared the acquired 3D geometric model and the cast obtained in a traditional way. Some differences in the geometries were reported, mainly due to a direct manipulation of the orthopaedic technician. The discussion of the results allows us to identify guidelines for further simulations finalized to reproduce on virtual digital models both the effects obtained on the physical cast by the technician and the interactions between socket and stump during movement.

In the proposed approach the main role is played by the geometric digital model of the lower leg residual limb, which replaces the plaster cast, and is the basis for a detailed socket design with CAD tools and the production of a physical socket mock-up with Rapid Manufacturing techniques.

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