Reverse Engineering and Rapid Prototyping Techniques to Innovate Prosthesis Socket Design

Giorgio Colombo[a*], Massimiliano Bertetti[a], Daniele Bonacini[a], Grazia Magrassi[a]
[a] Politecnico di Milano, Dip. Ingegneria Meccanica, via La Masa 34, 20156 Milano, Italy

ABSTRACT

The paper presents an innovative approach totally based on digital data to optimize lower limb socket prosthesis design. This approach is based on a stump's detailed geometric model and provides to substitute the plaster cast obtained through the traditional manual methodology with a physical model, realized with Rapid Prototyping technologies; this physical model will be used for the socket lamination. The paper discusses a methodology to reconstruct a 3D geometric model of the stump able to describe with high accuracy and detail the complete structure subdivided into bones, soft tissues, muscular masses and dermis. Some different technologies are used for stump acquisition: non contact laser technique for external geometry, CT and MRI imaging technologies for the internal structure, the first one dedicated to bones geometrical model, the last for soft tissues and muscles. We discuss about problems related to 3D geometric reconstruction: the postures of patient and stump for the different acquisitions, markers' definition on the stump to identify landmarks, alignment's strategies for the different digital models, in order to define a protocol procedure with a requested accuracy for socket's realization. Some case-studies illustrate the methodology and the results obtained.

Keywords: 3D geometrical model, reverse engineering, rapid prototyping, medical imaging, lower limb prosthesis.

1. INTRODUCTION

The paper introduces some important aspects of an innovative methodology which authors are developing , to customize design process of the lower limbs prosthesis. An important part of a prosthesis is the socket; it must adapt to the patient's morphology because it is the interface between the stump and the prosthesis. Socket's customization is essential in order to obtain the best adaptability to the patient's body, guaranteeing a high functional degree and comfort. Until now lower limb prosthesis have been designed and manufactured with handicraft methods, leaving out an adequate functionality and however depending from the skills of the orthopaedic technician, who must find the shape of the residual limb, since this is the first step in the socket design of a lower limb prosthesis.

The current design process (Fig.1) is based on a double-step realization of the stump's plaster cast; in the first one, the technician has to mould manually some plaster bandages pressing on the stump. After the bandages' solidification, the "mould" is obtained to use for the final stump plaster cast. During the first moulding, the technician manipulates the stump, producing deformations especially on fleshy parts, and such a configuration could be different from the resting configuration.

Aim of our activity is to propose a computer aided design methodology, based on digital models and numerical simulations in order to obtain the physical mock-up of the stump on which it could be made socket's lamination, applied to the transtibial prosthesis case. The proposed methodology has three technical relevant features: first, the reconstruction of a 3D geometrical model of the residual limb, then the numerical simulation of the structural behaviour of the stump, and finally the rapid manufacture of a physical mock-up of the stump.

In this paper we discuss about the first aspect that is the reconstruction of the 3D digital model of the stump, which replaces plaster cast. For this aim we have used, compared and integrated:

- Reverse Engineering[1] technologies, for the external surface limb acquisition;
- X-ray technique, such as Computer Tomography (CT), for the inner structure acquisition, divided into components (bone structure, muscle tissue, fleshy parts and dermis);
- medical imaging technique, such as Magnetic Resonance Imaging (MRI), used for complete residual limb acquisition that could be a CT substitute since it is a non-invasive operating technique.

---

[*] giorgio.colombo@polimi.it; phone +39 02 23998259

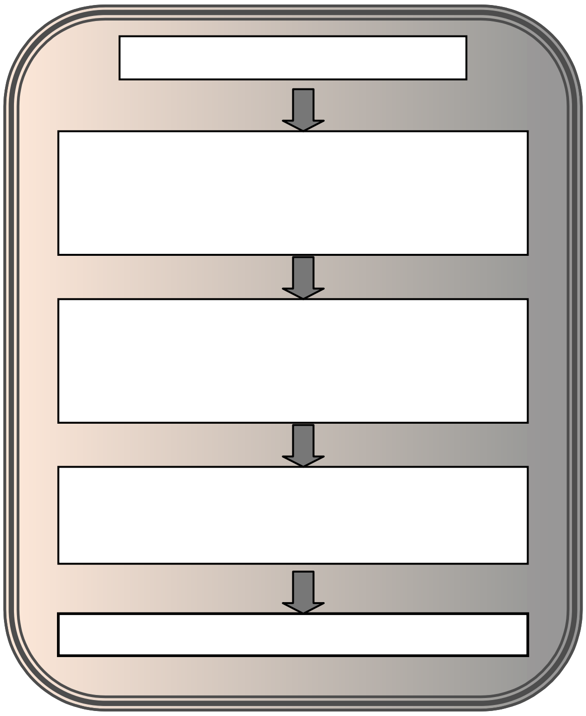

Fig.1 Current socket process.

All these three methods are used to reconstruct the geometric model of the external limb surface, CT and MRI are used also for the bone reconstruction; the integration between external surface and bone models allows obtaining a complete digital model of the residual limb. This model is essential to permit simulations, that repeat both technician's manipulations and stresses between stump and socket during patient' movement.

The expected result from simulation activities is the lower limb morphology adapted to realize a physical mock-up with Rapid Manufacturing techniques[2]; using this prototype it is possible to manufacture directly the structure of the socket, made of composite material.

The paper describes the procedure adopted to acquire morphology with the indicated methods, the characteristic of the digital models reconstructed, the merging between inner and external models to obtain the complete digital model.

2. METHODS ADOPTED ON STUMP'S MEASUREMENT

Problems related to stump's measurement have been analyzed in various studies. This practise is crucial in the design process of prosthesis and it needs to be repeated several times during the patient's life; the lower limb, in fact, is subject to continuous morphological changes, both in the short and in the long term and these changes require, when any significant variation occurs, the realization of a new socket.

Actually, the stump is measured manually, with obvious problems of accuracy depending on the instruments used[3], on the operators' skills[4,5], on the measurement conditions and on the status of the patient's stump. Therefore several measurement protocols have been developed; they define anthropometric standard dimensions which can be used in order to define significant markers on the limb (an example on Fig. 2), usually in correspondence of the articulations.

These markers are used as reference for the reconstruction of biomedical images, in FEM simulations and for human gait analysis[6,7]. In the examined test of trans-tibial amputee, important parameters are stump length (from the under patella support to tibia apex) and femoral condyle position: these points are the best fitted under the skin, so they are invested with less variations of shape and volume of the skin than the other stump parts.

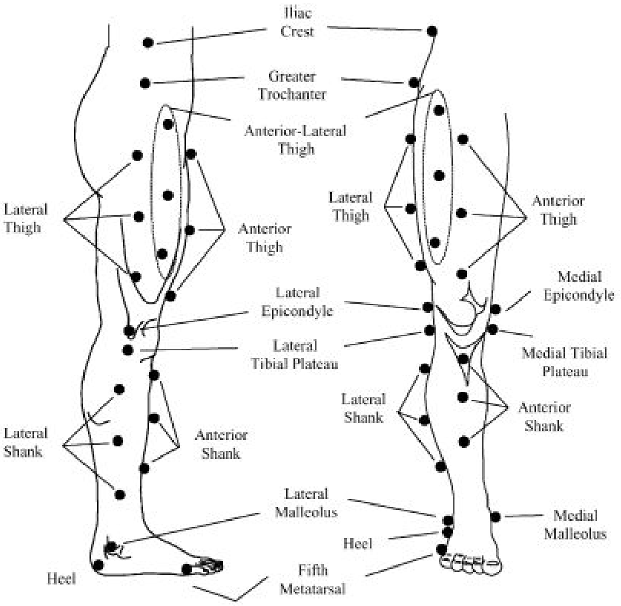

Fig.2 Marker positioning[8].

In some research, the Reverse Engineering techniques have been employed in order to estimate shape and dimensions of the human body[9,10] or its parts[11,12]; there are also studies about bone prosthesis applications, usually concerning measurements on physical prototypes of bones artificial joints [13], and of the residual limb plaster cast [14,15]. On residual limb prosthesis, studies have detailed residual limb analysis with imaging technologies such as CT[16], MRI [17] and ultrasound system[18], concerning limb shape and volume changes and permanent wearing socket's effects[19,20]. In the last years, there have been residual limb analysis[21,22] concerning integration system between medical imaging and CAD socket design, as it is yet developed in dental prosthesis[23] and tissue engineering[24].

3. A METHODOLOGY TO RECONSTRUCT GEOMETRIC MODEL

This paper deals with the problem of the definition of the best methodology, at the state of the art, for the limb geometrical model reconstruction; for this purpose, technological solutions described in scientific literature previously reviewed have been taken into account and compared. The acquisition of the external geometry of the stump and its inner parts has been considered; for the limb surface we reconstructed the digital models coming from the laser scanning and both medical imaging of CT and MRI. Bones are reconstructed from both CT and MRI, having a chance between them; in fact, it is known that MRI imaging cannot be used when patient has some metallic support into his bone after amputation. These two diagnostic systems have different application field though similar: CT is widely employed to reveal bones' fractures or problems, while MRI permits to detail with care muscular and cartilaginous diseases.

In order to guarantee the comparison among the digital models acquired by using the different methods, it is necessary to define some operative conditions for geometry acquisition; in particular:

- a patient's posture taken as reference. This posture should be as much as possible similar to the one adopted at the present time for the manual acquisition, which has been taken as reference;
- identification of fixed markers on the stump which will be used in order to verify the obtained dimensional parameters.

For patient's posture during the acquisition phase, we defined a configuration which reproduces lower residual limb's position during manual measurements for chalk manufacturing. We realized a device which supports the residual leg with an angle of ≅ 45° between femoral bone and tibiae, with patient lies down on the bed, and with the stump totally relaxed and without stresses and compressions over the masses. We realized this supporting device trying to reduce constraints on deformable stump parts, even these directly connected with standard laying position of CT/MRI scanners, which causes relevant deformations of flashy parts at stump's apex and gastrocnemio muscle. These deformations may produce problems to socket's comfort and functionality if not carefully considered into the design process.

In order to identify the markers, lead shot with diameter Φ = 2mm have been used: they can be seen both through the laser scanner and through CT, while in the MRI case some round tablets of vitamin E with diameter Φ = 3mm have been employed.

To guarantee repeatability of acquisition set, and to have some more fixed parameters for limb configuration, we realized a thermoplastic mask (see Fig. 3), modelled for the specific case-test: it is made of a sheet of Efficast ™, produced by Orfit[25], which is used to fix knee articulation in a static posture, useful for all acquisitions.

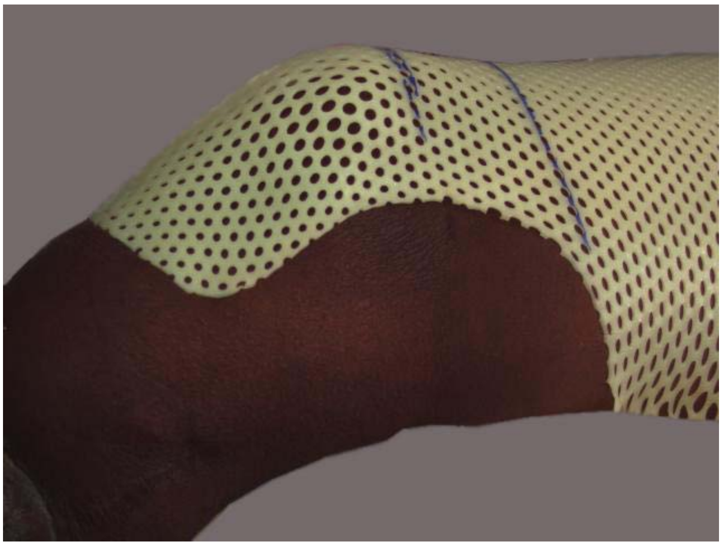

Fig.3 The mask to fix the knee.

We tested experimentally the different methods of acquisition, analysing four patients with amputated limb below the knee; the patients were three men and a woman, from 25 to 40 years old, with a stump length of approximately 10 cm below the tibiae plate.

4. ACQUISITION AND RECONSTRUCTION OF THE STUMP GEOMETRY

This paragraph describes procedures and results obtained in acquisition and reconstruction of the stump geometry using all the methods previously identified (see Fig.4). For what concerns 3D geometric model reconstruction, we highlights that only tasselled surfaces (in the .stl format) have been obtained. In the following, we describe, first, the three different measurement techniques applied to mentioned test cases, and then the main features of the geometric models reconstructed.

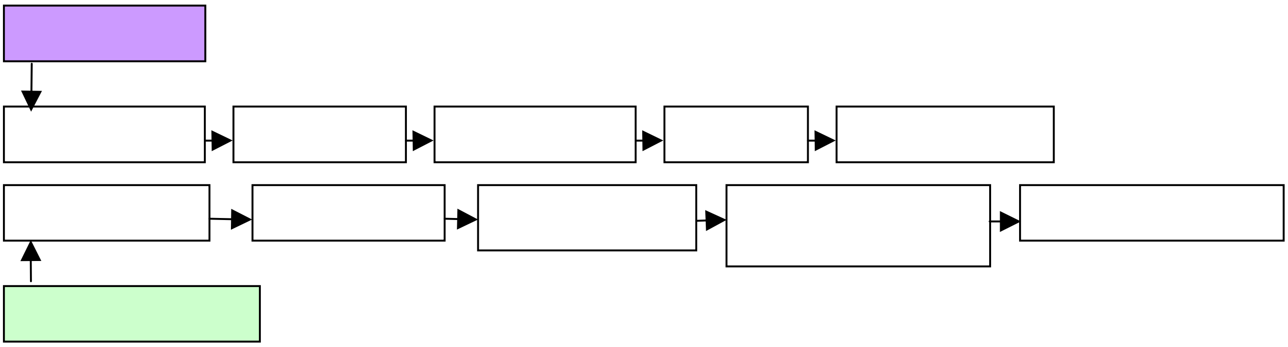

Fig.4 Main steps of the digital model reconstruction

4.1 Laser scanning

Non contact laser scanning may be a significant method to control the modifications of lower limb's morphology, especially for the global limb conformation and skin condition, and this is necessary both at the start of prosthesis design and throughout patient's life, to register further residual limb assessments and realize the necessary functional socket variations.

This methodology allows to:

- acquire, in a not invasive and dangerous way for the patient, the morphology of the stump;
- have 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's abrasions and blisters. Moreover, digital models permit to detect the variations of shape and volume due to incorrect pressures at the limb-socket interface, evidencing also the possible changes depending on the posture or on the health conditions of the patient.

We used a typical Reverse Engineering tool, the laser scanner Minolta Vivid 9i[26], which is normally used for industrial applications, equipped with a middle lens having f = 1.4 mm. In this application we adopted the following settings:

- in order to limit as much as possible the acquisition time and to avoid muscular contractions, a single stripe light is scanned, applying only a filter for noise reduction and edges' control;
- the depth of view is about 850mm (±100mm) to keep measurements into the standard instrument's field and guarantee laser acquisition accuracy.

We defined an operative procedure for the laser acquisition which includes:

- a setup which ensures a good patient's comfort;
- a scanning modality to have a short acquisition time;
- a level of accuracy to respect the fixed parameters;
- a level of completeness of the 3D digital model of the external stump surface, to define the different level of detail to use in the different process steps and applications.

The 3D digital models made of tasselled surfaces have been reconstructed with a good precision, being the standard deviation of the models' alignments about 1mm (±0,2mm). We accept this tolerance according to socket's operability: if the value is maximum, it will be balanced by the deformability of the internal part of the socket, made of polymeric material, and if the value is minimum it will be compensated with the use of a cotton stocking which is worn upon the socket.

The difficulties of the 3D digital reconstruction are connected to the stump deformability due to muscular contractions occurring during acquisition and with skin artefacts following the amputation surgery; then, the landmarks' definition and their positioning on stump are a crucial step.

We used a procedure based on Davis' protocol [27], with a personalization according to lower limb amputation; femoral epicondyles, patella plate and the tibia apex define the stump's length. In addition, other reference points have been considered, projecting the principal points into the sagittal and frontal planes, such as to create a grid for scans' alignment (Fig. 5-6-7).

The principal problems occurred during acquisition are caused by noise generated by downy skin on the stump, and by uncontrolled muscular contractions especially in the fleshy parts at the stump's apex (Fig. 8-9). They are been corrected verifying in each case that mesh deviation from the original remains on the fixed tolerance limits. In the same way, we reduced mesh triangulation to keep the digital model the best handled as possible without loosing surface details.

Fig.5 Test4 – landmarks on stump

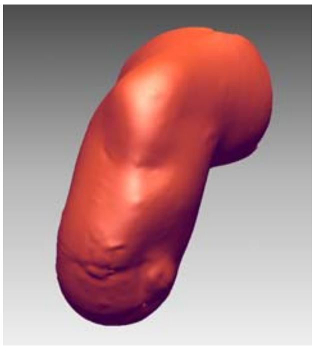

Fig.6 laser digital reconstruction

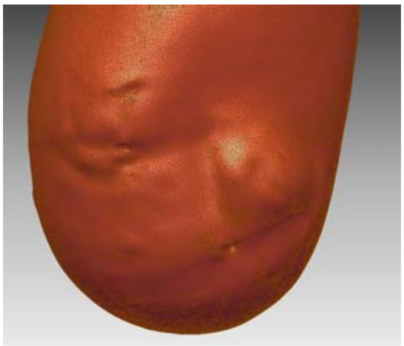

Fig.7 mesh detail (253200 triangles)

Fig.8 Test1- stump's skin

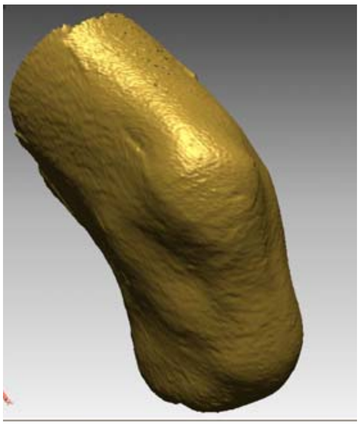

Fig.9 laser digital model with noise

4.2 CT acquisition

Computer Tomography (CT) medical imaging is a diagnostic technique which examines the inner body structures through two-dimensional X-ray images, taken around a single axis, each slice having a determined thickness. CT scanning can reveal a detailed image of soft-tissue and other body parts, with different grey level. This technology is particularly used to detect bones' disease after a traumatic incident, according to the good contrast between bones and the X rays; on the other side, it is an invasive medical diagnostic technique, which can be used with care.

For our activities, we employed the PICKER PQ 5000 by Philips-Marconi Medical System, into the Radiology Division of Ospedale Gaetano Pini, in Milan. Also in this case, we have four test cases, three men and a woman, having a stump length under the tibia plate of about 10cm. We adopted a slice thickness of 5mm to have a minimum X-ray exposure, according to an accurate bone reconstruction. 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 images were transferred from the medical workstation to a personal computer to be processed. During CT acquisition markers are used according to laser acquisition, as shown in Fig.10-11.

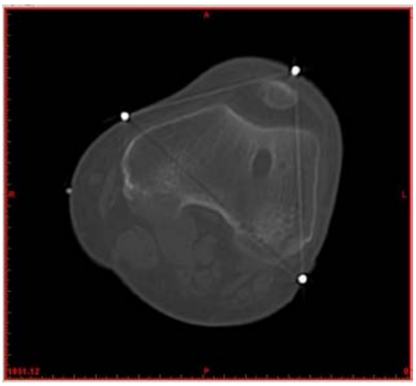

Fig.10 Test3 - CT image

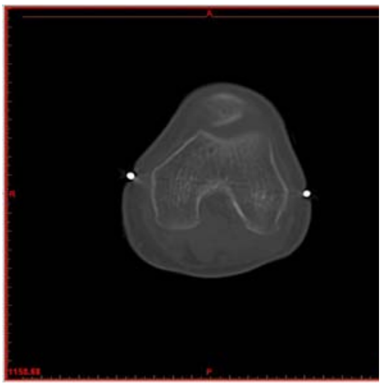

Fig.11 test4 - CT image

The 2D slices acquired from CT have been analyzed using the software Mimics 9.01 by Materialize[28]; we adopted the following procedure:

- a selection of points has been done through a segmentation mask, using thresholding and region growing action to separate the region of interest;
- a manual editing has been used for erase artefacts,

- the digital polygonal models of the skin and bones have been calculated.

Fig.12 Test1- CT skin reconstruction

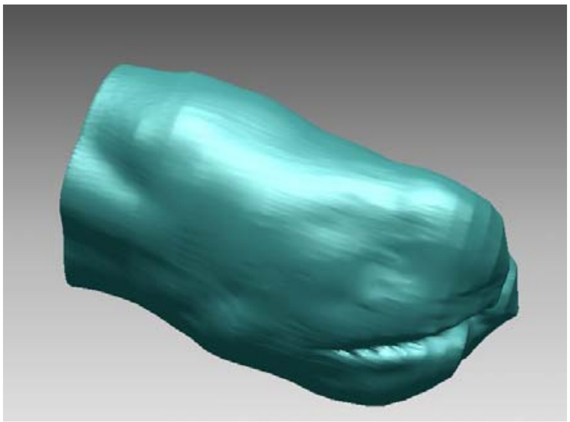

Fig.13 Test2- CT skin reconstruction

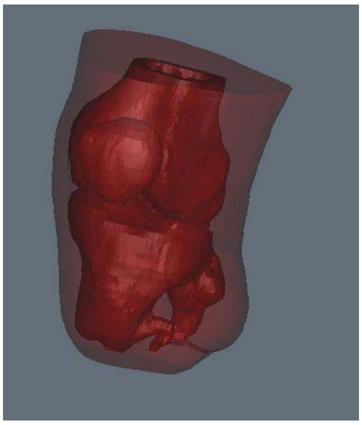

Fig.14 Test1- CT skin-bones model

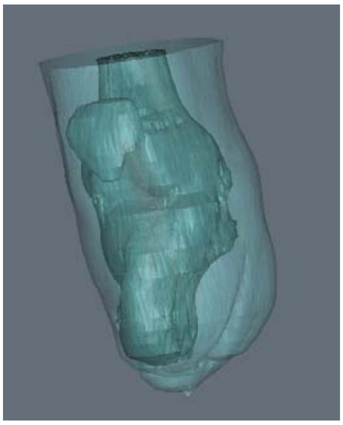

Fig.15 Test2 - CT skin-bones model

The resulting digital models have good quality in the 3D bone reconstruction, for which the thickness slice is sufficient to obtain the necessary detail; the external surface has a less definition referred to anatomic characteristics, such as cicatrix and abrasions, which have great importance in the socket-limb interaction (Fig.12-13-14-15).

For the CT acquisitions, we adopted the same limb support employed during laser acquisition, to keep the residual limb fixed in the delivered position; this support was easily integrated into the standard CT acquisition equipment tools.

4.3 MRI acquisition.

Magnetic Resonance Imaging (MRI) is a non-invasively high resolution technology which acquires multi-dimensional data not only in body transversal plane, as CT, but even in sagittal and frontal planes. MRI can acquires slices with high resolution and differentiation between soft and cartilage tissues, but quite now it is very expensive for normal research diagnostic and requires a long scanning time to acquire the whole stump, and moreover it may be affected by artefacts due to muscular movements.

In our test cases, we utilized a GE Medical Systems, 1,5 Tesla Signa Excite, at the Centro Diagnostico Italiano in Milan. We set the test parameters at these 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° (Fig.16-17).

MRI acquisitions concerned only three patients, because the femoral metal sheet of one amputee does not permit this data diagnostic system.

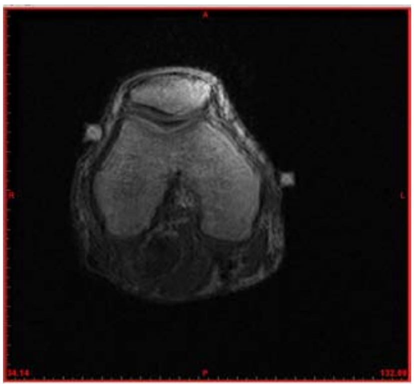

Fig.16 Test1- MRI image

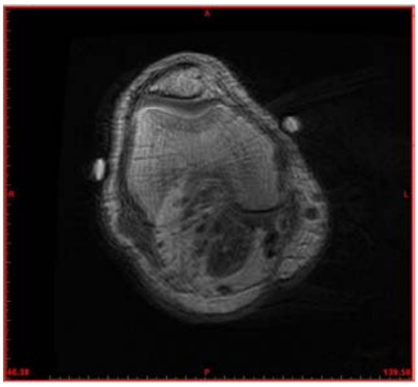

Fig.17 Test4 - MRI image

Some problems occur using our supporting device, whose integration with the MRI apparatus used for lower limb scanning was difficult; the magnetic knee bore has diameter of only Φ =40cm and requires horizontal leg positioning and our system needs a little more volume to be totally performing. We do not try open bore magnets because their magnetic field is less strength and produces a limited spatial resolution.
MRI slices were affected of noise, which needed a pre-processing filtering to improve definition, but loosing in detail quality; the reconstructed digital model has been recognized quite similar to the laser model, with a less accurate and detailed surface (Fig.18-19).

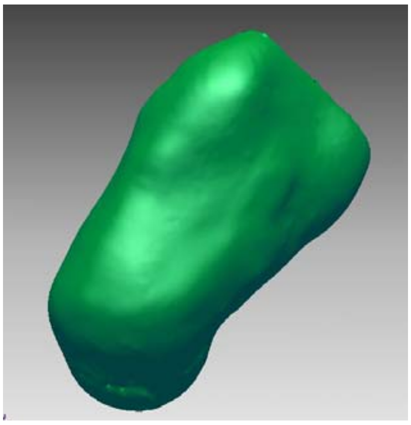

Fig.18 Test3 - MRI model

Fig.19 Test4 - MRI model

5. COMPARISON OF 3D DIGITAL MODELS

In this paragraph we discuss about the geometric models reconstructed by using the different methods illustrated. First, we analyse the quality of the external surfaces and then the complete model.

5.1 Surface model definition.

The comparison between the reconstructed 3D digital models of the lower limb surface permits to observe:

- the laser model has a high quality in morphological detail, necessary for the following studies of limb/socket interface stresses (Fig.20-21);

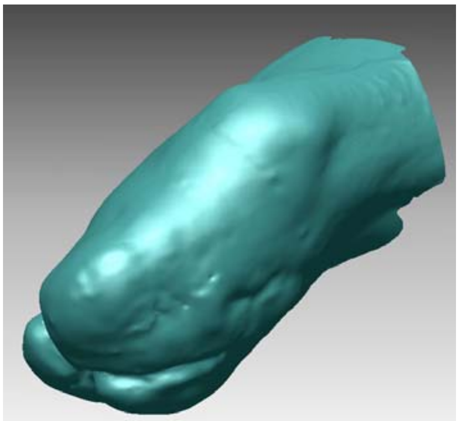

Fig.20 Test3- laser model

Fig.21 Test3- stump image

- the CT models have a less skin quality, depending on slice thickness, but hve a good correspondence with the laser model using the same reference markers typology (lead shot);
- the MRI models have some volume differences due to the little difference in posture during stump acquisition; they have requested some post-processing editing to control noise and roughness, but they present a surface sufficiently detailed (Fig.22-23).

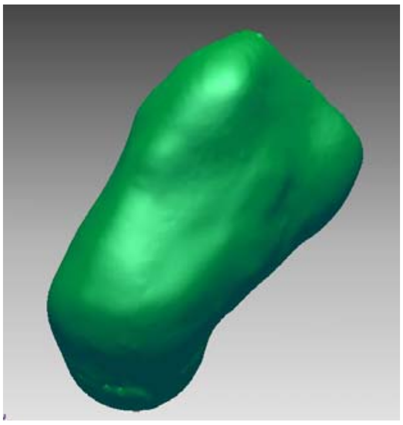

Fig.22 Test3 – MRI model

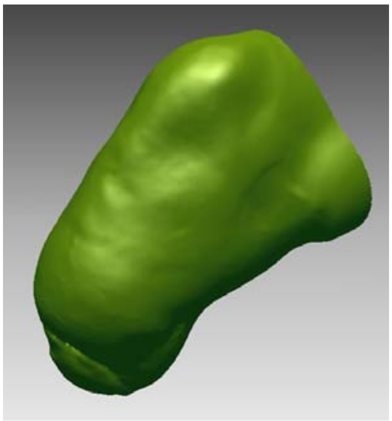

Fig.23 Test3 –laser model

In conclusion, we notice that the digital 3D model reconstructed with a Reverse Engineering system such a laser scanner presents a better correspondence with the real skin surface of which shows all the “abnormalities” due to amputation, stump conditions and socket’s possible interactions.
We use this model as reference for the complete 3D reconstructed model.

5.2 3d complete model.

To obtain the 3D digital integrated stump, with the external surface and the inner bone structure, we aligned the different model into the same reference global system, using the software Geomagic Studio 7.0[29] to verify the differences. We obtained a good models’ positioning, especially in the anterior limb part, corresponding to the tibiae, while variations are located in residual limb apex, where there are the flashy parts (Fig.24-25-26).

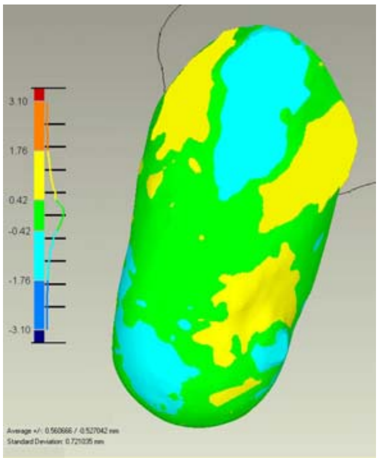

Fig.24 Test4 –laser/MRI comparison

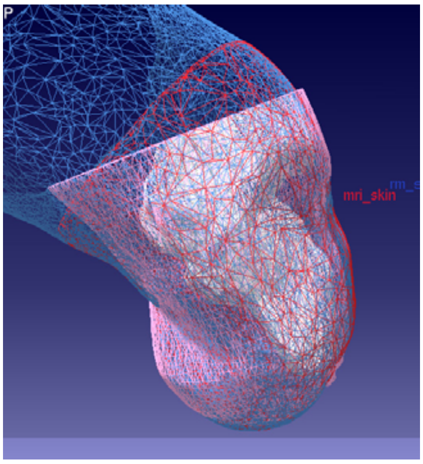

Fig.25 - models into global reference system

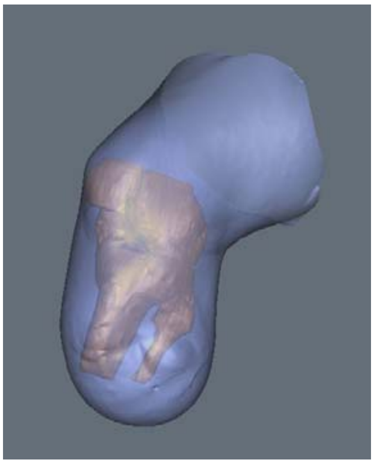

Fig.26 – laser/bone complete model

6. CONCLUSIONS AND FUTURE WORKS

In this paper we first present an innovative approach to prosthesis socket design and then a discussion about methods to reconstruct 3D geometric model of the stump. To this purpose, RE, CT and MRI have been considered; we develop some test cases to identify the best methodology to reconstruct geometric model. The results obtained have demonstrated that the integration of RE for the external surface and medical imaging (CT or MRI) for internal skeletal structure permits to obtain a high quality digital model for prosthesis socket design, and reduces errors of current measurement operations and traditional pre-casting process.

Further developments will concern:

- the comparison between the digital model obtained and that acquired from the plaster cast of the same residual limb through the traditional approach, to notice volume and detail variations;
- design of an apparatus which fitted the stump supporting device, to improve a better acquisition in reduced time for the proposed technologies, with attention for MRI specific application;
- simulations of interactions between socket and stump, to analyze stresses during moving and to obtain important feedback for socket design and modification.

ACKNOWLEDGMENTS

The authors would like to thank for providing us with medical scanning system the Ospedale Gaetano Pini and the Centro Diagnostico Italiano of Milan, and Intermedica s.r.l for Orfit equipments.

REFERENCES

1. T. Várady, R.R. Martin, J. Cox, *Reverse Engineering of Geometric Models - an Introduction*, Computer-Aided Design, Elsevier, vol. 29, n. 4, pp.255-268, 1997.
2. G. Fadel, *Rapid Prototyping and manufacturing technologies: accomplishments and potentials*, Proceedings of the TMCE 2004, april 2004.
3. Mark D. Geil, PhD, Consistency and accuracy of measurement of lower-limb amputee anthropometrics, J Prosthet. Orthot. 2005;42(2):131–140.
4. MW. Vannier, PK. Commean, KE. Smith, *Three-dimensional lower-limb residua measurement systems error analysis*, J Prosthet Orthot. 1997; 9(2):67–76.

5. P.K. Commean, KE. Smith, J.M. Cheverud, MW. Vannier, *Precision of surface measurement for below-knee residua*, Arch Phys Med Rehabil., 1996;77:477–86.
6. Cappozzo A., Catani F., Leardini A., Benedetti M.G., Della Croce U., *Position and orientation in space of bones during movement: experimental artefacts*, Clinical Biomechanics 11, 90-100, 1996.
7. Cappozzo A., U. Della Croce, A.Leardini, L. Chiari, *Human movement analysis using stereophotogrammetry. Part 1: theoretical background*, Gait and Posture 21 (2005) 186–196
8. Thomas P. Andriacchi, Eugene J. Alexander, *Studies of human locomotion: past, present and future* , Journal of Biomechanics 33 (2000) 1217-1224
9. Chris Boehnen Patrick Flynn*, Accuracy of 3D Scanning Technologies in a Face Scanning Scenario*, Proceedings of the 5th Int'l Conf. on 3-D Digital Imaging and Modeling (3DIM 2005)
10. N. D'Apuzzo, *Digitization of the human body in the present-day economy*, Proc. of SPIE-IS&T Electronic Imaging, SPIE Vol. 5665, 2005
11. G.Tognola, M. Parazzini, P. Ravazzani, F. Grandori, C. Svelto, 3-D *Acquisition and Quantitative Measurements of Anatomical Parts by Optical Scanning and Image Reconstruction from Unorganized Range Data*, IEEE Transactions on Instrumentation and Measurement, Vol. 52, no. 5, October 2003
12. A.Andrisano, E.Bassoli, A.Gatto, F.Leali, M.Pellicciari, *Reverse Engineering Methodology applied to complex virtual models development in the mechanical field*, XIV ADM, Bari, 2004
13. Lin YP, Wang CT, Dai KR, *Reverse engineering in CAD model reconstruction of customized artificial joint*, Medical Engineering and Physics - March 2005 (Vol. 27, Issue 2, Pages 189-193)
14. Ping He, PhD, PE; Kefu Xue, PhD; Yu Fan, PhD; Yiwei Wang, *Test of a vertical scan mode in 3-D imaging of residual limbs using ultrasound*, Journal of Rehabilitation research and development Vol. 36 No. 2, April 1999
15. Joan E. Sanders, PhD, Stuart B. Mitchell, MSE, Santosh G. Zacariah, Ph, Kelvin Wu, BSE, *A digitizer with exceptional accuracy for use in prosthetic research: a technical note*, Journal of Reabilitation Reasearch and Development, Vol. 40, No.2, March/April 2003, Pages 191-196
16. Smith KE, Commean PK, Robertson DD, Pilgram T, Mueller MJ. *Precision and accuracy of computed tomography foot measurements*, Arch Phys Med Rehabil 2001; 82:925-9.
17. S. Aritan, P. Dabnichki, R. Bartlett, *Program for generation of three-dimensional finite element mesh from magnetic resonance imaging scans of human limbs*, Med. Eng. Phys. Vol. 19, No. 8, pp. 681–689, 1997
18. Tania Douglas, Stephan Solomonidis, William Sandham, William Spence, *Ultrasound Imaging in Lower Limb Prosthetics*, Ieee Transactions On Neural Systems And Rehabilitation Engineering, Vol. 10, No. 1, March 2002 11
19. Michael W. Vannier, Paul K., Commean, Barry S. Brunsden, Kirk E. Smith, *Visualization of Prosthesis Fit in Lower-Limb Amputees*, Simulation and Modelling, sep/oct 1997
20. Paul K. Commean, BEE, Barry S. Brunsden, Kirk E. Smith, AAS, Michael W. Vannier, MD Below-Knee Residual Limb Shape Change Measurement and Visualization, Arch Phys Med Rehabil Vol 79, July 1998
21. YP Zheng, A. FT Mak, A.KL Leung, *State-of-the-art methods for geometric and biomechanical assessments of residual limbs: A review*, Journal of Rehabilitation Research and Development Vol.38 No.5, Sept/Oct2001, p487–504
22. Zheng Shuxian, Zhao Wanhua, Lu Bingheng, *3D reconstruction of the structure of a residual limb for customizing the design of a prosthetic socket*, Medical Engineering & Physics 27 (2005) 67-74
23. Lin, Chun-Li; Lee, Huey-Er; Wang, Chau-Hsiang; Chang, Keng-Hua, *Integration of CT, CAD system and finite element method to investigate interfacial stresses of resin-bonded prosthesis*, Computer Methods and Programs in Biomedicine Volume: 72, Issue: 1, September, 2003, pp. 55 - 64
24. B.Starly, Z.Fang, W.Sun, A.Shokoufadeh, W.Regli, *Three-Dimensional Reconstruction for Medical-CAD Modelling*, Computer-Aided Design & Applications,Vol.2,Nos.1-4, 2005, pp 431-438
25. www.orfit.com
26. www.konicaminolta-3d.com
27. R. B. Davis, S. Ounpuu, D. Tyburski, J. R. Gage, *A Gait Analysis Data Collection and Reduction Technique*, Journal of Human Movement Science, 5, vol.10, Newington, Connecticut, April 1991.
28. www.materialize.com
29. www.geomagic.com