Innovative Implementation in Socket Design: Digital Models to Customize the Product

U. Cugini[1], M. Bertetti[1], D. Bonacini[1], G. Colombo[1], C. Corradini[2], G. Magrassi[1]

[1]Politecnico of Milan, Department of Mechanics; [2]Orthopaedic and Traumatologic Clinic, University of Milan, Italy

umberto.cugini@polimi.it, massimiliano.bertetti@polimi.it, daniele.bonacini@polimi.it, giorgio.colombo@polimi.it, grazia.magrassi@polimi.it, costantino.corradini@unimi.it

Abstract

The paper presents an innovative approach based on digital data and computer tools to optimize lower limb socket prosthesis design. The kernel of the approach is a stump's detailed geometric model, with external surface and inner bones. To obtain this model, we integrated RE laser scanning and two medical imaging technologies, Computer Tomography (CT) and Magnetic Resonance Imaging (MRI). The model obtained can not be directly used to build the socket by using Rapid Manufacturing technologies. We demonstrate this assertion by comparing digital model of the limb with the positive plaster cast acquired by an orthopaedic technician during the traditional manual manufacturing process. The comparison evidences some differences concentrated on critical zones, whose deformations strictly depend on technician's manipulation. The analyses of the causes of the mentioned differences can furnish guidelines for physics-based simulations able to reproduce effects obtained by the technician.

Keywords: lower limb prosthesis design, custom socket, 3D digital modelling, reverse engineering.

1. Introduction

The paper presents an innovative approach based on digital data and computer tools to optimize lower limb socket prosthesis design; as described in the next section, design and manufacturing of a socket are processes where computer aided methodologies and tools are not intensively used. The main aspects of the methodology we propose are summarised in Figure 1. We consider, as the first time, the problem of the reconstruction of a digital model of the stump; it requires a measurement phase and a following CAD modelling task. Then, physics-based simulations on digital model are necessary to obtain deformed shape of the stump similar as much as possible to that one that stump assume during motion of the patient or during manipulations of orthopaedic technician. Finally, the last two steps concern the design of the socket over the deformed shape of the stump and the manufacturing of the socket using Rapid Prototyping (RP) techniques.

In previous years, some researchers have investigated aspects concerning the proposed methodology. To reconstruct the digital model, solutions described in literature have been taken into account and compared, beginning from stump's measurement procedures. Actually, the stump is measured manually, so several measurement protocols have been developed to control and reduce problems of accuracy depending on the instruments used (Geil 2005), on the operators' skills (Vannier 1997), on the measurement conditions and on the status of the patient's stump. Markers on the limb identify anthropometric standard dimensions, usually in correspondence with the articulations (Andriacchi 2000). In the case of trans-tibial amputee, important parameters are stump length (from the under patella support to tibia apex) and femoral-condyle position, these points identify zones with less variations of shape and volume of the skin than the other parts of the stump. Markers are also used as reference for the reconstruction of biomedical images and for human gait analysis (Cappozzo 1996).

In the last years, there have been residual limb analyses concerning stump's measurement and interactions with socket (Commean 1998), and its variations during patient's life (Zheng 2001, 2005); these studies evidence how to control modifications of lower limb's morphology, especially for the global limb conformation and skin condition, to guarantee a permanent prosthesis comfort and realize, when necessary, the necessary functional socket adjustments. All these researches highlight how digital-based technologies can help socket process design. Some studies analyze the interface pressure between the residual limb and the prosthetic socket, applying Finite Element Analysis tools to simulate pressure distribution and to define material properties assumptions (Ming 2000, Lee 2004).

Recently researches have investigated RP technologies applications both to the production of the positive plaster cast of the stump and to the manufacture the socket (Cheng 1998). Efficiency and velocity of RP technology are a valid support for "custom fit" products, and produces cost reduction even during test evaluation. Technologies such as Stereo Lithography Apparatus (SLA), Selective Laser Sintering (SLS) or

Fused Depositing Modelling (FDM) produce prototypes with strong mechanical properties compared with 3D Printing, but are much expensive, for what concern hardware, consumer materials and productive process (Freeman 1998, Herbert 2005).

The geometric model of the residual limb of the lower leg plays the main role on the approach we are proposing. This model is essential to permit physics-based simulations, detailed design with CAD tools and RP. In this paper we discuss methods and tools to reconstruct a geometric model of the stump and we demonstrate that this geometry is not directly usable to produce the socket, presenting a comparison between a geometric model obtained integrating RE and medical imaging technologies, with the plaster cast produced by means of the traditional manual process by orthopaedic technician.

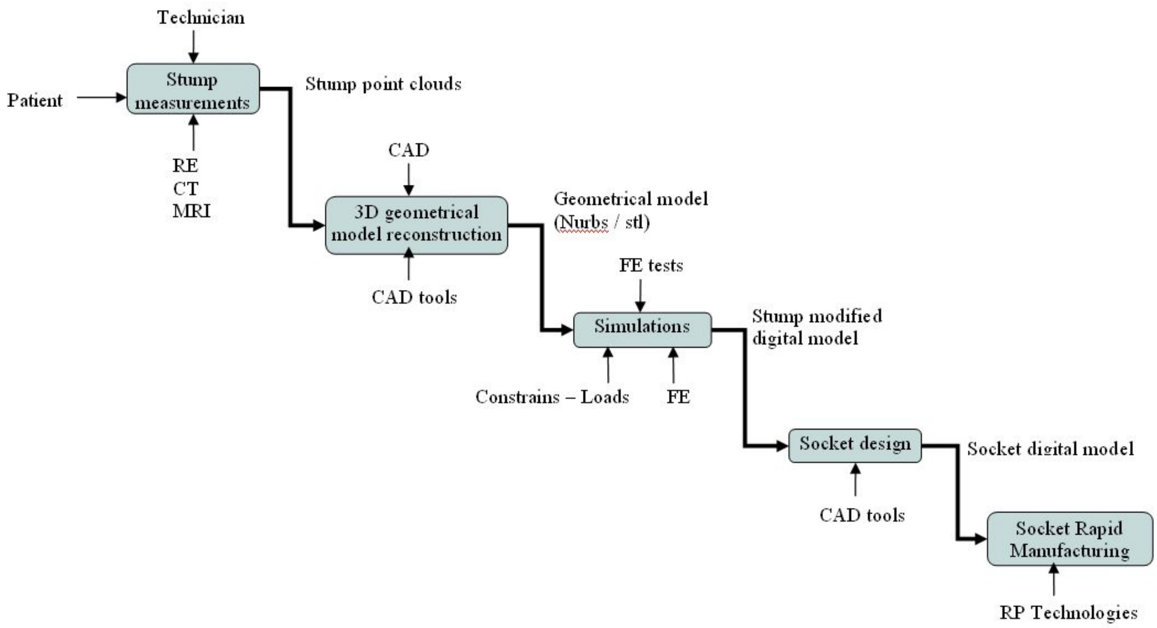


Figure 1 Proposed approach

2. Traditional manufacturing of a socket

Socket is the interface between the amputated lower limb and the kinematic chain of the prosthesis: unlike other components, such as links and foot are modular, socket is custom made on the stump, because it is responsible of prosthesis comfort and must guarantee amputee’s suitable movements.

Until now, sockets have been designed and manufactured with handicraft methods by an orthopaedic technician (Figure 2): he has to mould manually some chalk bandages on the stump, pressing on the landmarks which correspond to loaded zones of the stump into the socket (Figure 3), like the under patella zone and popliteal fossa.

Figure 2 Measurement of stump with liner

Figure 3 Chalk negative cast with critical zones

In this manner the technician acquires the shape of the stump; this is a manipulated model, subjected to deformations especially on fleshy parts, and such a configuration could be different from one technician by another, depending on his/her skill. Through chalk casting on the negative plaster cast, it is possible to obtain the stump model, comparing measures with the ones taken directly on the stump. If the measures are different, the orthopaedic technician files the model till the measures coincide: this last model is used to make socket by lamination. A specific attention, as shown in Figure 4 and 5, is due to the definition of the most critic zones of the stump, like the tibia apex and other bone protrusions (cyan zones into the positive cast), which are maintained without compression to avoid residual limb charge against socket.

Figure 4 Negative cast with opening into critical zones

Figure 5 Positive cast

The choice of the socket material is a very important aspect in the design and manufacturing processes of limb prosthesis; materials will influence the comfort of the prosthesis for amputee. Often, socket is thermoformed over a plaster cast of the residual limb after being heated at high temperature, usually around 300-400 °C. The hot plastic is moulded to the plaster model using vacuum pressure to ensure an exact fit over the cast.

3. Reconstruction of the digital model of the stump

The first step of the proposed innovative process considers the reconstruction of the digital model of the residual lower limb; to obtain this model we integrated different technologies such as medical imaging (Computer Tomography CT and Magnetic Resonance Imaging MRI) and a non contact laser scanning. The external geometry is modelled by data coming from the laser scanning; bones can be reconstructed from both CT and MRI (Colombo 2006). 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, realizing 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 and the stump is totally relaxed and without stresses or compressions on the muscular masses. In order to guarantee repeatability of acquisition set-up, and to have some more fixed parameters for limb configuration, we used markers to identify anthropometric standard points. They identify zones with fewer variations of shape and volume than the other stump parts. We used lead shot markers both for laser scanning and CT, tablets of vitamin E in the MRI, as shown in Figures 6 -7.

Figure 6 Stump with markers

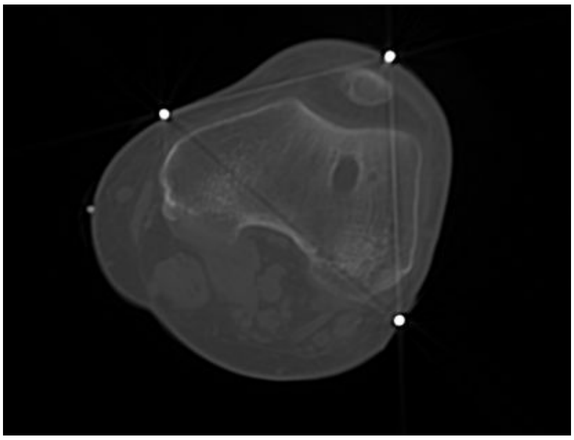


Figure 7 CT image with markers

To acquire the geometry of the limb external surface, we used a typical Reverse Engineering tool, the laser scanner Minolta Vivid VI-9i™, which permits to obtain a model with a high quality in morphological details, necessary for the following studies of limb/socket interactions (Figure 8).

The 3D digital models made of tasselled surfaces have been reconstructed with a good precision, the standard deviation of the models' alignments was about 0,3 mm (±0,1mm) for all the 4 test-cases we considered the difficulties of the 3D digital reconstruction are related to stump deformability due to muscular contractions occurring during acquisition.

We accept this tolerance according to socket's operability: amputees always wear some liner on the residual limb to avoid damages to the skin, and its thickness compensates little shape variations.

This methodology, which assures both 3D digital data and RGB textures, allows:

- To acquire, in the less invasive way for the patient, the morphology of the stump
- 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's abrasions and blisters
- 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

In CT analyses we adopted a slice thickness of 5mm, to assure the minimum X-ray exposure according to an accurate bone reconstruction. MRI slices have dimension 20x20 cm, 256x256 pixel, pixel size = 0.78/0.82 mm, to reduce the acquisition time and avoid muscular movements (Figure 9).

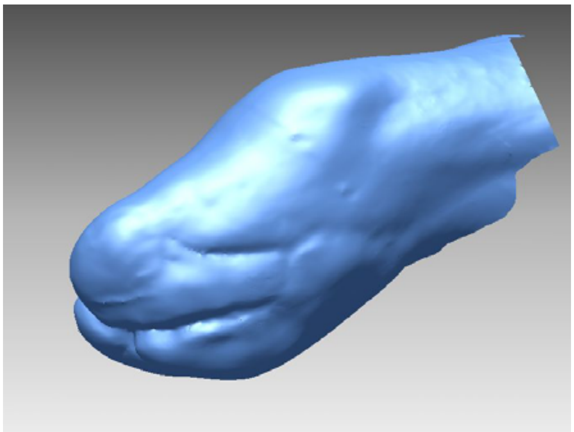


Figure 8 Laser digital model

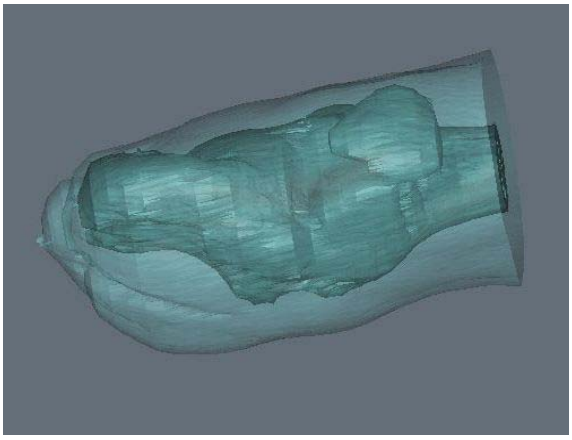


Figure 9 Complete digital model

This methodology was tested experimentally on 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 (trans-tibial amputation).

4. Comparison of stump's digital models

To evaluate the possibility to use previously described model as a virtual cast to design and manufacture socket, we compare this model with the digital one obtained through RE of positive plaster cast made by an orthopaedic technician. In this manner, we want to highlight possible differences and critical zones, whose deformations strictly depend on technician's manipulation.

We considered a positive plaster cast, obtained from the limb wearing a Thermoliner™ Cushion TFFR, 6 mm thickness, by Alps™, and 3D digital model, whose volume was increased of a surface offset of the same thickness. The comparison shows that volume variations concern mainly the posterior muscular masses, which are more manipulated from technician, while the anterior part has the same global shape, due to the presence of the tibia (Figure 10).

In detail we notice that:

Proceedings ArtAbilitation 2006: ©ArtAbilitation/SoundScapes ISBN 87-7606-015-2

- The digital models correspond into bones critical zones, such as tibia protuberances, at both corner to the crest (Figures 11 and 12) and at the inferior extremity (Figures 13 and 14): 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) is outside the stump.

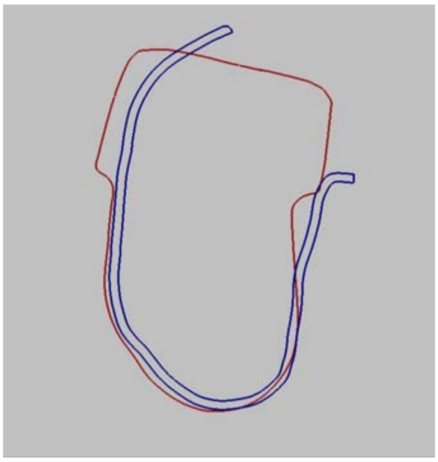
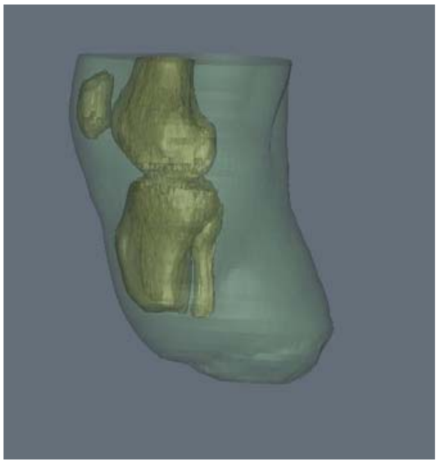
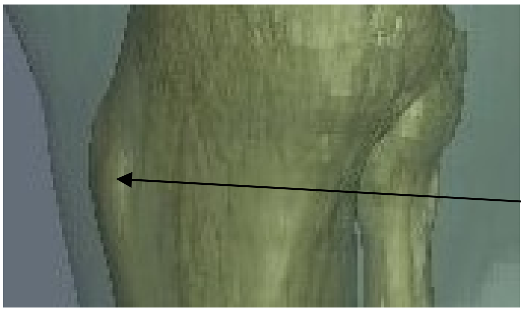
a)   b)

Figure 10 Sagittal section on limb and plaster cast: a.) sectioned, b.) 3D limb with bones.



Tibial crest

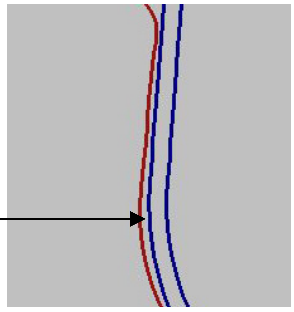
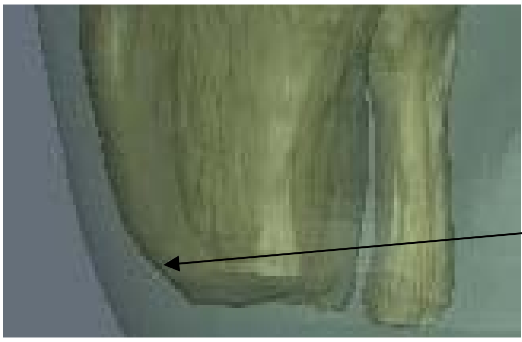


Figure 11 Tibial crest.

Figure 12 Detail on tibial crest.



Tibial apex

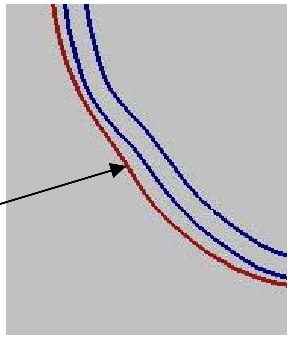


Figure 13 Tibial apex.

Figure 14 Detail on tibial apex.

Significant differences between plaster cast and the stump are localised in two zones, where stump digital profile (double blue line) exceeds the plaster cast one. These situations occur:

- At the popliteal zone (Figures 15 and 16), where orthopaedic technician exerts pressure on stump, to guarantee the maximum socket adherence and create a closing zone to enable socket movement and to avoid stump contact with the bottom of the socket

- At the fleshy parts that remain on the bottom of the stump (Figures 17 and 18), which orthopaedic technician manipulates to reduce and compact volume, which is useless to socket functionality

These observations highlight the zones whose modifications are directly connected to technician's manipulations during plaster cast acquisition; further simulations to define interactions that generate this modification will be done on this digital model, adapted to be used with FE tools.

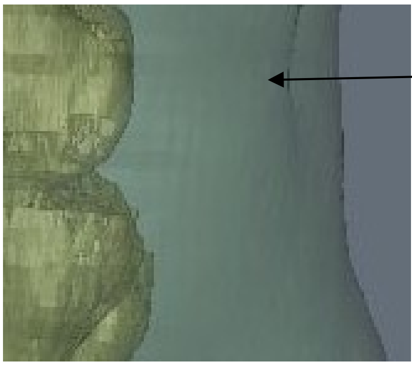


Figure 15 Popliteal zone

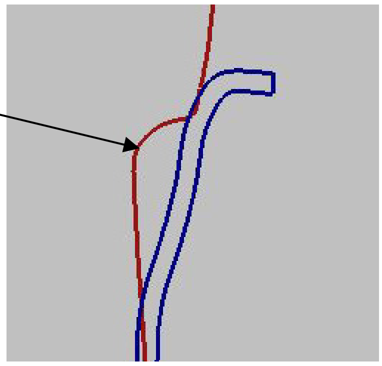


Figure 16 Detail on popliteal zone.

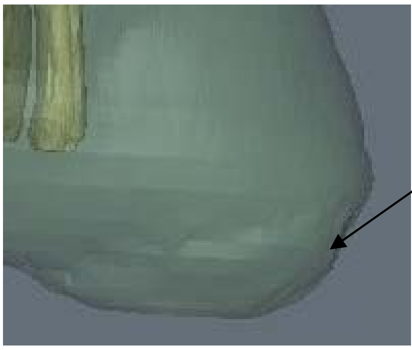


Figure 17 Posterior fleshy parts.

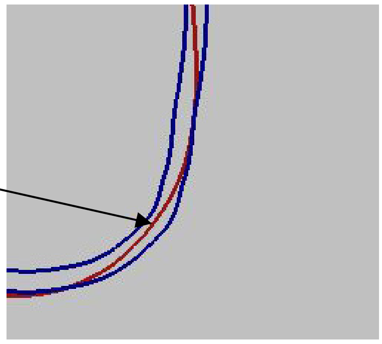


Figure 18 Detail on posterior fleshy parts.

5. Future works

As previously stated, further activities will concern physics-based simulations to evaluate interactions between limb and socket in order to improve design procedure. To this purpose, we must be able to determine pressure distribution at the interface between limb and socket depending on forces acting on the prosthesis during the movement of the patient. Experimental setup to measure this map is very important to obtain data necessary to refine simulation procedure and results.

The last topic of the proposed approach concerns the use of Rapid Manufacturing (RM) technologies to produce a socket of high quality and completely adequate to realize its function. In our approach we intend to use RM to produce a cast equivalent to that one produced in traditional way by orthopaedic technician; then it is possible to form physical socket customised for the specific patient. Experimental tests and setups must be defined to verify behaviour of the socket and evaluate the validity of the proposed approach.

6. Conclusions

In this paper we present a methodology to customise prosthesis socket. All the phases are "computer aided" and all the data involved in the process are digital. The paper, in particular, discusses problems related to geometric model of the stump. First, we analyse three different technologies to reconstruct geometric model, in particular RE based on laser scanning to acquire external geometry of the stump and CT and MRI for the inner parts. The acquired model can not be used to produce directly the cast and then the socket; we demonstrate this assertion by comparing geometric model acquired and the cast obtained in a traditional way. Some differences in the geometries have been highlighted; they are due to a direct manipulation of the orthopaedic technician; the discussion of the results permit to identify guidelines for further physics-based simulations finalised to reproduce in virtual model effects obtained in physical cast by the technician.

Acknowledgements

This research has been partially funded by MURST, Italian University and Research Ministery, under the project PRIN05 "DESPRO". The authors would like to thank for providing us: for medical scanning, the Ospedale Gaetano Pini and Dott. Costantino Corradini, the Centro Diagnostico Italiano of Milan, Dr. Sergio

Papa and Ing. Stefano Rampoldi; for the equipments used on the tests, Intermedica s.r.l for Orfit equipments and Mrs. Antonia Rocchi, Ortopedia Panini snc of Milan and Mr Marco Buzzi, Alps and Mr. Fabio Vendraminetto for Alps liners.

References

Alps South Corporation, http://www.easyliner.com; http://www.alpsitaly.com/sections/sec-liner/liner.htm

Andriacchi, T.P. & Alexander, E.J. (2000) *Studies of human locomotion: past, present and future*, Journal of Biomechanics, 33, 1217-1224

Cappozzo, A., Catani, F., Leardini, A., Benedetti, M.G. & Della Croce, U. (1996) *Position and orientation in space of bones during movement: experimental artefacts*, Clinical Biomechanics, 11, 90-100

Cheng, T.K., Sin, P.L.V., Fye, T.K. & Lin, L.S. (1998) *Automation of prosthetic socket design and fabrication using computer-aided-design/computer-aided-engineering and rapid prototyping techniques*, The First National Symposium of Prosthetics and Orthotics, Singapore

Colombo, G., Bertetti, M., Bonacini, D. & Magrassi, G. (2006) *Reverse engineering and rapid prototyping techniques to innovate prosthesis socket design.* In Woods, A.J., Dodgson, N.A., Merritt, J.O., Bolas, M.T. and McDowall, I.E. (eds.) Proceedings SPIE Vol. 6056, Three-Dimensional Image Capture and Applications VII, San Jose, CA, 15-19 January 2006, pp. 223-233

Commean, P.K., Brunsden, B.S., Smith, K.E. & Vannier, M.W. (1998) *Below-knee residual limb shape change measurements and visualization*, Arch Phys Med Rehabil., 79 (7) 772-82

Freeman, D. and Wontorcik, L. (1998) *Stereolithography and prosthetic test socket manufacture: a cost/benefit analysis*, Journal of Prosthetics and Orthotics, 10(1) 17

Geil, M.D. (2005) *Consistency and accuracy of measurement of lower-limb amputee anthropometrics*, Journal of Prosthetics & Orthotics, 4(2) 131-140

Herbert, N., Simpson, D., Spence, W.D. and Ion, W. (2005) *A preliminary investigation into the development of 3-D printing of prosthetic sockets*, Journal of Rehabilitation Research & Development, 42(2) 141-146

KonicaMinolta, http://www.konicaminolta-3d.com

Lee, W.C.C., Zhang, M., Jia, X. and Cheung, J.T.M. (2004) *Finite element modeling of the contact interface between trans-tibial residual limb and prosthetic socket*, Medical Engineering and Physics, 26(8) 655-662

Ming, Z. and Roberts, C. (2000) *Comparison of computational analysis with clinical measurement of stresses on below-knee residual limb in a prosthetic socket*, Medical Engineering and Physics, 22, 607-612

Orfit, http://www.orfit.com/en/orthopedie/index.html.

Vannier, M.W., Commean, P.K. and Smith, K.E. (1997) *Three-dimensional lower-limb residua measurement systems error analysis*, Journal of Prosthetics & Orthotics, 9(2) 67-76

Zheng, S., Zhao, W. and Lu, B. (2005) *3D reconstruction of the structure of a residual limb for customizing the design of a prosthetic socket*, Medical Engineering and Physics, 27(1) 67-74

Zheng, Y.P., Mak, A.F.T. and Leung, A.K.L. (2001) *State-of-the-art methods for geometric and biomechanical assessments of residual limb: a review*, Journal of Rehabilitation Research and Development, 38(5) 487-504

Prof. Umberto Cugini is a Professor of Mechanical Drawing, CAD and Virtual Prototyping at the “Politecnico di Milano”, Technical University. He is the coordinator of the PhD School of Design and Products Development Methods and member of Foundation of Politecnico. As coordinator of the Kaemart research group, he investigates new solutions for industrial applications and to develop innovative prototypes. The main research areas concern: PLM/CAD/CAM/CAE, VP, Robotics, and related technologies as modelling, rendering, simulation, knowledge based techniques, business process reengineering, and human-computer interaction. Research activities are carried out in collaboration with industrial partners and academic research groups in Europe, U.S.A. and Japan.

Dr. Massimiliano Bertetti has a MA degree in Industrial Design. He worked as an industrial designer for a firm in customising products for electronic consumer. Since 2004, as PhD at Politecnico of Milan he is involved into a product design project, which is aimed at customization of the socket of lower limb prosthesis. His field of interest is: 3d acquisition techniques and 3d surface model reconstruction.

Dr. Daniele Bonacini has a MA degree in Mechanical Engineering since 2001, he worked four year in automotive field, as Project Manager, following the whole design chain from concept design and prototyping, to product manufacturing. Since 2005 as PhD at Politecnico of Milan, he develops the research in the orthopaedic prostheses field, regarding Carbon Fiber Foot. He run Paralympics Games 2004 in Athens.

Prof. Giorgio Colombo is Associate Professor of CAD Lab, Mechanical Drawing and Computer Graphics at the"Politecnico di Milano" Technical University. He has developed researches in parametric design, simulation methods and techniques, Knowledge Based Engineering and Design Automation, Virtual Reality and haptic devices. He was/is the coordinator of national research projects and participates to international programs.

Dr. Costantino Corradini is an Orthopaedic and Traumatology Surgeon at the Orthopaedic Institute G.Pini, researcher of Locomotorium pathologies at the University of Milan, Faculty Medicine and Surgery and researcher of Sport-Trauma Human Laboratory by University of Milan.

Dr. Grazia Magrassi has a MA in Civil Engineering at Politecnico of Milan; she works as free-lance engineer for architectural and industrial projects. Since 1984 she works with Politecnico of Milan, doing research activities on 3D acquisition and computer graphics, both at the Design and Engineering Faculty for the 3D modelling. Researcher at Politecnico since 2001, she studies 3D acquisition techniques and laser scanning applied to Reverse Engineering and Rapid Prototyping.

Proceedings ArtAbilitation 2006: ©ArtAbilitation/SoundScapes ISBN 87-7606-015-2