Patient-Specific Optimization of Prosthetic Socket Construction and Fabrication Using Innovative Manufacturing Processes: A Project in Progress

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Abstract

Despite improved medical prevention and successful treatment of potential risk factors, the number of new amputations is constant over last years. According to the demographic changes and developments the number of amputations will increase and will cause considerable health care system costs. The current prosthetic socket construction and fabrication process does not take patient specific parameters into account, is based onto subjective estimations, competence and capabilities of the orthopedic technician and therefore causes a high rate of inappropriate prosthetic supplies. This essential drawback clearly shows that a substantial necessity exists to develop more objective planning systems and to gain a higher quality in the prosthetic socket construction. The central objective of the presented work is to improve the currently empirical process of prosthesis design in orthopedic technology with the aid of modern imaging techniques and computer technology by taking into account patient-specific consistence of the amputation stump. Based on patient-specific 3-D models, the 3-D visualization, quantification and simulation of the individual biomechanical tissue changes in the amputation stump in a static state, as well as under dynamic conditions during the interaction with the prosthetic socket will be evaluated using finite element analysis. The computer-aided visualization and virtual simulation of soft tissue deformation and of the contact forces in the interface between the patient-specific deformable model and the amputation stump at the computer individually planned model of the prosthetic socket will serve as basis for a reproducible construction and fabrication of individually adjusted exoskeleton prosthetic socket systems as well as a computer-simulated “virtual try-on” before construction and fabrication of the prosthesis even in the absence of the patients. The manuscript will present the aims on capturing and quantifying the complex process of tissue changes during the prosthetic treatment, in particular the effect of biomechanical changes in structure and load distribution within the amputation stump in the simulation. In the following we would like to present our implementation concept to optimize the current prosthetic socket construction and fabrication process by combining three existing powerful software products (Mimics, 3-matic and ANSYS) into one uniform software platform. Based on this virtual study of influencing factors and planned changes of the final result, it would be possible for the first time to verify the clinical efficiency of prosthesis assembly and to establish an objective quantifiable quality control.. Through the developed and optimized workflow the manufacturing process will be cheaper and enormous shorter. Through the use of telemedicine based analyse and supply systems even states where none or less specialists are available would benefit from the technology. An important market is therefore also seen in developing countries, where until now no efficient orthopaedic technology exists.

SOCIAL IMPACT

In 2003 Germany registered a total number of 83.407 amputees. Despite improved medical prevention and successful treatment of potential risk factors, the number of new amputations is constant over last year's [1]. The group aged of over 65 years old is highly represented with a number of 57.947 amputees per year (69%). According to the demographic changes and developments the number of over 65-years-olds, related to 100 persons in the working age between 20 and 65 years, will increase from today 26 to 36 in 2020 and to 54 in 2040. Patients with amputations cause considerable health care system costs. This fact will be reflected in the future according to the described demographic changes related to the negative correlation between increased health care system costs and decreased social insurance proceeds [2]. But the most important medical therapy concept for amputees is to provide prosthetic supply and to enable this patient collective to participate in active life and to socially reintegrate [3]. Due to this therapy, patients regain mobility, can still feed themselves and even partially reintegrate to professional life, whereby, potential occurring care-giving expenses can be reduced.

CURRENT PROBLEM

The essential problem for every orthopedic technician is to construct a well fitted prosthetic socket according to the existing amputation stump to optimally close the human-prosthetic interface [4]. The challenge is to create an optimal shaped prosthesis socket which definitely attaches to the stump, stabilizes the prosthetic joint and which induces the stump movement over the entire prosthesis. However, the prosthetic socket must not create too high pressure to the stump's soft tissue in order to avoid low perfusion areas, pressure marks and wound healing problems. A homogeneous pressure distribution over the entire stump must be obtained under static and dynamic pressure conditions. In addition, an optimal shaped prosthetic socket must consider the individual soft tissue properties of the amputation stump. A stump with fat tissue preponderance must handle totally different compressions than a stump with muscle preponderance. These facts pose an enormous patient specific challenge to the orthopedic technician.

The current prosthetic socket construction is carried out solely according to the external shape of the amputation stump using manual casting methods [5, 6]. The effusion of the cast creates a positive model which serves as a negative form to shape the prosthetic socket using plastic material [7]. The construction process is carried out according to empirically gathered regulations and is based onto subjective estimations, competence and capabilities of the orthopedic technician [2]. The conducted shape changes during the fitting process are not objectively quantifiable and only take the external stump shape into account, neglecting the biomechanical soft tissue deformation of the entire stump [8]

The current prosthetic socket planning method does not take patient specific parameters into account and therefore causes a high rate of inappropriate prosthetic supplies [9]. To gain the best fitted prosthesis, numerous test prosthetic sockets are needed, resulting in high material costs and considerable labor costs of 30-40 working hours per patient. The quality assessment of the final prosthetic socket is solely based on the subjective patient's perception and therefore an objective quantification of the final quality is limited [10]. Despite lacking data, experts consider that 60% of the prosthetic supply does not match the desired quality criteria. The results are tremendous: increasing health care cost, secondary disorders like arthrosis, back pain, open wounds which even lead to complex plastic surgical treatments which results in readjustments of the prosthetic socket [3, 10, 11]. This highly subjectively embossed supplying philosophy leads to different available competing prosthetic systems which all claim to be the optimal stump supply [2, 9, 10]. This essential drawback clearly shows that a substantial necessity exists to develop more objective planning systems and to gain a higher quality in the prosthetic socket construction.

IMPROVEMENTS IN PROSTETIC SOCKET CONSTRUCTION & FABRICATION

CONSTRUCTION

3-D Surface Imaging

In last year's new technologies were applied to optimize the shape assessment of amputation stumps. 3-D surface imaging systems enables a more precise capturing and quantification of the external shape of the amputation stump [2, 12]. The 3-D captures only the static condition of the stump and cannot consider the dynamic interactions between the stump's soft tissue and the planned prosthetic socket. Using the gained 3-D surface data, a CAD (Computer Aided Design) based constructed 3-D stump model is chosen out of an existing database and adequately shaped to fit the surface geometry of the amputation stump. The virtual modeling is performed using specific software adapted to the needs of orthopedic technicians [13]. The gained data are sent to a CNC (Computer Numeric Control) milling machine to produce a positive model and to construct the socket in the conventional technique [14].

Radiological Imaging

Another approach to detect the external shape of the amputation stump is the CAD based prosthesis socket modeling using computer tomography (CT) or magnetic resonance imaging (MRI) of the amputation area. Using these two-dimensional (2-D) sectional images of the amputation region the external shape is determined and the socket is modeled based onto these 2-D data with the help of CAD software. Although a 3-D reconstruction of the anatomical region would be possible according to the DICOM data [4, 10], the relative 3-D position of the different anatomical structures are not taken into account. Solely the 2-D contours of the anatomical structures are used for the CAD optimized socket construction. Despite the integration of objective DICOM data, the main problem of soft tissue deformation in the amputation stump is not considered to optimize the socket construction. CAD modeling for prosthetic socket construction is extremely empiric, based on static assessments of the external shape and non repeatable measurements and is influenced by the subjective experience of the orthopedic technician [15]. These radiological construction methods facilitate the static shape assessment, but do not represent an advance in quality compared to the classical casting method.

Gait and Pressure Distribution Analysis

The described methods only represent static description of the amputation stump. Therefore, first approaches using gait and pressure distribution analysis are described to analyze the interaction between the stump and the socket and to evaluate the impact to the whole body movement of the patient [16-22]. These dynamic analyzing methods guarantee an objective quantification of the resulting interaction during the gait cycle and offer a visualization of the gait pattern. In addition, an optimization of the human-prosthetic intersection is available using punctual pressure distribution under static and dynamic conditions, but only surface information is gained. A visualization of the resulting deformations of the internal hard and soft tissue which is mainly responsible for the blood supply of the amputations is not delivered.

Finite Element Method (FEM) Simulation

Therefore, in last year's research activities focused on the 3-D reconstruction of anatomical regions using modern radiological imaging (CT and MRI) to implement these models to FEM simulation [24]. The physical behavior of biological tissue can be virtually simulated using specific numerical formulas. With FEM it is possible to quantify the deformation of anatomical structures caused by the prosthetic socket compression. The FEM is well established for industrial purposes and is also applicable to medical and biomechanical objectives [25, 26]. There are some approaches regarding the prosthetic-stump-interaction and soft tissue deformations in the literature, but no generally accepted implementation concept does exist because the actual scientific knowledge has to be considered as preliminary [27, 28]. The applied biomechanical FEM simulation models are too simplified using isotropic, non linear material parameters [29]. Until today only static models has been applied but dynamic simulation models are needed not only to simulate variable external effects but also material interaction during walking under varying pressure conditions [31].

FABRICATION

The diverse planned construction shape of the prosthetic socket can be fabricated using different manufacturing methods. Beside the manual casting and the following plastic modeling can be optimized using CAD software.

Computer Aided Design (CAD)

The innovational character in the fabrication of CAD assisted prosthetic sockets using 3-D surface imaging is based on the fabrication process acceleration using CNC milling machines by producing a positive model. The final fabrication process stays the same, only the process is accelerated.

RAPID PROTOTYPING (RP)

Another method to speed up the fabrication process is the use of RP [31]. RP techniques are more often used to manufacture end products and represent a fast, flexible and tool-free manufacturing process based on virtual 3-D data (CAD, STL). RP produces the final product in different layers using physical and chemical effects without manual detour and additional configurations. The original RP procedure stereo lithography (STL) was enhanced by novel procedures (SLS, FDM, 3-D Printing) and show promising applications for an innovative prosthetic socket fabrication process.

Das ursprüngliche RP-Verfahren der Stereolithographie (STL) wurde um neuartigere Verfahren (SLS, FDM, 3-D Printing) erweitert und zeigen viel versprechende Ansätze für eine innovative Anwendung in der Prothesenschaftherstellung [26-36].

NECESSITY TO COMBINE MODERN CONSTRUCTION AND MODERN FABRICATION

Despite the ongoing renewals in prosthetic technology, there is a great need for developing an objective method for planning the prosthetic socket shape taking into account the biomechanical properties of the stump, both considering static and dynamic load cases. Based on CT / MRI data, the soft-tissue geometry can be segmented and virtual simulation with the aid of the Finite Element

Analysis can be conducted in order to calculate the deformation and compression of the stump due to the contact to the prosthesis. Thus, simulation of the physical behavior of the patient-specific characteristics of the stump tissue can be conducted with numerical methods to satisfy mathematical laws. Then, the obtained simulation results may be compared to true conditions for validation. This allows simulation and thereby virtual planning of the prosthesis shape with an included optimization of the fit even before production. In case of sub-optimal planning a quick and cheap correction of the virtual model can be performed. The design ensures a more precise adjustment of the socket and thus permits the optimization of existing manufacturing processes.

Nowadays, there is still a gap between the planned socket shape and the uncertainty on the fit of the resulting product to the stump that can be closed by using the here presented methods for all existing manufacturing processes e. g. CNC milling. The development of such a method improves the existing process for the manufacturing of the conventional prosthesis using CAD based planning data. Furthermore, this virtual method of optimization now also offers the possibility of implementing modern manufacturing techniques such as rapid prototyping in the process chain. By using the RP-product manufacturing process, the entire work flow from data acquisition for 3-D reconstruction of the soft tissues of the amputation stump to the computational optimization and numerical simulation of the prosthetic socket interaction can be established in terms of rapid manufacturing. The optimization of the socket before production would also allow virtual experiments and the application of new materials and their response to changes in prosthetic forms (e.g. wall thickness changes, etc.). With the ability to analyze the product behavior even before production with simulation techniques in the virtual stage, it is possible to maximize benefits. With a well-considered choice of materials and waste avoiding and effective use of matter, opportunities for companies are created to develop patient-specific products very quickly but also to produce them at lower cost.

Since these methods can be used to study the biological properties of the stump as well as its interaction with the prosthesis, they will have an impact on the surgical technique as well. New types of amputation can objectively be reviewed in this context and their suitability for a certain prosthetic socket can be inspected. Therefore, the aim must be to include all of these different technologies of three-dimensional measurement, visualization, quantification and simulation of patient-specific soft tissue deformation under different load conditions to optimize the construction of the prosthetic socket. Only by including all of these relatively newly developed tools into one work flow, the overall process is applicable for improving the quality of life of amputation patients.

PROJECT AIM

The central objective of the presented work is to improve the currently empirical process of prosthesis design in orthopedic technology with the aid of modern imaging techniques and computer technology by taking into account patient-specific consistence of the amputation stump and is peer-reviewed and funded by the Bayerische Forschungsstiftung (www.forschungsstiftung.de) in Germany. The project aim is to capture and simulate the complex processes of changing soft tissue properties during the prosthetic treatment, in particular the effect of biomechanical changes in load to be supplied within the amputation stump and the interaction with the prosthetic socket. Using modern gait laboratory analysis and pressure distribution measurements, the biomechanical tissue changes can be quantified and are taken into account for the creation of a physically realistic virtual 3-D model of the amputation stump.

Based on patient-specific 3-D models, the 3-D visualization, quantification and simulation of the individual biomechanical tissue changes in the amputation stump in a static state, as well as under dynamic conditions during the interaction with the prosthetic socket will be evaluated using finite element analysis. The computer-aided visualization and virtual simulation of soft tissue deformation and of the contact forces in the interface between the patient-specific deformable model and the amputation stump at the computer individually planned model of the prosthetic socket will serve as basis for a reproducible construction and fabrication of individually adjusted exoskeleton prosthetic socket systems as well as a computer-simulated “virtual try-on” before construction and fabrication of the prosthesis even in the absence of the patients.

Today, the central problem of orthopedic technology is to construct a prosthetic socket that fits as good as possible to the geometry of the amputation stump. The empirically developed production methods that are used in orthopedic technology today are a purely manual production technique, which leads to a very large proportion of failures in patients with associated symptoms and furthermore to increased costs for the health system. Therefore, there is an urgent need to optimize the prosthetic socket construction and fabrication that should be performed with the consideration of patient-specific material behavior of the amputation stump.

The manuscript will present the aims on capturing and quantifying the complex process of tissue changes during the prosthetic treatment, in particular the effect of biomechanical changes in structure and load distribution within the amputation stump in the simulation.

With this approach the following goals for an optimized prosthetic socket construction and fabrication should be achieved by implementing modern and innovative manufacturing processes to the current procedure:

1. Optimization of the prosthetic socket of the lower and upper limbs after amputation, minimizing the handicap, reducing side effects through non-suitable prosthesis.
2. Reproducible and consistent high quality of care, reducing the rate of wrong treatment with resulting increase in efficiency by sophisticated clinical validation (gait and pressure analysis).
3. Computer-aided visualization and simulation of soft tissue deformation and of the interaction forces between the patient-specific deformable model of the amputation stump and the planned prosthetic socket. This allows a computer-simulated virtual fitting of the prosthesis even without the presence of the patient.
4. Optimization of existing manufacturing processes and development and integration of new manufacturing processes (Rapid Prototyping)
5. Claim of new markets by high level innovations with regard to health care quality and efficiency of the method with a high economical and social potential (third world countries, central production facilities, telemedicine, etc.).

In the following we would like to present our implementation concept to optimize the current prosthetic socket construction and fabrication process by combining three existing powerful software products (*Mimics, 3-matic and ANSYS*) into one uniform software platform.

IMPLEMENTATION CONCEPT

The presented project will intent to develop a specific software platform for orthopedically medical applications and to combine scientific and technical approaches to an innovative implementation concept **(Figure 1)**. Based on the CT or MRI data of different amputations stumps, the relevant tissue components (skin, fat, muscle and bone) will be segmented and 3-D virtual volume stump models (STL) will be created and the optimal prosthesis socket construction taking soft tissue properties into account will be simulated.

The essential module of this project forms the combined software platform for segmentation (Mimics, Materialise GmbH, München, Germany), meshing and 3-D modeling (3-matic, Materialise, München, Germany) and virtual simulation of the optimal fitting of the prosthesis socket (ANSYS, CADFEM GmbH, Grafing, Germany).

The Mimics/3-matic forward engineering combination is unique worldwide and optimal fits to the project challenge. The workflow will be the following: CT/MRI data will be imported and segmented by Mimics and a closed 3-D STL model is created. 3-matic is not solely capable to generate 3-D volume meshes but also able to design and modify directly on the virtual 3-D STL model. Through this innovative step one can avoid time-consuming and error-prone reverse engineering steps. On the one hand the first reverse-engineering step (STL → CAD) would take place by modeling in common CAD software solutions and on the other hand the second reverse-engineering step (CAD → STL) would take place during the manufacturing process using RP procedures or CNC milling machines, both working on STL data basis. These double reverse-engineering steps will result in a loss of accuracy. The Mimics/3-matic package enables to work on one date basis and easily transfer STL data to ANSYS, also working on STL data basis. The combination of these 3 software products guarantee fast and precise operations in terms of rapid manufacturing. Another benefit working on STL data basis is the fact that 3-matic can be directly responsive to the FEM simulation results by ANSYS **(Figure 1, red arrow)**. If a suboptimal simulation result is gained by ANSYS a redesign can be accomplished by 3-matic and an optimization **(Figure 1, green arrow)** will take place and a reintegration to the consecutive construction process will take place before the final manufacturing step will start in terms of a negative feedback. Consequently, the socket geometry can be newly prepared (optimized) if ANSYS register a pathological pressure at a specific point. The combination of these different software solutions would be worldwide the first practical medical application in terms of a rapid manufacturing process. After the optimized prosthesis socket has passed the FEM analysis (ANSYS) the final fabrication step will follow. In this step different RP procedures will be analyzed regarding their clinical feasibility. The Selective Laser Sintering (SLS) and the Fused Deposition Modeling (FDM) will play an important and cost effective role and both techniques will be evaluated in the project. Newly applied fabrication materials will numerical evaluated regarding quality rating and practicability. Especially the needed nominal wall thickness of the prosthesis socket will be simulated, optimized and analyzed regarding needed firmness and rigidity. In a final step the clinical validation will take place. In gait and pressure distribution analysis the optimized prosthesis socket will be finally analyzed and if a potential suboptimal fitting is detected by the patient and the analyzing system, a last negative feedback to the 3-matic level is embedded into the construction and fabrication process.

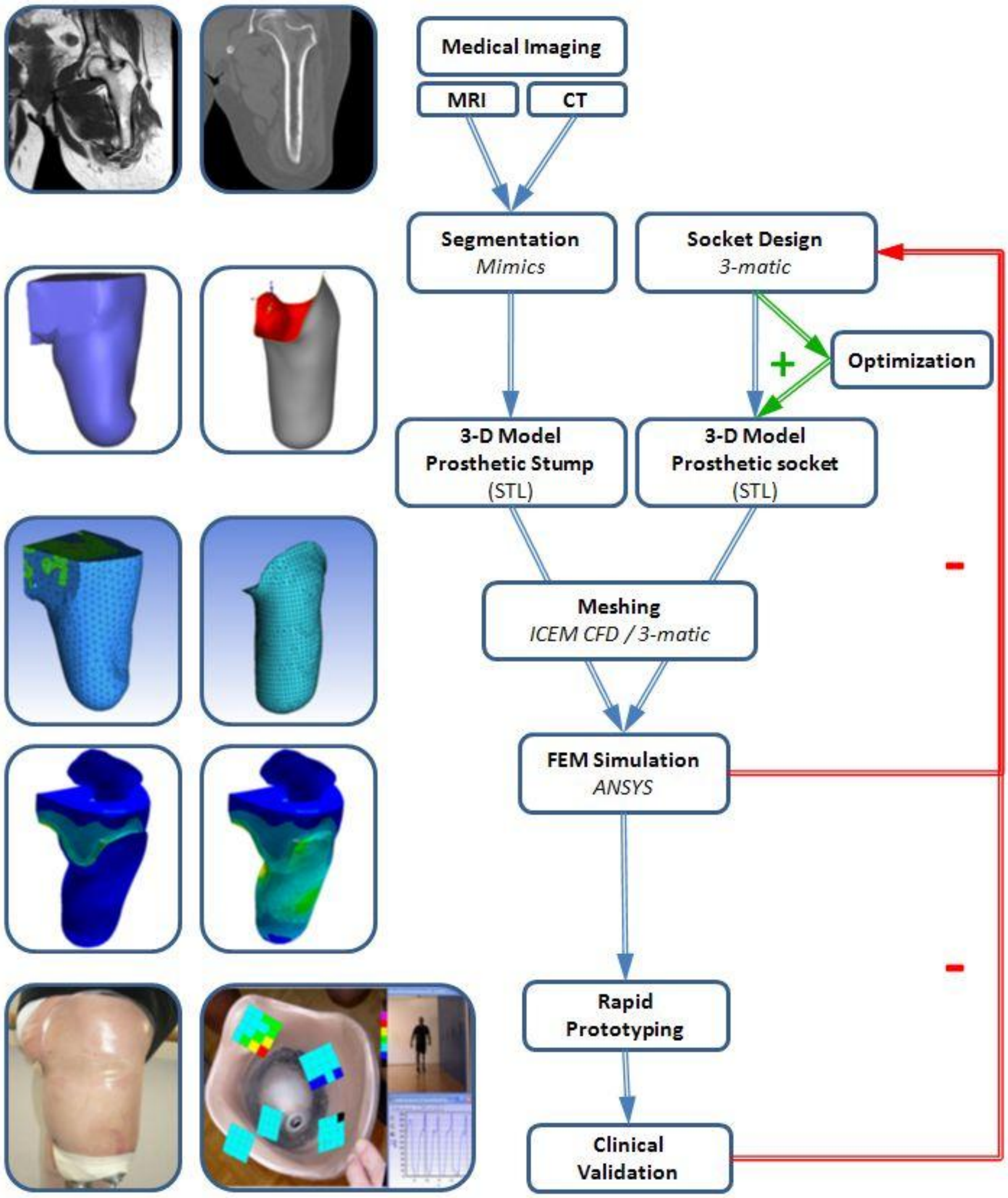

Figure 1: *Optimization workflow overview*

WORKFLOW OPTIMIZATION

In the following specific processes are presented to optimize the presented workflow steps and to guarantee a fast, precise and accurate prosthesis socket construction and fabrication in terms of a rapid manufacturing process. Main focus will be the interaction of the different software components (*Mimics, 3-matic and ANSYS*) as a powerful software platform combination in the final product design.

MEDICAL IMAGING

For a reasonable simulation of the prosthetic stump a 3-D model of the main 3 tissues (fat tissue, muscle mass, bone) is required. The standard medical imaging methods for obtaining such geometries are CT and MRI. Medical imaging data obtained by CT are in general more accurate and because of the correlation between Hounsfield units (HU) and tissue density allow an automatic segmentation using tresholding. Such segmentations can provide sufficiently accurate 3-D geometry for creating a FEM model of the prosthetic stump in about 8-10 minutes **(Figure 2)**. Major shortcoming of the CT data acquisition is the radiation exposure to the patient.

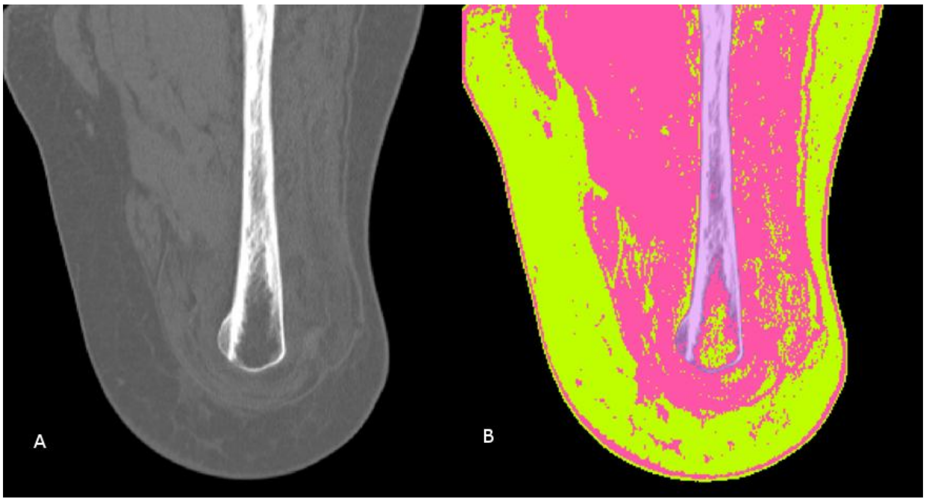

Figure 2: *(A) Example segmentation of a CT scan of a prosthetic stump. (B) Using tresholding a reasonably accurate model with soft tissue, muscle and bone can be obtained.*

Because of its noninvasive nature MRI is well suited for diagnostic purposes. But segmentation and 3-D modeling using MRI face the examiner with remarkable problems regarding automatic segmentation because it does not allow such a simple correlation between HU and tissue density. The grey values in the MRI do not correlate to HU's **(Figure 3)**. Therefore, the different tissues need to be identified and segmented by hand in general. This is a very time consuming process and strategies for an automatic segmentation are needed. Using Mimics and applying a certain workflow which will be presented in the following, the time needed to obtain useful 3-D geometries can be greatly reduced.

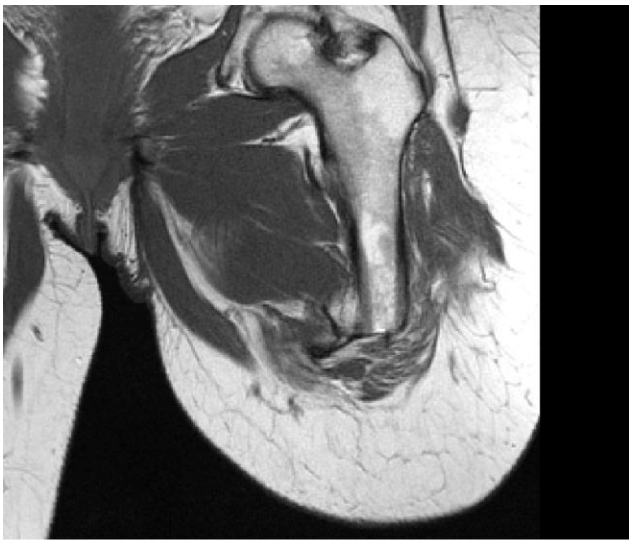

Figure 3: *MRI of a prosthetic stump. The grey values don't correlate directly with the different tissue densities and extensively limits the automatic segmentation process.*

SEGMENTATION AND 3-D MODELLING

The main limiting problem in segmenting the 3-D geometry of an idealized muscle mass (neglecting the exact geometry of the separate muscles) using MRI, is that tresholding also includes parts of the outer boundary of the fat tissue. This problem can be solved by defining a specific workflow in ***Mimics*** that allows segmenting the muscles fast and easily. The steps of our created workflow are as follows:

6. **The mask of the full geometry (including fat tissue, muscles and bones) is extracted**.

Tresholding is used to obtain as much of the stump geometry as possible **(Figure 4)**. The dark parts of the muscles and bones create cavities in the resulting mask **(Figure 4B)**. The 3-D geometry is computed from the mask and wrapped using small parameters for *Smallest Detail* and *Closing Distance.* Calculating the mask from the wrapped geometry returns what will be referred to as the *full* mask **(Figure 4C)**.

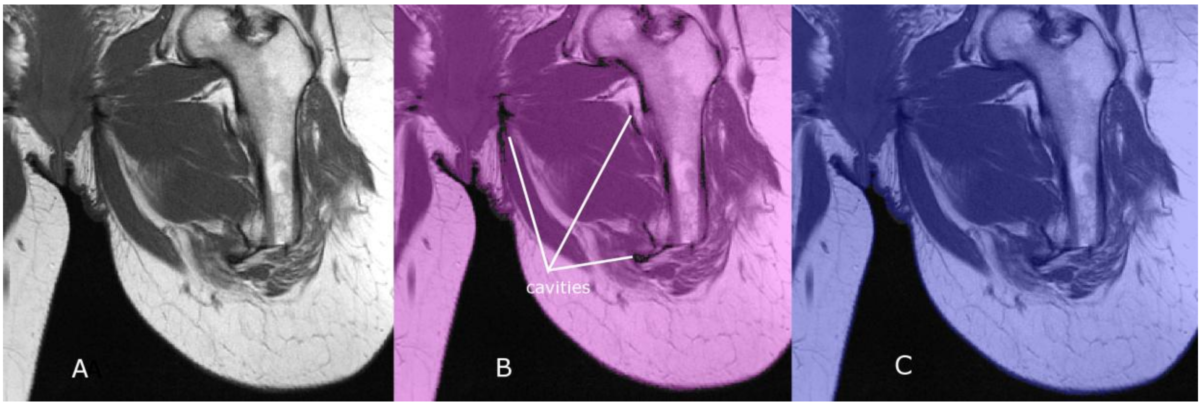

Figure 4: *(A) Raw images of a prosthetic stump, (B) mask of the full geometry extracted using tresholding with visible cavities, (C) mask of the full geometry after wrapping, cavities are removed.*

7. **The mask of the muscles is extracted using tresholding**.
   When tresholding is used to extract the muscles also the outer surface and cavities are also segmented. This mask will be referred to as mask *A* **(Figure 5A)**.
8. **The *full* mask is eroded.**
   Using the erode operation from the morphology operations feature of Mimics the outer layer of the *full* mask can be removed. This mask will be referred to as mask *B* **(Figure 5B)**.
9. **Intersection of *A* and *B* masks**
   By intersecting the masks *A* and *B* the dark outer layer from the mask *A* is removed **(Figure 5C).**

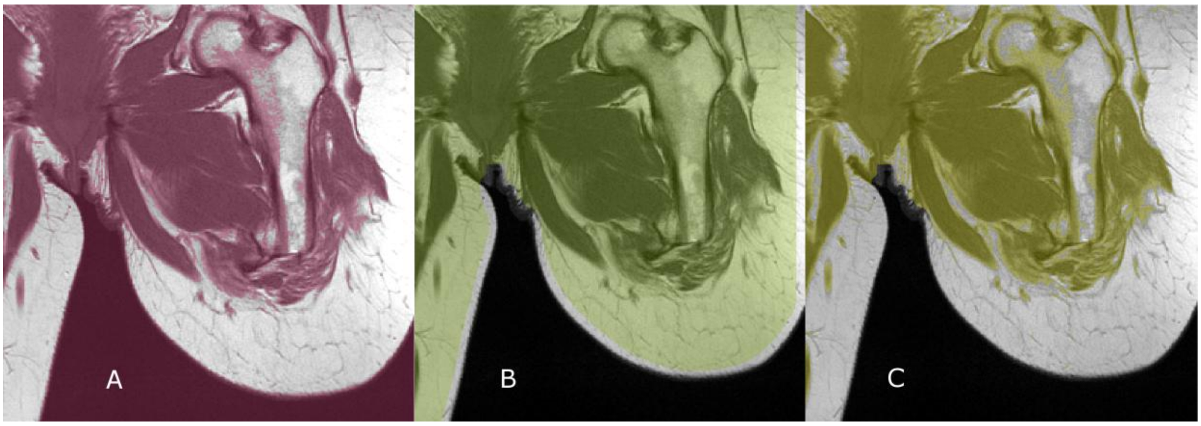

Figure 5: *(A) Muscles segmented using tresholding (mask A). (B) eroded mask of the full geometry (mask B). (C) Final segmentation of the muscles by intersecting masks A and B.*

10. **Simplification of the muscle geometry**

    In order to create a reasonably complex model of the prosthetic stump, the 3-D geometry of the muscles is calculated and wrapped. This reduces the complexity of the model and allows a simple creation of a FEM mesh. However, in this process the femur is also included. This will be referred to as the *muscle* mask **(Figure 6A)**.

11. **Segmentation of the femur using LiveWire**

    The only left part of the geometry needed for a FEM model is the femur. The bone tissue must be in general segmented by hand in MRI images. However by using LiveWire in *Mimics* this can be done in a very short time. Subsequent wrapping and smoothing can give a very accurate geometry of the femur. This will be referred to as the *femur* mask **(Figure 6B)**.

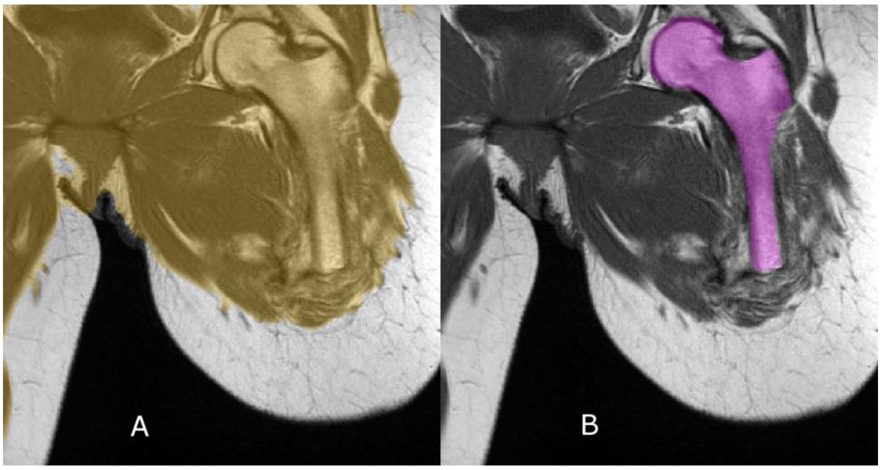

Figure 6: *(A) Simplified muscle geometry (including femur). (B) Femur segmented using LiveWire.*

12. **Separation of the different tissues using Boolean Operations**

    The *muscle* mask is completely contained in the *full* mask and the *femur* mask is completely contained in the *muscle* mask. This allows us to use Boolean operations **(Figure 7)** to extract the geometry of fat (*full* - *muscle*) and muscle (*muscle – femur)*.

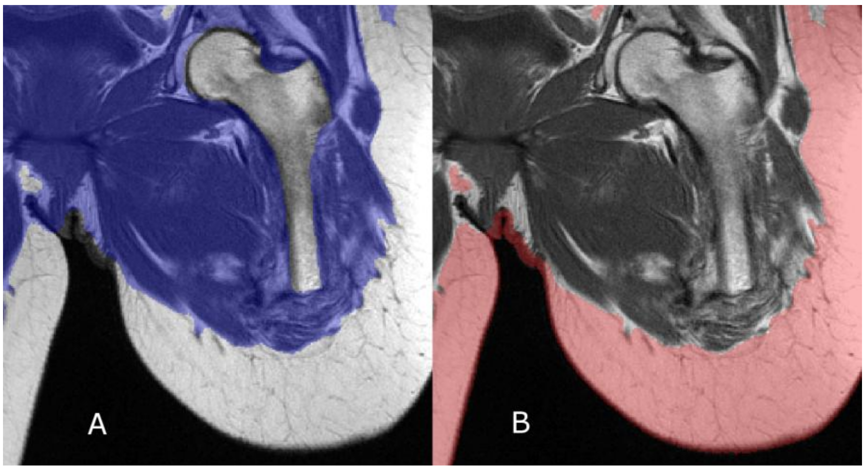

Figure 7: *(A) Final mask of the muscle mass (B) fat tissue.*

The whole workflow takes 15 minutes for an inexperienced user and thereby allows a clinical application. With these final geometry of fat tissue, muscle and femur a biomechanical model of the prosthetic stump can be created **(Figure 8)**. The 3-D geometries are exported as a STL model which can be loaded to ICEM CFD to create a FEM mesh for ANSYS simulation.

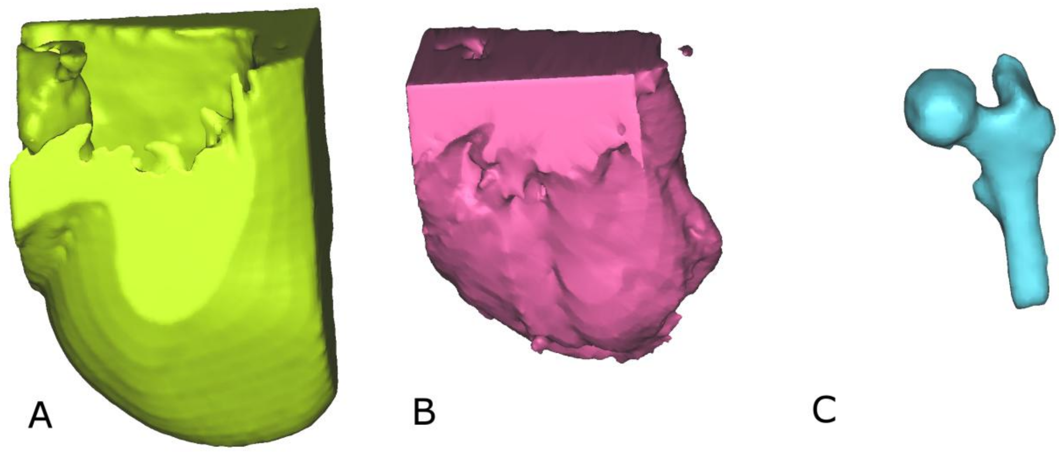

Figure 8: *The final 3-D models of the prosthetic stump. (A) Fat tissue, (B) muscle mass and (C) femur.*

FEM SIMULATION

In order to virtually design and test a prosthetic socket, we need to model the socket as well as the prosthetic stump. Having created a surface model of the 3 different tissue types (fat tissue, muscle, bone) in *Mimics*, a FE Mesh of the stump can be created using ICEM CFD **(Figure 9A)**. The socket model can be meshed as well using ICEM CFD if CAD or STL design data is present **(Figure 9B)**. This is however not an easy process, because of mostly insufficient quality of such data for meshing which requires complicated healing of the geometry. In the future the patient specific socket design and the meshing will be done in 3-Matic **(Figure 9C)** and allows a direct forward engineering export of the surface mesh to ANSYS **(*see Figure 1:*** *Optimization workflow overview***)**.

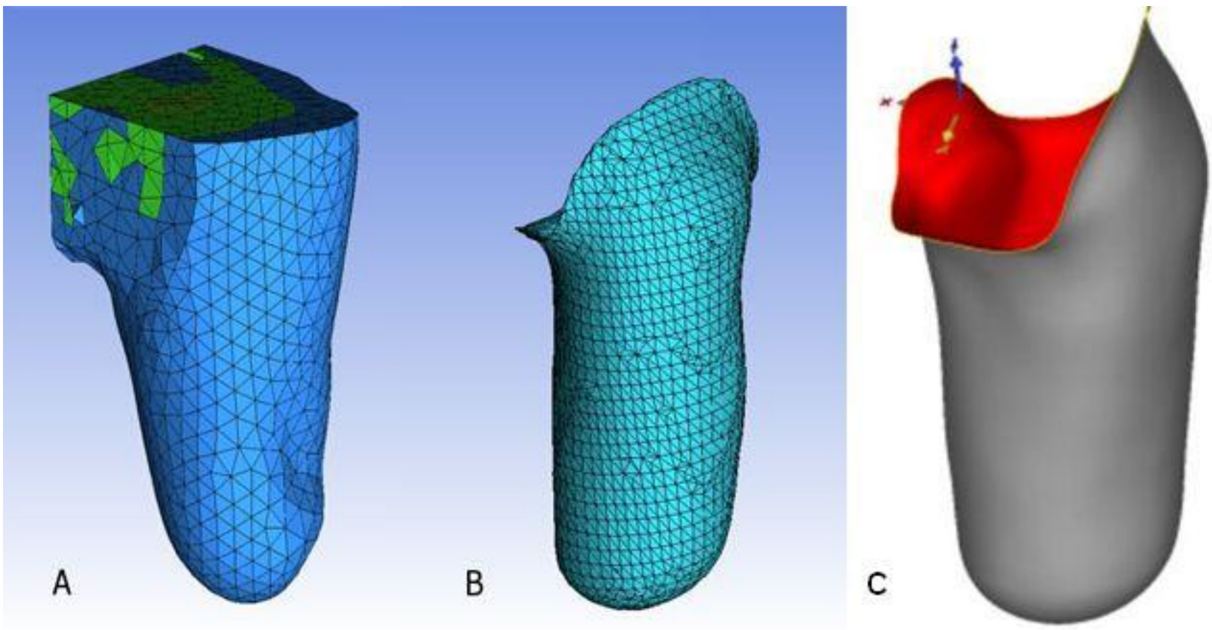

Figure 9: *Example of a prosthetic stump mesh (A) and socket mesh (B) created with ICEM CFD and future patient specific 3-D socket design with 3-matic.*

In ANSYS the muscle is modeled using the two-parameter Mooney-Rivlin material model, because of its computing efficiency. Its strain-energy function used in ANSYS is as follows:

$$W = C_{10}(\overline{I_1} - 3) + C_{01}(\overline{I_2} - 3) + \frac{1}{d}(J-1)^2$$

Where W is the strain energy, $\overline{I_1}$ and, $\overline{I_2}$ are the first and second deviatory strain invariants and J is the determinant of the deformation gradient. The parameters C_{10} and C_{01} are obtained from literature (e.g. [1]) with values $C_{10} = 30\ \mathrm{kPa}, C_{01} = 10\ \mathrm{kPa}$ and $d = 1.667 \times 10^{-5}\ \mathrm{Pa}^{-1}$. For the fat tissue a hyperelastic model is chosen with a second order polynomial strain-energy function. This is defined as follows:

$$W = \sum_{i+j=1}^{2} C_{ij}\,(\overline{I_1} - 3)^i\,(\overline{I_2} - 3)^j + \sum_{i=1}^{2} \frac{1}{D_i}(J-1)^{2i}$$

Where W is the strain energy, $\overline{I_1}$ and, $\overline{I_2}$ are the first and second deviatoric strain invariants and J is the determinant of the deformation gradient. The Parameters are chosen from literature [2] with the values $C_{10} = 85.56\ \mathrm{kPa}, C_{01} = -58.41\ \mathrm{kPa},\ C_{20} = 39\ \mathrm{kPa},\ C_{11} = -23.19\ \mathrm{kPa},\ C_{02} = 85.1\ \mathrm{kPa},\ D_1 = 3.65273\ \mathrm{MPa}^{-1},\ D_2 = 0\ \mathrm{MPa}^{-1}$.

The socket and bone are modeled as linear elastic with parameters $E_{bone} = 7300\ \mathrm{MPa}, \mathrm{v}_{bone} = 0.3$ for the bone and $E_{socket} = 30000\ \mathrm{MPa}, \mathrm{v}_{socket} = 0.3$ for the socket. The aim of the simulation is to compute the pressure of the socket on the prosthetic stump **(Figure 10)**. For this purpose normally the pulling of the socket over the stump needs to be simulated. However this is a computationally hard task because of contact problems between the socket and the stump. Because of that the socket is widened (e.g. as if under thermal strain) and moved over the stump and then returned to its original shape. Like this, we get a computationally simpler model with nearly the same results **(Figure 11)**.

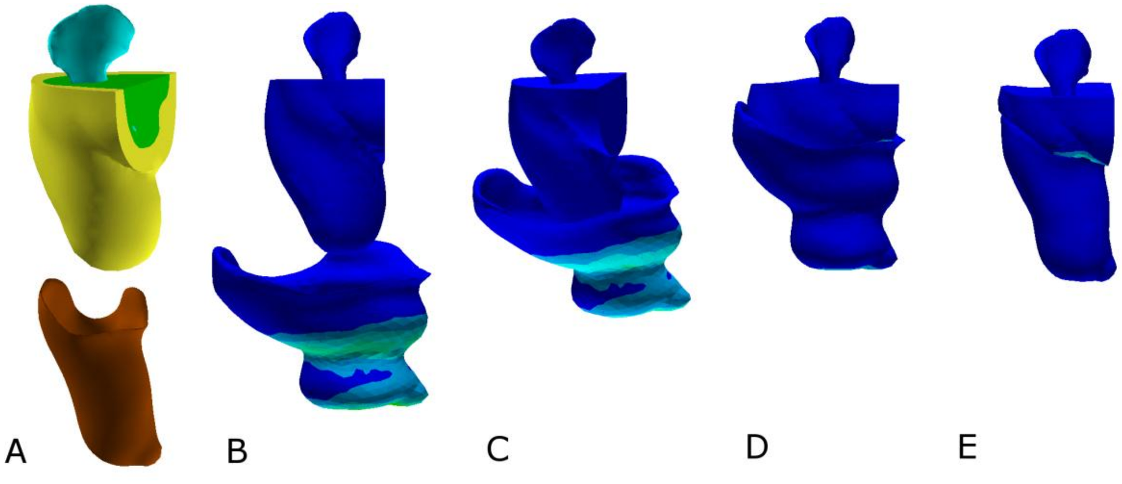

Figure 10: *(A) initial model, the socket and stump are separated. (B) Socket is widened. (C) Socket is moved over the stump. (D) Socket is compressed to return to its original shape. (E) The socket in its final position.*

A model set up like this can be computed in a few hours. It is robust and easy to automize, making it a feasible model for clinical application. However a validation of this model is yet part of our future work. We hope to refine the model parameters to make the model more reliable.

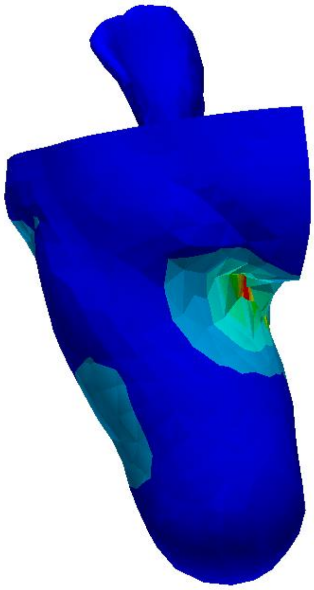

Figure 11: *The resulting pressure distribution in the stump. The locations with stress maxima are visible. Without a further validation of the model, this is only a trend prediction.*

VALIDATION OF SOFT TISSUE DEFORMATION

The next step will be the validation of the actual simulation data. The applied simulation models will be validated using up-right MRI data. This MRI acquisition enables to accomplish the amputation region in a standing position without any soft tissue deformation compared to the normal acquisition in lying position. An up-right MRI scan will performed in standing position with and without an optimal fitted prosthesis socket and in lying position with and without an optimal fitted prosthesis socket. Using our developed optimized segmentation workflow for MRI's, the different 3-D models will be created. In this step the deformed lying amputation stump with and without socket will be virtually erected into the standing position with and without socket. The results of the final simulation geometry will be compared with the segmented 3-D model and therefore serve as a validation tool for the applied numerical simulation model. This work is currently in progress and we will be glad to refer shortly.

TECHNICAL AND SOCIAL INNOVATION

With the planned method it would be possible to assemble computer optimized patient specific prosthesis sockets in a so far unknown quality taking into account biomechanical tissue parameters of the amputation stump. Therewith, an integrated procedure would be given to fulfill the heterogeneity of the amputation patterns as well as the necessity to capture body regions in different body positions.

Through simulation of soft tissue deformation in the amputation stump and the interaction with the prosthesis socket, an optimization of the current prosthesis supply is obtained and even a virtual try-on of the socket in absence of the patient would be possible. Based on this virtual study of influencing factors and planned changes of the final result, it would be possible for the first time to verify the clinical efficiency of prosthesis assembly and to establish an objective quantifiable quality control. Different anatomical aspects of the amputation stump can be included with the developed mathematical simulation model. Thus, different physical calculations can be performed, which can simulate diverse pathologic conditions of the stump (swelling, low soft tissue coat etc.). Biomechanical property consideration is not possible with conventional construction systems. The patient specific examination of static and dynamic loads inside the prosthesis is now available and allows a higher qualitative prosthesis socket construction and fabrication. This guarantees a huge reproducibility in the different phases of the production process and integrates the application of the progressive principles of rapid manufacturing in the currently empirically embossed manufacturing process. Through a computer aided optimization it is for the first time possible to close the gap between prosthesis shank planning and all existent production processes regarding to the non objective compilation of fitting accuracy of the prosthesis socket and to realize an optimal economic use of the innovative RP method. From previous experience it is to deduce that resulting inappropriate services under consideration of the particular manufacturing method is caused by the suboptimal planning of the prosthesis socket. Through optimization of this step and the consideration of the patient specific properties, the inappropriate service will be reduced in all manufacturing techniques and costs will clearly decrease. With the developed and optimized workflow **(Figure 1)**, the manufacturing process will be cheaper and significantly shorter. The rate of inappropriate fabrications will be clearly reduced, which describes an important economic factor regarding to the accommodation of a constant increasing number of affected patients and the potential installation of central manufacturing structures. Health economic considerations and calculations will still more dominate the medical daily routine in the future. Commercial and scientific cooperation have to stay further innovative and coincidental consider basic conditions of the public health sector. This form of objective evaluation of clinical efficiency is a promising supporting device for assistance in assessor's work and for verifiability of relevant aspects in health care. Until now no biomechanical model exists which combines these complex analyzing possibilities. For the first time, diverse biomechanical processes can be inspected by this mathematical simulation model and research concerning defined soft tissue interactions can also expanded to other body regions. Especially regarding to supply quality and optimization of the prosthesis socket constructions in the field of physically handicapped competitive sports presents this project interesting connectivity. Simulation systems, which consider the tissue properties are useful in medical education and in clinical and practice daily routine and demonstrate an interesting market for ambitious companies in the field of medical engineering and biomechanics.

ECONOMICAL POTENTIAL

The result of the project will be a method and a software for the optimization of prosthesis sockets construction and fabrication. A selling market for the software product would be clinics and medical disciplines with orthopedic relevance. Innovative companies with specialization in material efficiency testing, this field represents an interesting activity. Also the innovative manufacturing methods in the field of RP surely represents further development potential in the future, especially in novel construction possibilities of prosthesis sockets in combination with new findings in material science. Analysis of the necessary data can take place in specific centers of competence with attached factories. The communication possibility over the World Wide Web allows an international connection of economy and science to quickly and effectively satisfy a global social economic demand. Using telemedicine based analysis and supply systems, even states where none or fewer specialists are available would benefit from the technology. An important market is therefore also seen in developing countries, where until now no efficient orthopedic technology exists.

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