Computational Methods in Applied Sciences

João Manuel R. S. Tavares
R. M. Natal Jorge *Editors*

Computational Vision and Medical Image Processing

Recent Trends

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International Center for Numerical Methods in Engineering (CIMNE)
Technical University of Catalunya (UPC)
Edificio C-1, Campus Norte UPC
Gran Capitán, s/n
08034 Barcelona, Spain
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Editors

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Editors
João Manuel R. S. Tavares
Universidade do Porto
Fac. Engenharia
Departamento de Engenharia Mecânica
Rua Dr. Roberto Frias
4200-465 Porto
Portugal
tavares@fe.up.pt

R. M. Natal Jorge
Universidade do Porto
Fac. Engenharia
Departamento de Engenharia Mecânica
Rua Dr. Roberto Frias
4200-465 Porto
Portugal
rnatal@fe.up.pt

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Preface

Nowadays, computational methodologies of signal processing and imaging analysis for 2D, 3D and even 4D data are commonly used for various applications in society. For example, Computational Vision systems are progressively used for surveillance tasks, traffic analysis, recognition process, inspection purposes, human-machine interfaces, 3D vision and deformation analysis.

One of the main characteristics of the Computational Vision domain is its inter-multidisciplinary nature. In fact, in this domain, methodologies of several other fundamental sciences, such as Informatics, Mathematics, Statistics, Psychology, Mechanics and Physics are regularly used. Besides this inter-multidisciplinary characteristic, one of the main rationale that promotes the continuous effort being made in this area of human knowledge is the number of applications in the medical area. For instance, statistical or physical procedures on medical images can be used in order to model the represented structures. This modelling can have different goals, for example: shape reconstruction, segmentation, registration, behavioural interpretation and simulation, motion and deformation analysis, virtual reality, computer-assisted therapy or tissue characterization.

The main objective of the ECCOMAS Thematic Conferences on Computational Vision and Medical Image Processing (VIPimage) is to promote a comprehensive forum for discussion on the recent advances in the related fields and try to identify areas of potential collaboration between researchers of different sciences.

This book contains the extended versions of nineteen papers selected from works presented at the second ECCOMAS thematic conference on Computational Vision and Medical Image processing (VIPimage 2009), which was held at the Engineering Faculty of the University of Porto, Portugal. It gathers together the state-of-the-art on the subject of Computational Vision and Medical Image processing contributing to the development of these knowledge areas and showing new trends in these fields.

The Editors would like to take this opportunity to thank to the European Community on Computational Methods in Applied Sciences, the Portuguese Association of Theoretical, Applied and Computational Mechanics, the University of Porto, all sponsors, all members of the International Scientific Committee and to all Invited Lecturers and Authors.

Faculty of Engineering
University of Porto, Portugal

João Manuel R.S. Tavares
R.M. Natal Jorge

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Dynamic Radiography Imaging as a Tool in the Design and Validation of a Novel Intelligent Amputee Socket

George Papaioannou, Dimitris Tsiokos, Goeran Fiedler, Christos Mitrogiannis, Ilya Avdeev, Jake Wood, and Ray McKinney

Abstract It is apparent that socket fit is the most common source of dissatisfaction in amputees and part of a growing medical and socioeconomic problem. Even the most up to date trans-tibial socket designs are not capable of coping with the issue of continuous stump volume change that is apparent within a day, week, month or season of socket use. Intelligent sockets integrating variable volume (VVSS) with elevated vacuum (EV) systems hold that promise but have yet to reach completion in feasibility studies. This is mainly due to delays in the relevant technological maturity, cost and poor assessment methodologies. These challenges can be overcome by current advantages in dynamic radiography imaging. These advantages are presented with an example of a novel socket design as: a) solutions to problems of direct socket-stump motion measurement, and b) as tools for calibrating socket control hardware and computer aided socket design. Imaging can therefore be integrated as part of an expert clinical system for imaging-driven computer-aided socket design and evaluation (cost-labor effective).

Keywords Intelligent transtibial socket · Elevated vacuum · Variable volume · Dynamic radiography · CAD-CAE

1 The Need for Novel Socket Designs in a Constantly Increasing Amputee Population

Limb loss is obviously a severe medical condition that has potentially life changing consequences. Prevalence of amputation has been addressed by analyzing a large number of US hospital discharge records (20% of total in US) issued between 1988

G. Papaioannou (✉), D. Tsiokos, G. Fiedler, C. Mitrogiannis, I. Avdeev, J. Wood, and R. McKinney
Wisconsin Institute for Biomedical Health Technology, Director of "MOVE Center", Department of Civil Engineering and Mechanics, College of Engineering and Applied Science and Department of Occupational Therapy, College of Health Sciences, University of Wisconsin, Milwaukee, P.O. Box 784, Milwaukee, WI 53201-0784 414 326 0665

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and 1996 [18]. The average annual number of limb-loss-related hospital discharges is 133,325 nationwide (∼3% increase per year). Vascular conditions were by far the most common cause with 82% overall (46.19 per 100,000 persons in 1996). Corrected for population effects, the total number of amputations increased by 27% over the period of the study. Incidence rates for lower limb amputations vary between 0.1 and 1.9/10,000 for most western countries [19]. Amputation rates are by trend increasing around the world. In the US this rate increased from 63 per 10,000 diabetics in 1980 to 81 per 10,000 diabetics in 1987. *An estimated 1.6 million Americans were living with limb loss in 2005, (estimated to become 3.6 million by the year 2050)* (total cost of Amputee healthcare exceeds 4.5 Billion annually in US [20, 75]. Continuous research was also conducted to establish how well prostheses are perceived by their respective users [45]. Of the participants (1538 persons: 18–84 years old) 94.5% had prosthesis and used it extensively. However, only 75.7% were overall satisfied with their prosthesis, *where the socket fit was least acceptable (75.5%)* behind appearance (80.4%) and weight (77.1%). *It is apparent that socket fit is a major challenge in Prosthetics and Orthotics (P&O), the most common source of dissatisfaction in amputees and part of a growing medical and socioeconomic problem.*

2 Current State-of-the-Art Socket Evaluation Methodologies Are Inefficient in Assessing Trans-Tibial (TT) Socket Problems

Trans-tibial amputations have a clear advantage over higher-level leg amputations since the knee joint remains functional and less mass is substituted by the artificial leg. Nonetheless, the bony structure and the low soft tissue coverage make it susceptible to pressure and friction related injuries. Long established and still commonly used designs are the *Patellar Tendon Bearing Socket (PTB) and the "Kondylen Bettung Muenster" (KBM)* socket. However, a well working PTB or KBM socket will inevitably spark a deflection related patellar reflex every time the user steps on the prosthesis with an ever so slightly flexed knee disrupting the natural walking pattern and inducing a range of undesired consequences, such as exaggerated metabolism. Alternative socket concepts can be summarized under the category *Total Surface Bearing sockets* (TSB). The intention is essentially that weight transfer, controllability, and suspension are realized by improved evenly distributed contact pressure with the aid of silicon liners and locking mechanisms to provide full skin-material contact and design flexibility [69]. Comparative studies [32, 69] confirmed that "a more physiological walking pattern with the TSB socket is apparent, and is therefore recommended as to "be used effectively in the rehabilitation of trans-tibial amputees"." *However these studies suggest that the TSB socket is not capable of coping with the issue of continuous stump volume change that is apparent within a day, week, month or season of socket use. Many amputees end up having several socket rectification sessions every year.*

Most patients experience stump volume changes within a single day or over the course of seasons and in response to temperature, activity, nutrition and pressure.

Most promising, and best established approaches to address that problem today are *elevated vacuum (EV) suspension sockets*. The principle of elevated vacuum is to achieve a better pressure distribution either mechanically (e.g. Otto Bock Harmony trans-tibial [68] or by means of an electric pump). Negative pressure is deployed, to *"expand the soft tissue and bring it closer to the socket wall"*, avoiding soft tissue compression. All *vacuum assisted socket systems (VASS)* work with a silicon or gel liner with or without a pin lock, and a pump mechanism that provides the desired negative pressure over ideally the entire stump surface (Fig. 1q). The first comparison studies with the Harmony system [7] found that the stump volume decreases by 6.5% on average in a custom made TSB socket after 30 min of walking,

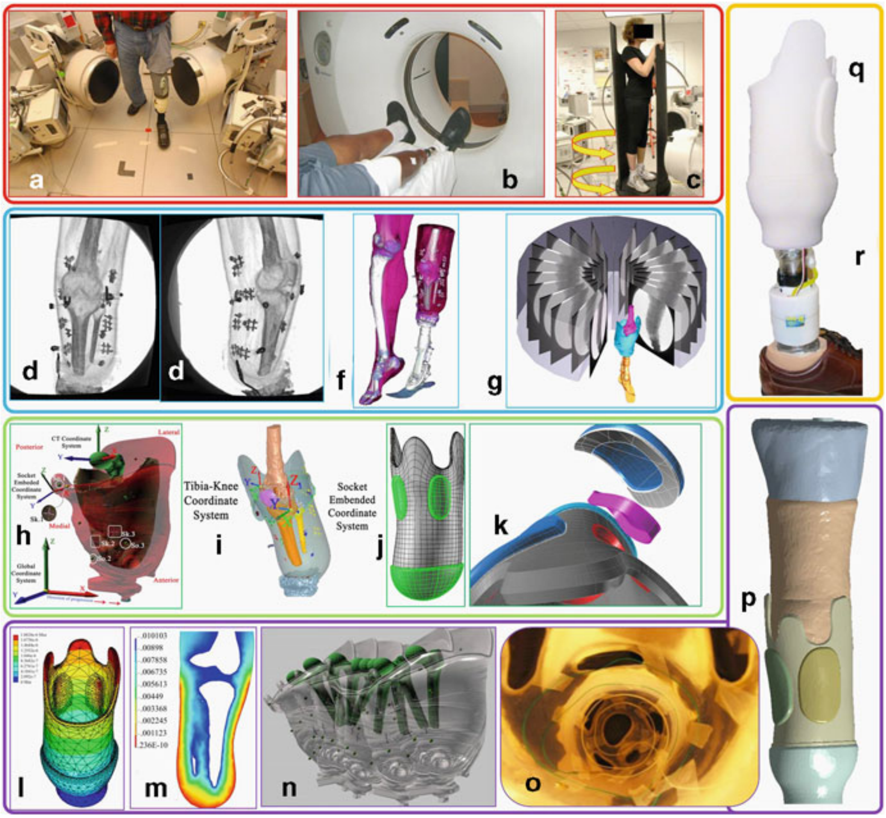


Fig. 1 The role of imaging in SMARTsocket's overall reverse engineering approach to socket design and evaluation is critical. The procedural steps to any socket rectification protocol are presented in Fig. 5. Imaging modalities for amputee screening include (**a**) DRSA, (**b**) CT, (**c**) turn table dynamic radiography. Samples of images obtained of the three modalities are shown is (**d–g**) respectively. Note the abundance of skin-socket markers and that a careful data fusion protocol is used to co-register 2D and 3D information from all scans in (**h, i**). Finally the socket rectification protocol (**j–k**) with CAD-CAE tools precedes the virtual fitting in (**p**) while an iterative computational modeling evaluation process is under way in (**l–n**). Rapid prototyping of the final virtual prototype is warranted in (**o, q, r**) to establish the SMARTsocket integration with the prosthetic parts

whereas it was maintained and even increased by 3.7% when elevated vacuum was used. The tibia displacement was also clearly less with the vacuum pump and a more tight suspension of the prosthesis was achieved as the participants confirmed. A follow-up study [23] concluded that *a socket that is 4–6% undersized with no deep voids is recommended for the fitting of trans-tibial amputees*. It has been also reported that the measurable reduction in positive pressure aids the level of compliance of TT sockets [5]. The study also reported that changes in contact pressure over the step cycle were of different range for different subjects – something that could not be explained in the article, but might hint at the necessity to vary the socket volume anyway for optimized fit. The aforementioned studies used casting and water displacement procedure to assess stump-volume which poses questions on the clinical validity of the method. The tissue outside the donned socket changes volume instantly and donned stump volume is much different than undonned stump volume. It is also a very laborious and messy procedure. Another controversy exists on the potential disadvantageous effect of exposure of tissue to just prolonged negative pressure. In a later study [10], the use of VASS sockets and locomotor capability index promoted wound healing in amputees with skin ulceration. *In all of these studies it was suggested that alternate positive and negative pressure exposure within boundaries could prove more beneficial to tissue healing and health* [5, 7, 10, 23]. Although EV-VASS technology significantly improves socket performance, it does not eliminate the need for additional rectifications due to the issue of continuous stump volume change (even past stump maturity).

Variable volume socket systems (VVSS) have been proposed as a solution to the variable stump volume problem. Modifying the volume of the prosthetic socket in order to accommodate changes in the stump geometry has been attempted during the last decades. In the 1990s, many different systems with patient-adjustable air bladders were marketed, however they were gradually abandoned due to feasibility and manufacturability challenges [54]. The most recent project which yielded patents is the SVGS system, developed by Simbex LLC around 2003 [24] but has rarely been heard of since. It consists of a variety of water filled bladders, connected by a well thought-out array of pipes and valves. The fluid based volume management system provides a way of accounting for changing stump volumes. Similar variable sockets have been used in the field of interim-fittings, where early prosthesis must allow for a swift and uncomplicated adaptation [27]. *Most likely reasons for the decline of these technologies (VVSS) are lack of feasibility due to bulkiness, no consideration of shear effects, lack of accurate and precise real-time control of transferred pressure/shear, weight, leakage, wear and tear and problems with manufacturing and maintenance. In addition, the controlling elements of these systems are yet to be fully calibrated with real life input from strenuous activities. This would require a sophisticated in-vivo unobtrusive indirect stump-socket measurement method, which could be used to calibrate a real-time continuous feedback mechanism (sensor-to-actuator) that returns information of the socket-stump interface (pressure and shear magnitude and direction) to the VVS system.*

This accurate calibration leads to successful socket fit involving pressure, shear, deformation and slippage measurement and monitoring between the subject's skin, the residual limb tissues and the socket. These measurements have been conducted for about 50 years involving fluid-filled sensors, pneumatic sensors, diaphragm deflection strain gauge [67], cantilever/beam strain gauge [55] and printed circuit sheet sensors [14,29,67,74]. *In-vivo* socket-pressure measurements are also possible with commercial capacitive, piezoelectric, ink-film based products [11,14,46]. *However, these sensors possess many disadvantages such as accuracy, hysteresis, signal drift, response to curvature, spatial resolution, temperature sensitivity, installation instability* [3] a*nd unknown shear coupling effects* [11, 16, 44, 46, 49]. An ideal system should be able to monitor real interfacial stresses continuously, both the normal (pressure) and shear component (dynamic slippage). The challenge of measuring slippage within the socket is yet to be efficiently tackled by the prosthetist in and outside the laboratory.

In this direction, research in Computed tomography (CT) allowed the incorporation of patient-specific stump-socket geometry into a CAD/CAM system, performing modifications, and milling a plaster positive likeness. Despite being static analyses, these studies offered high image quality and the benefit of seeing below the skin. However, significant CT disadvantages from movement artifacts were reported. A number of spiral X-ray computed tomography (SXCT) studies [13, 25, 61, 62, 64, 65] demonstrated that the SXCT scanner is sufficiently precise and accurate for distance and static volumetric quantitative socket-fitting studies. Simpler methods involving ordinary radiographs analyzed different static 2D positions between bone and socket during different parts of a gait cycle. The next level of static, yet 3D analysis, is the use of Roentgen Stereogrammetric Analysis (RSA) to completely characterize socket and stump interactions in all six degrees of freedom with a biplane (stereo) imaging three dimensional (3D) configuration [8, 30]. RSA socket-stump motion studies have reported variation of 10–30mm in the vertical motion and 0–15 mm in the AP motion [63]. Ultrasound techniques were also used to assess femur movements within trans-femoral sockets [15]. Similarly, conventional gait analysis cannot "see" below the skin or past the socket and its accuracy cannot effectively address dynamic movement [37, 39]. *Currently there is no way of accurately addressing the rate of slippage, shear and stump pistoning and their direction during the performance of dynamic tasks by amputees*. There is, therefore, a need to identify new methods for quantification of the dynamic interaction between the residual limb and the prosthetic socket with visualization paradigms that the clinician is trained to interpret.

3 Integrating Dynamic Radiographic Imaging with Computer-Aided Design and Computational Modeling in Socket Evaluation

In recent years these state-of-the-art-and-Science perspectives of technology integration are starting to be employed in the P&O arena to increase yield and reduce labour and cost. According to a National survey [50] of US Prosthetists and

Orthotists, the development of "smart" prosthetics will require development of basic knowledge and understanding of the mechanics of socket fitting as well as technological advancements in soft tissue characterization. As such, *dynamic imaging-driven, template-based computer aided design (CAD-CAE) tools employing fast-track learning offer great promise in the process of socket rectification at the virtual environment with the associated reductions in cost and labour*. As of recently, Dynamic Roentgen Stereogrammetric Analysis (DRSA) has been introduced as an accurate tool for dynamic in-vivo measurement of stump/socket kinematics [37, 38, 41, 42]. The method allows direct observation of tissue deformations during activities of daily life, such as walking or stepping down stairs, and during more strenuous higher-speed activities such as jumping or running. The DRSA method (Fig. 1a) is one order of magnitude more accurate that current conventional *in-vivo* motion analysis techniques (socket-stump and residual bone pistoning motion can be assessed with as much as 0.03mm translational and 1.3° rotational accuracy [37–39]). Shear forces, and the so called stump pistoning information can be derived from the dynamic slippage between the residual bone, skin and socket wall using the 3D displacement history of tantalum markers tracked from the DRSA data. Absolute and relative displacements between residual bone, skin and socket wall have been reported in several studies for several below knee amputees using DRSA [37–39].

This patient specific accurate kinematics information can also improve the efficiency of computational modeling. Computational modeling can in turn reduce the iterative cycles between experimental testing and socket fabrication-prototyping. Finite element methods (FEM) are becoming more common ground in socket engineering for two major methodological reasons: (1) FEM models produce full field information on the stress, strain, and motion anywhere within the modeled objects and (2) Parametric analysis for an optimal design is possible. To date, prescribing the displacement boundary conditions at the nodes on the outer surface of the socket or liner is the protocol used for most socket rectification simulations [9, 52, 59, 72, 73]. Similar studies suggest that only qualitative identification of the tolerant and sensitive areas is possible with current methods. Dynamic imaging could also address this issue in addition to calibrating the patient specific FE models with respect to material properties [6, 43, 71]. *A fully scalable patient specific FE model driven by high accuracy in-vivo internal residual bone-stump-socket DRSA kinematics would be the ideal engineering analysis method for this problem.*

From a biomechanics perspective these analyses could help resolve some current state of the art contradictions of fairly common beliefs and everyday practices, suggesting that some stump areas are designated for higher load bearing purposes than others. They suggest that these areas are patient specific so customization of socket is necessary. Apart from that, these studies do not conclusively answer how to translate the result into practical applications. In addition, there are remaining questions regarding the practicability of the necessary technical effort, and the consideration of shear forces, which are believed to contribute significantly to most socket comfort problems. *Dynamic imaging, offers, due to its accurate, indirect non-invasive and unobtrusive characteristics a solution to these problems of direct measurement (relying on kinematics assessment of the outside of socket only) and* *computational modeling. It can therefore be integrated as part of an expert clinical system for imaging-driven computer-aided socket design and manufacturing (cost effective electronic as opposed to actual prototype based socket rectification).*

4 SMARTsocket: An Example of Integration of Dynamic Imaging, CAD-CAE and FE Methods in Socket Evaluation

An example of performance validation with the synergy of the three methodologies is presented for an intelligent socket system that combines variable volume socket system (VVSS) technology with an elevated vacuum system. Although the EV socket component is in the process of undergoing full feasibility study and has been fitted to hundreds of amputees by our prosthetists, the integration of the two systems is yet to see the fruits of a complete feasibility study. The novel system proposed here (acronym: SMARTsocket) intends to complete the advanced performance of EV sockets *by dealing with the variable stump volume problem* that occurs during prolonged use of the socket or at very strenuous activities such as athletic endeavors or heavy-duty work. The new socket and the new methodologies for each efficient validation intend to give amputees an advanced level of autonomy in terms of enabling them in conditions of demanding strenuous mobility [28, 34, 35, 66].

SMARTsocket combines two technologies (EV+VVSS) thus offering for the first time *real-time* controllability of socket elevated vacuum and overall socket volume by incorporating counter-shear actuators for readjusting the pressure/shear distribution across the stump-socket interface. All parts are fabricated by Lincolnshire Manufacturers SA and assembled by our prosthetists. The feasibility study includes sensitivity, operability, safety, durability and efficiency (structural, functional) testing. Functional tests in clinical trials are currently under way for the validation of the new system. We use reverse engineering methodologies in our approach to tackle this complex problem (Fig. 1). A summary of the main tested hypotheses justifying the rationale behind the integration of the elevated vacuum socket and the adaptable volume socket being tested is presented next:

1) *Hypothesis 1: Vacuum equalizes stump pressures*. It is known that a vacuum system equalizes pressures, stabilizes fluid levels and helps vaporize perspiration [1, 4, 5, 21, 22, 26]. Carl Caspers, a prosthetist in St. Cloud, Minnesota along with Dr. Glenn Street at St. Cloud State University [7, 12, 17] are the inventors of one of the first mechanical vacuum pumps. The major limitation of the conventional prosthesis, referred to as a PTB type socket is that it employs varying pressurized areas within the sockets. Upon stump volume reduction the prosthetist advises the patient to add socks or pads to tighten the socket. However, by applying more pressure to the limb, more volume changes occur (fluid compression) and the cycle will repeat itself. Stump volume reduction is a result of the properties of the soft tissue (the interstitial fluid is very pressure sensitive). It is common ground that basic fitting of a PTB socket requires some compression [4, 5]. The reasons

those sockets are made somewhat snug are to prevent rotation of the prosthesis, to keep it from falling off, and to support body weight, among other functions. It has been reported [14] that it takes approximately 10.544 gr of positive pressure per square mm to perform these functions. The mere act of an amputee applying the prosthesis to the remaining limb places approximately *6.803 gr of positive pressure* that one would otherwise not be subjected to. The interstitial fluids are very pressure sensitive. This complex non-linear and viscous phase of deformation will depend mainly upon the rate of loading (anisotropy and non-homogeneity are also very difficult to control when planning for the cast). The body reacts by "releasing" some of the fluid. This is somewhat like letting a little air of a balloon. When enough fluid is released, the internal pressure drops down to its normal settings. The body "wins this battle" every time.

We hypothesize that it is initial application of positive pressure that creates the change in the volume of the interstitial fluid with an escapade of undesired events after that. It has been shown that with the conventional socket, the average below-the-knee amputee can shrink 6–7% of their limb volume a day and 12–13% on an above-the-knee amputee [7, 56]. Of course, this varies with the size and makeup of the patient's limb. However, in a properly fit vacuum system, the change is typically $<1\%$. Our previous work suggests that patients do not experience significant problems in a fitting until they reach a 3–4% level of change but quantification of this change is yet to be effectively addressed with conventional methods. Typically, our prosthetists take the casting under 558.8 mm of vacuum (Fig. 1). The plaster is not molded or shaped, as is done with the conventional PTB. Patients have their own unique shape and this method is not trying to change that. As a matter of fact, wherever a modification is applied with bare hands, a pressure gradient is created and that will be the likely area where patients might expect strange interactions. After a cast has been taken with the 558.8 mm of mercury in vacuum, it is simply removed and then a global reduction of 4% around the entire cast [7, 12, 17] is sculpted. In other words, it is not any tighter or looser in anyone spot over another.

2) *Hypothesis 2: Choosing an appropriate liner is necessary for socket performance*. The next item that is crucial to our method of fitting is the use of the *urethane liner* (Fig. 2). The liner can change shape slightly become thicker or thinner, become quite firm or very soft. For a below-the-knee amputee, if we simply roll on the modified urethane liner and allow them to step into the socket, it will be fairly tight. It is the exact shape of the patient's limb, but with the thickness of the liner, it is then compressed 4%. As the patient puts the limb into the socket, the material will move towards the path of least resistance. This means that since it is a new socket and there are not any loose areas or voids at the socket, the liner will move up and out of the socket. Typically on a below-the-knee patient it will move about $5/8''$ and closer to $1''$ on an above-the-knee patient. *Again this value is empirically estimated and not possible to quantify with conventional measurement technologies*. This is expected since this donning process is patient specific. This value also differs even between donning sessions for the same patient. When the patient stands in that socket, as their

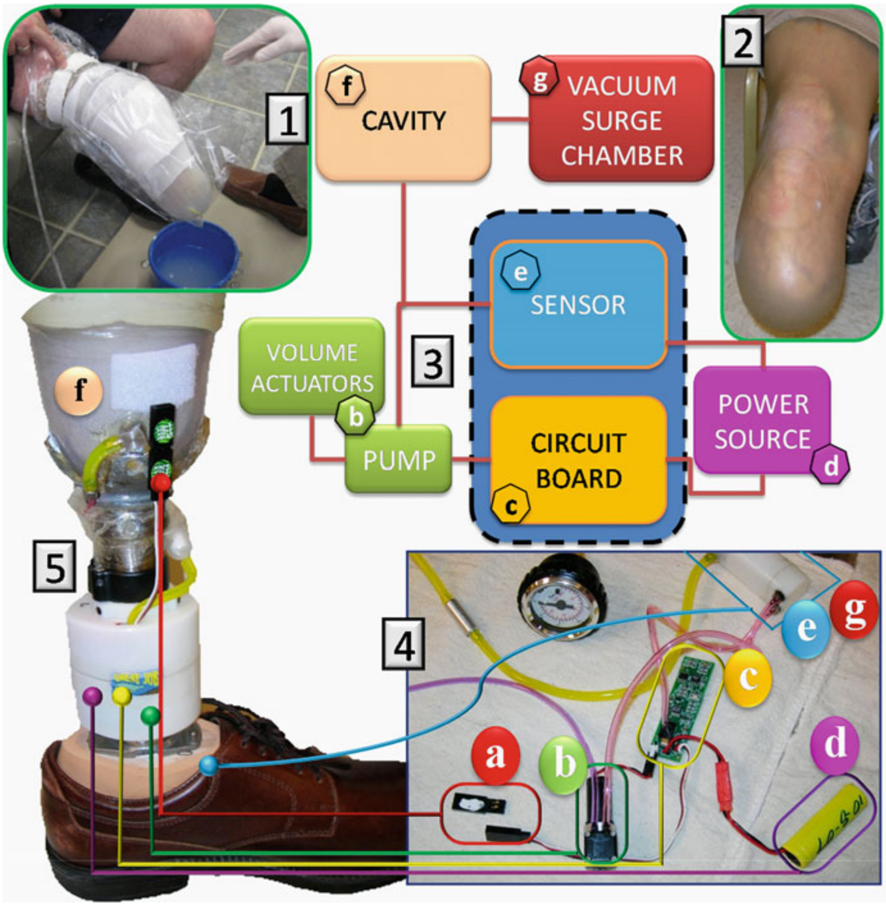


Fig. 2 (1) The SMARTsocket casting method uses the principle of vacuum and minimal sculpting by the prosthetist. The cast assumes the contour of the stump with negative pressure applied equally everywhere in the segment; (2) The Urethane liner that forms the negative cavity with the socket; (3) Flowchart of the operational components of the SMARTsocket system. SMARTsocket comprises of an elevated vacuum system for maintaining a negative pressure in a cavity between a socket of a prosthetic device and a positive pressure system of actuators that can change the overall socket volume if necessary. (4) The system (parts are fabricated by Lincolnshire Manufacturers SA and assembled by our prosthetists) comprises of a concealable vacuum surge chamber: 20.41 g (**g**), a vacuum and inflating reversible pump: 24.66 g (**b**), a variable positive pressure actuator (**b**), a power source: 21.97 g, (**d**) and microcontroller: 5.67 g (**c**), USB switch: 1.70 g (**a**), housing tubing, tubing connectors: 45.54 gr, and means for sensing pressure (**b**) and actuating (**g**) the system. The sensor triggers an actuation event when the negative pressure decays to a predetermined differential from atmospheric pressure. This actuates the vacuum pump to increase the negative pressure in the cavity and the opposite actuation event when the negative pressure reaches a predetermined threshold (de-activation of the vacuum pump). Similarly the positive pressure pump inflates the air-bladders to increase the stiffness of the socket locally or change the socket volume (increase or decrease it)

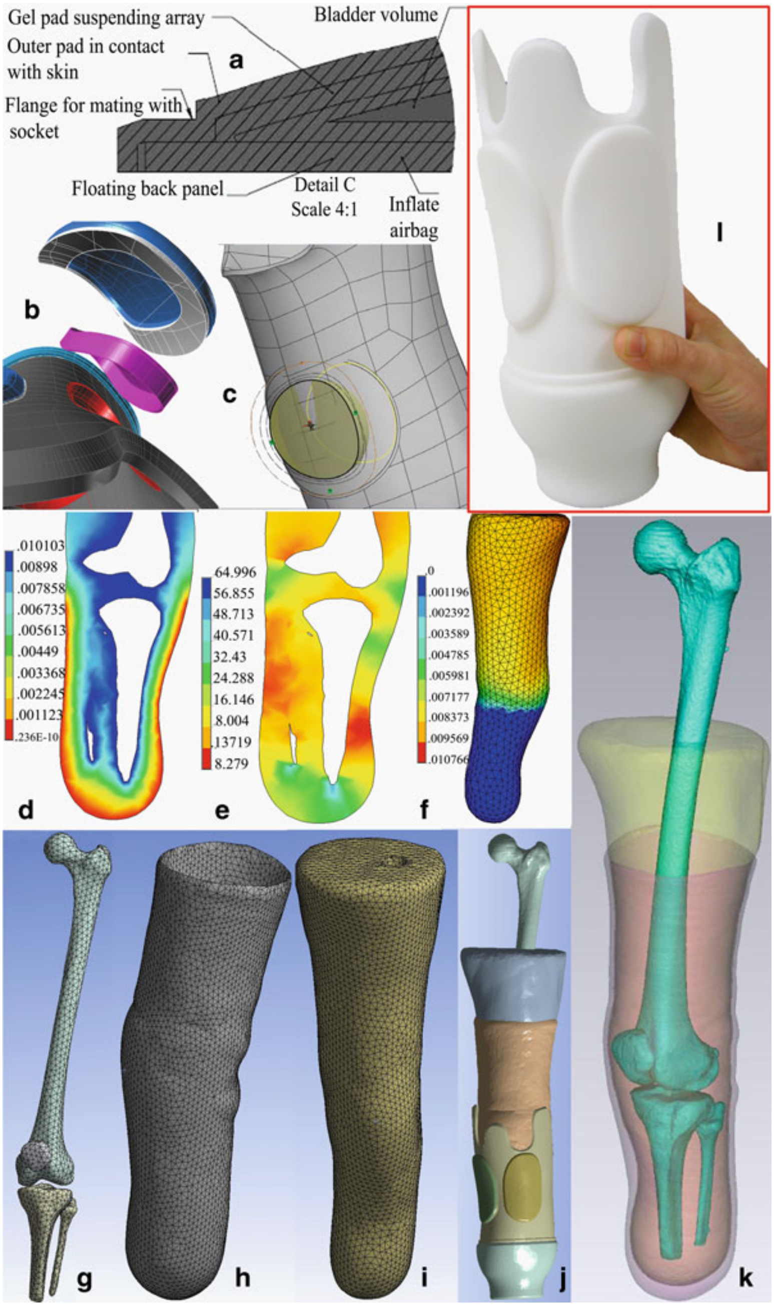
limb begins to change volume (at this point we have not added vacuum) and as they walk, they will push fluid out and the limb will shrink. The urethane absorbs partially the change in loss of volume. Although this is very dynamic, the adjustment can only come up to about 4–5%, i.e. only a portion of the average shrinkage. Again this estimate is very difficult to quantify objectively. The vacuum system will take over from there. Realizing that it was positive pressure that was creating the change, we designed the socket with enough negative pressure to offset the changes caused by positive pressure. A minimum of *457.2 mm of mercury vacuum (or higher)* is enough to offset the negative effects of positive pressure. However this is an empirical value that must be validated against an unobtrusive method with objective assessments.

3) *Hypothesis 3: The vacuum system vaporizes perspiration*. Perspiration is a significant problem for most amputees. It is apparent that within the conventional socket, it is warm, dark and moist, a perfect breeding ground for bacteria and the undesired onset environment for a blister-ulcer. Physics suggests that we can move the evaporation point around by manipulating the temperature and atmospheric pressure. Keeping that in mind, flash vaporization of moisture takes place at approximately 711.2 mm of mercury when the body temperature is 37 °C. With a pump that can deliver up to 660.4–2844.8 mm of mercury of vacuum, while it is not instantaneous and not flash, it takes only a short time (literally a small fraction of a second) to vaporize perspiration. In other words, the vacuum socket can convert that excess liquid into a vapor and the vapor can be excreted through ports of pump back into the "atmosphere" (Fig. 2). The end result is that the patient's limb is kept dry. This hypothesis is very easy to test; prolonged use of EV sockets can be assessed by simply undonning them and test for socket humidity with a humidity tester.
4) *Hypothesis 4: The vacuum system cannot solve the volumetric changes resulting from very strenuous activities (running, jumping, bearing heavy weights, stopping suddenly)*. The current system applies to every day walking and normal ambulation. We have shown that when patients are involved in heavy labor and athletic endeavors, they will be subjected to higher rates of loading that challenge the vacuum system technology. To this end we integrated the variable volume socket (VVS) to the EV principle. At the proof-of-concept stage of the prototype the system is static (no real time operation). The user inflates or deflates the actuator based bladders in the socket before performing a strenuous task (running) that requires higher socket suspension and stiffness. This system is not yet capable of responding to real-time changes in volume but it can still allow us to change the positive pressure and the overall socket volume if necessary before the EV functionality kicks in.

A miniaturized electronic pump (Fig. 2) (about the size of a pen 4 cm long, 15–20 gr), can be fitted inside the shin tubs or inside feet-shoe. Figure 2 presents the full technical characteristics of the system. This pump can be hidden for cosmetic reasons but its size helps eliminate the weight and increase the application of volume to these patients. The advantage of the electronic system, besides the cosmesis and weight is the fact that it does not require, as the mechanical ones (Harmony), to be walked on and compress a piston to draw up the vacuum. The patient can actually be sitting all day and the circuit board and the motor will make sure the patient stays within a very therapeutic range. The socket's pressure boundaries have been set at 190.5–546.1 mm of mercury. We know that we need to have vacuum of at least 381 mm (or higher) in order to control some of the shrinkage of the limb and vaporize the moisture. This is one of the highest values of vacuum to be obtained to our knowledge. For this function most of the systems require between 200 and 300 mA and several volts per day and the unit has to be charged every night. Our system is a very low voltage system requiring only 15 μV for daily operation. That means that the power that is used to operate one of these other systems in a day will power our system for the better part of several months.

The major challenges in tackling hypotheses 1, 4 are related to (a) accurate 3D volumetric imaging of the socket stump interface and (b) accurate 4D imaging of stump-skin slippage and pistoning. Stump-skin slippage and pistoning within the socket can cause discomfort, internal limb pain and eventually skin ulcers as a result of the excessive pressure and shear within the socket. Classical 3D CT methodologies present *three challenges*: (1) the image matrix must be higher than the commonly used clinical 512 × 512 resolution matrix which produces poor socket-stump geometry information particularly when defending hypotheses 1, 2, 4; (2) the issue of patient irradiation. The expected equivalent dose for the CT scan of the full socket-stump for above knee amputees is 2 mSv [57] with about two-thirds of this corresponding to the below knee scan; and (3) the CT can only convey static information on stump-socket geometry and cannot assess its dynamics behavior.

To overcome challenges one and two our group has been using a turntable technology that is introducing a low irradiation method for volumetric imaging. It combines the method of Biplane Dynamic Roentgen Stereogrammetric Analysis (DRSA) instrumentation with a turntable configuration that allows 3D scanning of extremities during load bearing at a fraction of the irradiation [37, 39] (Bioimerosin Laboratories SA, WI, USA) (Figs. 1c and 3). The system functions as a fluoroscopic or digital radiography device with the exception that the patient is rotated (180–360°) while standing on a supportive turntable. Although normal fluoroscopy or digital radiography is limited in high-speed acquisition, DRSA due to its high end camera and lens systems is capable of acquiring images at a high resolution matrix (1150 × 1150) and high data acquisition rate (up to 1000 Frames/s). This capability offers sampling of sequences of high resolution of images of the amputee extremity in less than 3 s (360° rotation). This axisymmetric cone-beam stack of image sequences (Fig. 3b) (the high sampling rate offers a very small sampling interval solving the issue of blurring due to motion artifacts and resulting in very high out of plane resolution) can be reconstructed during post-processing using COBRA software (Exxim Computing Corporation, CA, USA). Both one plane and biplane DRSA (which requires half the rotation period) configurations can be used. The software offers efficient ways to register the DRSA X-ray system in 3D, using the projection data [31, 39]. This is essential for Cone Beam Tomography with C-Arms or unconstrained biplane radiography. The most important aspect of this technology is that during a single DRSA turntable scan an exposure of 110 mR is estimated



Gel pad suspending array
Bladder volume
Outer pad in contact with skin
a
Flange for mating with socket
Floating back panel
Detail C Scale 4:1
Inflate airbag
b
c
l
.010103
.00898
.007858
.006735
.005613
.00449
.003368
.002245
.001123
.236E-10
64.996
56.855
48.713
40.571
32.43
24.288
16.146
8.004
.13719
8.279
0
.001196
.002392
.003589
.004785
.005981
.007177
.008373
.009569
.010766
d
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[70] which translates into an equivalent dose of approximately 0.2–0.3 mSv. The expected equivalent dose for the CT scan of the pelvis is 2 mSv [57].

The third challenge is overcome with our new in-vivo method of assessment of three-dimensional (3D) direct, unobtrusive socket-stump kinematics/slippage of strenuous activities (high speed of motion) using Biplane DRSA instrumentation [37–41]. During these studies our group screened 50 patients (20 EV, ten TSB and ten SMARTsocket trans-tibial socket wearers). Results from the ten amputees with SMARTsocket sockets enrolled in the study approved by the University of Wisconsin Milwaukee IRB committee (see papers [37–41] for detailed methods and protocols) are presented here. The subjects were asked to perform several strenuous activities (fast walking, fast stop, running, jumping, ascending/descending stairs, pivoting) while their socket-stump kinematics was assessed with DRSA. The DRSA method is one order of magnitude more accurate that current conventional *in-vivo* motion analysis techniques (socket-stump and residual bone pistoning motion was assessed with as much as 0.03mm translational and 1.3° rotational accuracy [37–39]. The method is capable of assessing skin strain and engineering shear (between clusters of tantalum paint skin markers and socket markers) with the same accuracy. A model-based (markerless) method (MBT) for tracking of the residual limb was also demonstrated. Quantitative measurement bias between DRSA (marker based) and the MBT method ranged from −0.012 to −0.11 mm (depending on coordinate axis) for the residual bone and from 0.004 to 0.048 mm for the socket [38]. The above studies produced mixed results that stress the patient specificity in socket fitting. The methods offer a more holistic representation of the downward slippage trend of proximal side of stump with respect to the socket and an even more characteristic and of higher magnitude downward – and anterioposterior – slippage at the distal side.

Maximum slippage at strenuous tasks reached values of *151 mm for fast-stop tasks and 19 mm for the step-down task* (all patients) in the distal stump side after the impact phase of these strenuous activities. Displacement between skin-to-skin marker pairs reached maximum values of approximately 10 mm for the step-down

Fig. 3 Taking a 3D, high-resolution scan by a laser digitizer (Minolta 910) and fusing it with CT and the DRSA turntable volumetric data allows manipulation of the socket geometry using computer-aided design tools. (**a–c**) Steps of the CAD method using templates that significantly reduces the time needed to add bladders (**a**) shows a sagittal cut in the bladder pad of the SMARTsocket; Note the different bladder virtual components in (**b**) and (**l**). A virtual socket fitting process follows in (**g–k**): The surface data is improved first and molding of the patient-specific socket data onto a "solid" socket template with the bladders, circuitry and conduits follows. After creating a solid model of mesh data, a (drug and drop) pad data (airbag) can be inserted and a modifiable model, based on existing template-based airbag/pad database, (**b–c**) is obtained. A 3D FEA is then generated; (**d–f**) show the residual limb deformation under the vertical displacement imposed on the truncated bones. The soft muscle tissues are modeled as a Neo-Hookean hyperelastic material. (**d**) Total displacement (Vertical deformation field) of the residual limb soft tissue inside the socket (centimeter). Graph (**f**) shows the 3-D structural mesh (24,895 tetrahedral elements) and (**e**) the Vertical normal stress distribution (kPa); photo (**l**) shows the final rapid prototyping of the computationally validated socket trials and up to 24 mm for the fast stop trials. Maximum skin strain was dependent on the position of the skin markers. Distally positioned skin marker-pairs demonstrated mainly anterioposterior displacement between each other (maximum relative strain: 13–14%). Maximum relative strain for the proximal side was 8–10%. In the worst case relative engineering shear (γ) between selected skin marker clusters that form orthonormal meshes ranged between 81.5° and 129° for the sudden stop trial. Figure 4 shows a visualization paradigm of stump-socket-residual limb kinematics of the ten BK amputees wearing the SMARTsocket. Switching the vacuum pump off had a detrimental effect is socket suspension and slippage leading to excess pistoning effect (approx. 20–30% increase). It is obvious though that even with the vacuum on the system cannot handle the accelerations due to the loading rates of the strenuous activities. Our work in-progress is looking into the crucial question of: "what would be the effect of repeating these tasks with the actuator bladders on,

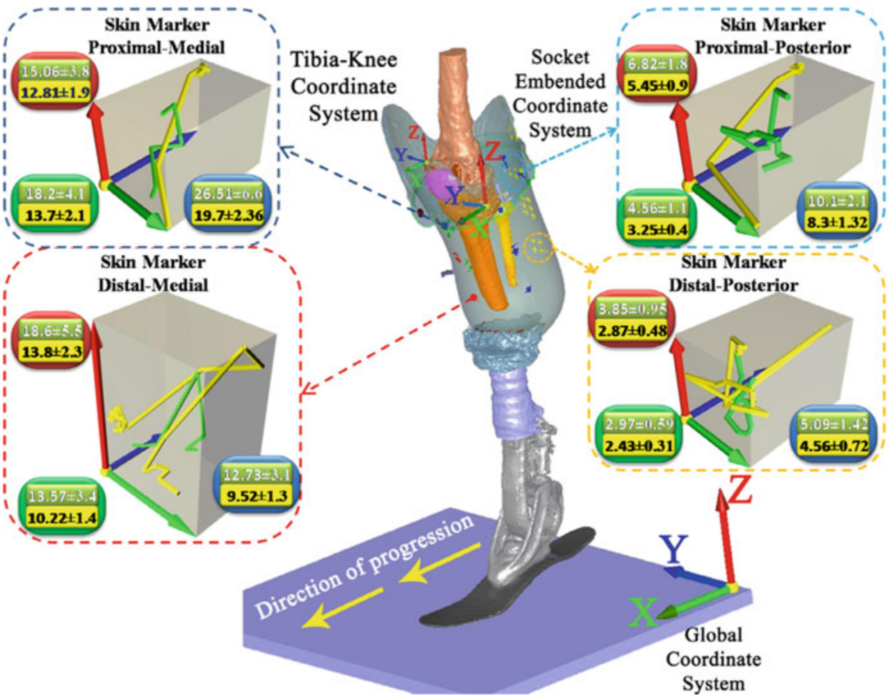

Fig. 4 Fusion of DRSA, CT and turntable radiography data produces these 3D slippage maps (distances in millimeter) between stump-skin markers and socket during a step-down trial for ten patients. Switching the vacuum pump off (*gray line*) had a detrimental effect in socket suspension and slippage leading to excess pistoning effect as compared to vacuum pump on (*black line*). It is obvious that even with the vacuum-on the system strangles with the accelerations due to the loading rates of this strenuous activity. Note also that the maximum values of the X, Y, Z axes are given for the no-vacuum (*top*) and vacuum-on (*bottom*) trials (six trials for all ten patients ±SD). The magnitude of skin perturbations in selected areas of the stump was clearly larger (20–30%) when the vacuum was switched off

i.e. having the internal socket volume reduced and then reapply the vacuum effect?" *In brief, this highly-accurate, in- vivo, patient-specific, unobtrusive dynamic information, presented using 3D visualization tools that were up to now unavailable to the clinician-prosthetist, is part of our novel core reverse engineering approach is expected to impact the iterative cycle of socket fitting and evaluation.*

The protocol for DRSA assessment includes two to four visits in total to the imaging laboratory which means minimum four to maximum ten DRSA turntable/dynamic radiography trials. The total amount of radiation exposure that the patient will receive over the two years of the study is about 1.4–1.8 mSv or 1400–1800 mrem focused on knee-shank area. This dose is approximately equivalent to the exposure that one is expected to receive from normal daily living activities over 4.6 years. This level of radiation has not been shown to cause harmful effects in adults. The expected equivalent dose for an ordinary clinical CT scan of the pelvis is 2 mSv [57]. With an overall number of six DRSA tests (=three with each socket) which is on average the amount of visits, exposure will sum up to an equivalent dose of 2.0 mSv. This amount is in the range of a one fourth of the exposure of a clinical CT scan of the trunk [57], with 20 mSv being the TLV (threshold limit value) for annual average dose for radiation workers, averaged over five years (ACGIH – American Conference of Governmental Industrial Hygienists).

A static and dynamic 3D imaging based performance index (virtual socket fitting and strain-deformation maps for all types of strenuous activities) using this 3D visualization tools is constructed for each patient. This index is crucial in our effort to optimize socket performance and reduces the overall socket rectification labor and cost (almost 50% less visits to the prosthetist).

The detailed socket rectification protocol is shown in Fig. 5 (also Fig. 1). After the first DRSA patient screening (with original socket) and after taking the patient new (or first ever interim) cast a virtual process of socket rectification takes place. Taking a 3D high-resolution scan by a 3D laser digitizer (Minolta 910) and fusing it with CT or the DRSA turntable volumetric data allows us to manipulate the socket

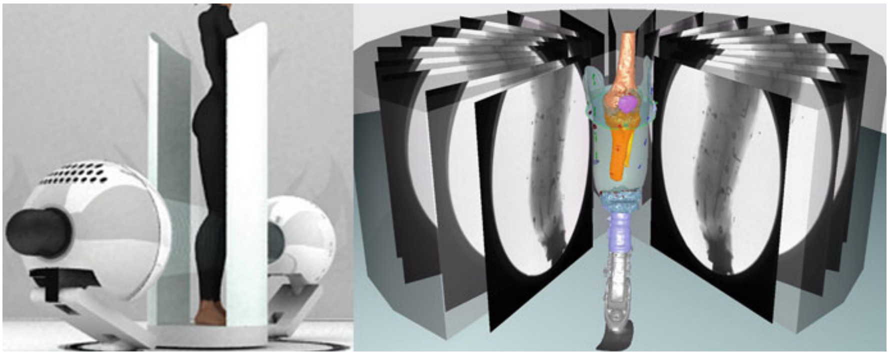

Fig. 5 (**a**) (*Left*) The DRSA turntable digital radiography scanner (see also Fig. 1 in use) and (**b**) (*right*) the axisymmetric cone-beam stack of image sequences that can be reconstructed during post-processing by registering the DRSA X-ray system in 3D, using the projection data [31, 39]

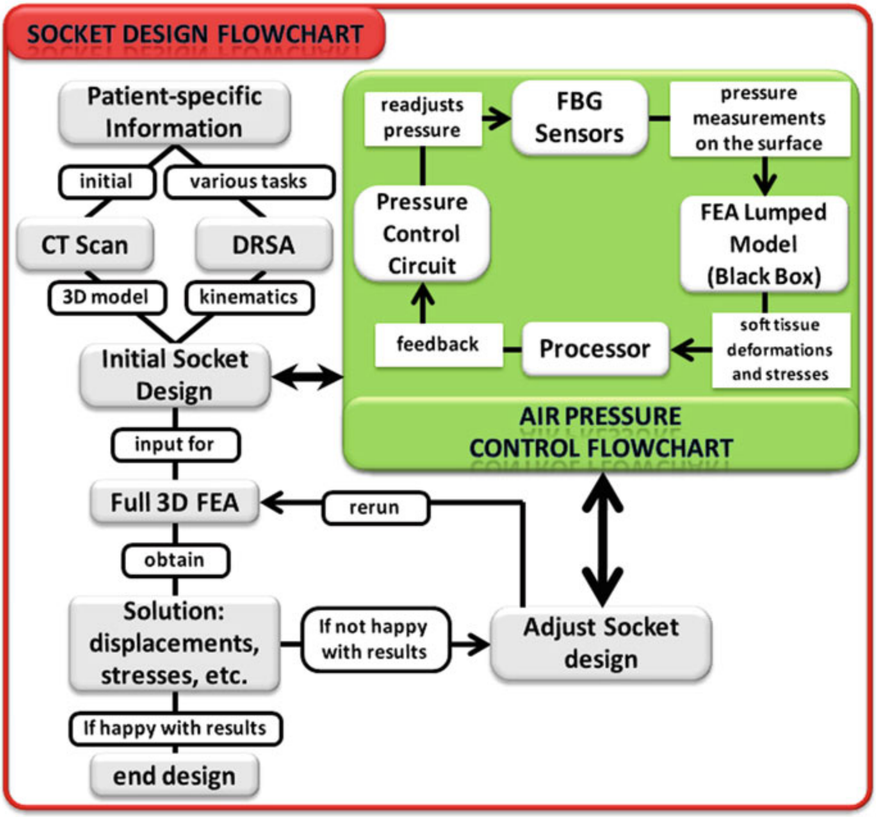

Fig. 6 Socket design and rectification flowchart showing the initial scanning of the amputee with all imaging modalities followed by the first socket design (with virtual and actual prototyping and fitting) and the iterative computational fitting process. The intermediate flowchart (*in green*) contains the tuning of the air-pressure hardware protocol based on the dynamic measurements obtained using a DRSA data driven FEA lumped model approach

using computer-aided design tools. Without this method, inserting the urethane and air bladders in the patient-specific sockets would be a laborious trial-and-error process. We have developed a CAD method using templates that significantly reduces the time needed to add bladders. We start by improving the surface data and molding the patient-specific socket data onto a "solid" socket template (Fig. 6). After creating a solid model of mesh data, we can insert (drug and drop) pad data (airbag) and create a modifiable model based on existing template-based airbag/pad database. *Using the flex tool of SOLID WORKS (Dassault Systèmes SolidWorks Corp. Santa Monica, CA), we can match the curvature of the socket to that of the pad, allowing for a perfect fit between socket and pad, thereby laying the foundation for geometry creation to remove indent in socket for pad insertion*. Once the SMARTsocket virtual prototype (mesh) is finished, the finite element model preparation begins.

The models are currently used to study the structural integrity of the socket (Fig. 6) using parameterization for the choice of material properties and boundary conditions from the high–accuracy, in-vivo kinematics acquired by the DRSA patient trials. Accurate socket models and fully validated patient-specific finite element (FE) models of the lower extremity are being developed for all patients [36, 43]. The current computational efforts focus on accurate characterization of strains and stresses in both the soft tissues of the residual limb and at the limb/socket interface. Early parametric finite element analysis (FEA) studies were used to qualitatively describe the behavioral trends rather than specific stress values (see review in [60]). Simplified, axisymmetric 2-D representations of the residual limb were proposed in the early 1990s to examine the effects of socket rectification, friction between the residual limb and prosthetic socket, and socket material properties on the interface pressures [51, 52]. Later, more complex, but geometrically generic 3-D models were proposed to investigate the influence of prosthetic design parameters and limb geometry on the interface stress distribution [58]. The models treated the socket and the bones as rigid, non-deformable bodies. The soft residual limb tissues were assumed to behave like linear elastic isotropic homogeneous materials. Recently, the simplified 2-D FEA models showed to be useful for developing real-time FEA modeling tools, which could be used in the clinical environment [47]. The simplified models also showed importance of such factors as (a) patient-specific geometry of the limb/socket, (b) non-linear material properties of soft tissues and liners, and (c) accurate kinematic tracking of limb/socket relative motion. Patient-specific FE modeling allows us to obtain qualitative and quantitative results, such as limb/socket interface stresses [48], temperatures, soft tissue strains and stresses [48], and mechanical response of the socket. Greater understanding of muscle tissue non-linear material behavior led to the development of 3-D, patient-specific, non-linear FEA models for computing internal stresses and strains in the muscle flap of residual limbs [48]. An MRI analysis of a patient used in the study determined the patient had a relatively thin muscle flap layer and almost no fat tissue [48]. The patient-specific stress state depends on the stump geometry (both soft and hard tissues), mechanical loading (patient's weight and type of physical activity), and the socket response (geometry, deformation, and pressure feedback in elevated vacuum (EV) sockets). In addition, many amputees wear silicone inserts to improve the fit, which adds an extra design parameter. *The goal of this part of the socket evaluation work is to supplement and significantly enhance the physical socket fitting with virtual fitting*. We present here also an exempt of a methodology of using 3D static and dynamic imaging data to perform 3-D, non-linear finite element analysis (FEA) for fitting TTA sockets, which is driven by high-accuracy dynamic radiography. The preliminary FE models include the socket, the silicone liner, and the residual stump (soft tissues, fibula, and tibia bones). The socket is assumed to be made of homogeneous isotropic linear elastic material (Modulus of Elasticity of 1.1 GPa and Poisson's ratio of 0.38). Both bones are considered to be rigid. The soft tissues are assumed to be homogeneous isotropic and compressible. We are comparing various material models of the soft tissues: linear elastic, hyperelastic [2] and viscoelastic [33, 48]. The urethane liner is represented by a linear elastic material model (Modulus of Elasticity of 0.004 GPa). We also assume that there is no slip between bones and soft tissues, while the coefficient of friction between the liner and the socket is set to 0.7 [53]. Time-transient kinematic boundary conditions are applied to the rigid bone surfaces using data obtained from the high-accuracy dynamic radiography (DRSA) (Fig. 5). The socket is kinematically constrained at the bottom. A series of quasi-static, non-linear numerical experiments is conducted by varying bone displacements from the unloaded limb stage to the full weight (the most compressed) stage. The analysis gives us: (1) surface stress distributions (both pressure and shear) (Fig. 5), (2) soft tissue internal strains and stresses, (3) boundary slip conditions, and (4) internal socket stresses for various loading scenarios. The fully transient analysis, which accounts for impact and other inertial effects, is considered next. As a rule if the parameterization and modeling is successful, a rapid prototyping procedure begins for the socket (Fig. 5). *This analysis offers for the first time a full patient-specific analysis of stresses and deformations towards an optimum virtual socket that can be prototyped faster with less expense and less labor*. We then incorporate the results of the patient-specific FE analysis into the design of the vacuum control system. The dynamics of the limb/socket system is very complex, but we are in the process of constructing a reduced-order dynamic model from a series of 3-D analyses. We are currently developing a methodology to automatically generate a transfer function between external loads (applied displacements and external pressures) and system response (e.g., point deformations, maximum stresses) using polynomial functions.

5 Conclusion

Delays in technological maturity, cost and poor assessment methodologies in novel socket designs prevent their adoption in the clinic. Current advantages in dynamic radiography (DR) imaging were used here to remedy the problems of direct socket-stump motion measurement, and socket calibration for a new socket design. The results showed that the socket with elevated vacuum functionality always outperforms competition when assessed with high accuracy imaging information. *This overall reverse engineering approach is expected to impact the iterative cycle of socket fitting and evaluation*.

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