Prosthesis Socket Design through Shape Optimization

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ABSTRACT

Design and manufacturing of socket are difficult activities due to the requirements that this component has to fulfill. Digital models and virtual prototyping techniques have been integrated in the socket development process trying to attain radical improvements of outcomes. However, although these tools allow to decrease the use of physical prototypes and experimental tests on patient, socket shape optimization results still insufficiently supported. In this regard, the adoption of design optimization techniques represents an opportunity to address the recalled problem. Design Optimization is rather common in several engineering fields and Shape Optimization has been widely adopted as useful tool to assist designers in searching for optimal solutions dedicated to prosthetic systems. Starting from these premises, the paper describes an approach to design socket prosthesis, which is based on Shape Optimization. The functional and ergonomic requirements of socket are analyzed and subsequently translated into optimization drivers. Moreover, implementation and integration issues of the proposed approach within the socket development process are investigated. Eventually, an application to a case study is presented aimed at preliminarily verifying potentialities and applicability. The outcomes obtained from this experience are encouraging and suggest to deepen the investigation.

Keywords: prosthesis socket, shape optimization, design, CAD, CAE.
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1 INTRODUCTION

The socket is an important part of prosthesis, which accomplishes the function of supporting amputee's limb during standing phase and gait cycle. Among the several requirements the recalled component must ensure, comfort and safety represent essential qualities whose performances are strongly affected by the biomechanical behavior of the socket–stump interface [21]. Therefore, the development of comfortable and safe prosthesis involves an accurate searching of the required fitting between amputee's anatomy and inner surface of socket. The expected result is currently obtained through a thorny activity, carried out by an iterative handmade process performed by skilled technicians [3]. In brief, such an approach involves the use of an initial physical prototype, which is further modified after some wearing tests, according to the feedbacks provided by the patient. Hence, the attainment of the optimized socket results in a time consuming task for technicians as well as in a boring activity for patient. Furthermore, the massive use of physical prototypes makes the whole process expensive in terms of costs.

During the last years several efforts have been concentrated on conceiving alternative ways to speed up the whole prosthesis development process and reduce the overall patient involvement. As witnessed by literature, digital modeling of human body and virtual prototyping techniques have been widely adopted as means to accomplish the just recalled objectives.

For instance, in [4] the authors investigate the use of 3D Laser Scanner and Magnetic Resonance Imaging to obtain a 3D CAD model of the patient residual limb. An approach based on Computer Tomography and Image Processing is suggested in [17] where the 3D virtual model of internal bones and skin constituting the patient residual limb is derived starting from tomographic images. Moreover, Finite Element Method (FEM) is a well acknowledged technique for physics-based modeling of socket-limb systems, suitable for simulating the biomechanical behavior of the interface. Several experiences witness the usefulness of FEM in studying the interactions between stump and socket surface, allowing the identification of the main critical aspects without the need of performing experimental tests. Some relevant contributions in this regard are provided in [18, 19] and, more recently, in [7, 13, 14] where FEM is adopted to investigate the effects of inertial loads generated during the walk on the contact conditions at the socket-residual limb interface.

The encouraging results of these investigations have led to the development of first prototypes of computer-aided systems for socket design purpose, which try to integrate together CAD, FEM and Rapid Prototyping techniques. For instance, in [8] the authors present an approach where CAD is used to obtain a first design of socket according to the limb anatomy, and FEM is employed to verify the socket-limb fitting by evaluating the pressure distribution on the interface. A different methodology, based on Selecting Laser Sintering technique, has been developed in [6] to manufacture sockets. The suggested framework involves the establishing of an overall socket design, the execution of structural analyses using FEM to verify the functional response and the validation of results by comparing the obtained numerical outputs with experimental data. Another approach based on the integration of different kinds of computer aided tools is that presented in [3, 5], which implements best practices used by orthopedic technicians in order to ensure high-level quality prosthesis socket. In the recalled method, a parametrical CAD model of the socket is derived starting from the virtual prototype of the stump, this model is subsequently verified with respect to comfort and structural requirements through FEM. According to the outputs of simulations, the virtual model of socket is modified by technicians and verified until it fits the patient stump. Afterwards, the socket is manufactured using Rapid Prototyping techniques. The proposed approach has been further developed in [2], where some of the authors have recently presented a fully integrated CAE environment specifically dedicated to the design of prosthesis. Eventually, a preliminary study concerning a methodology to carry out verifications of socket fitting according to ergonomic requirements is presented in [12]. In the cited approach, computational analysis is used to check the pressure distribution on the limb by taking into account the pain tolerance of the patient, then the results are used by orthopedic technicians to identify meaningful modifications of the socket shape.

The above survey clearly highlights that the benefits arisen from the considered approaches consist in a drastic reduction of physical prototypes and also in a definitively minor involvement of the patient. These positive results make more sustainable the whole socket development process in terms of costs and time. However, it is worth of noting that the fitting of the socket shape with the anatomy of the stump still results an insufficiently supported and time-consuming activity. Indeed, it involves several iterations where technicians have to define suitable adjustments to improve the socket performances, modify the virtual prototype according the identified improvements and check the compliance of the new design with the requirements by executing further simulations. Therefore, it is manifest that the optimization process is still carried out by “hands”, although it is performed on virtual prototypes rather than on physical ones. Starting from these premises, the paper investigates a preliminary approach to assist the design of socket prosthesis, which is based on the adoption of Shape Optimization (SO) as means to speed-up the overall development process. SO is a common technique in engineering design, which allows to automate the search of a design solution capable to fulfill the requirements at the maximum extent while satisfying the imposed design constraints. The adoption of SO to support socket optimization can, thus, represents an opportunity that is worth to be investigated for further improving the whole prosthesis development process.

The content of the paper is organized according to following main paragraphs. Section 2 provides some hints about the fundamentals of SO while in section 3 the criteria taken into account for the design of prosthesis socket are summarized. Section 4 describes the socket optimization, providing details about the task and its implementation, and shows an illustrative example of its application. Eventually, in section 5 discussions and conclusions concerning the investigated issues are presented together with possible further developments.

2 SHAPE OPTIMIZATION

The usage of computers for design optimization is rather common in several engineering fields since 80's; however during the last years new optimization tools and algorithms have been developed to solve specific design problems, in [16] an extensive survey is presented. Designing by optimization means translating a design task into a mathematical problem with the following basic entities:

- One or more objective functions, i.e. the performances of the system that designer wants to reach or to improve.
- A set of design variables, i.e. the parameters of the system affecting the objective function.
- A set of constraints representing the requirements the system has to satisfy.
- A set of loading conditions representing the loads that the system experiences during its lifecycle.

The optimization algorithm finds the value of the design variables which minimizes, maximizes, or, in general, "improves" the objective function while satisfying the constraints.

Among the different kinds of optimization approaches, SO is the one able to modify the outer boundary of a system. The shape is made parametrical through a finite element model whose nodes coordinates constituting the mesh, together with other parameters of the system, are considered as design variables. FEM is used to assess system performances by simulating its behavior under the assigned loading conditions. The optimization algorithm changes the design variables, i.e. the node coordinates, until the desired performances of the system (i.e. the objectives) are obtained and the constraints (i.e. the requirements) are satisfied. The output of the optimization cycle is represented by a "deformed" geometry of the starting shape, as shown in Fig. 1.

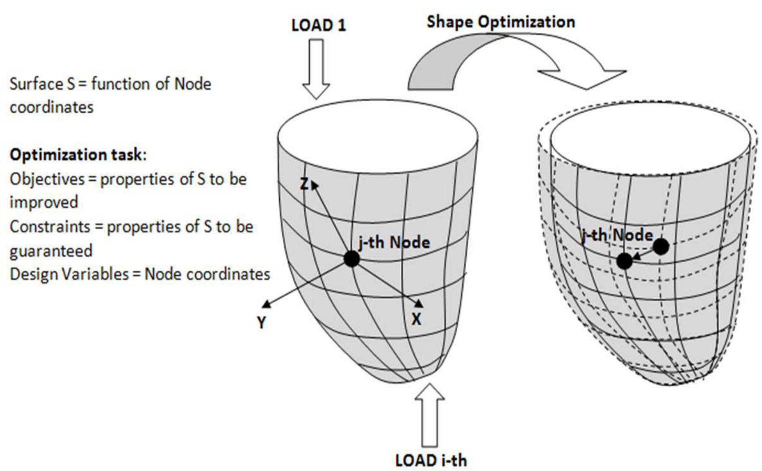

Fig. 1: Shape Optimization. The surface of a system is parameterized according to the coordinates of the nodes constituting the finite element mesh. These coordinates are considered as design variables of the optimization. At the end of the process the resulting optimized shape is "deformed" with respect the starting one, according to the objectives and constraints of the optimization process.

The optimization process can use two different approaches to find the optimal design, the mathematical one or that based on Genetic Algorithms. It is not in the scopes of the present paper to discuss the peculiarities of the recalled algorithms however, for the sake of comprehension, it is worthwhile to provide some hints about their advantages and disadvantages. Mathematical algorithms implement gradient based methods to find the optimal design, for this reason they sometimes may experience problems in identifying the global optimum solution especially when the objective function is not convex. On the other hand, they are capable to manage optimization problems involving a large number of design variables, allowing fast convergence. Genetic Algorithms adopt genetic hybridization as means to identify the best solution. The process is initialized through a population of several individuals, i.e. different feasible design solutions, which are combined together giving rise to further generations of individuals. The genetic process goes ahead until the individual that improves the optimization objectives at the maximum extent and satisfies all the constraints is identified. With respect to the mathematical approaches, Genetic Algorithms are definitely more robust in identifying the best solution since they do not suffer of problems related to local minima, but they require more computational resources especially for design problems characterized by a high number of design variables.

According to the literature, SO has been more and more adopted during the last years as reference tool to guide designers in the ideation of solutions dedicated to prosthetic systems. For instance, in [1] a method for numerical shape optimization which minimizes interface stresses, has been applied to design artificial joints. Recently, in [9] a procedure for structural shape optimization of reinforcement fibers using finite element analyses has been presented and applied to design hip prosthesis. In it, the effects of fiber orientation are investigated to obtain the optimal shape of bone cement reinforcement. Furthermore, the impact of three-dimensional shape optimization on response and failure probability of a cemented hip prosthesis is investigated in [22]. These research works, and several others available in literature, witness the usefulness of Shape Optimization to assist technicians in identifying effective design solutions.

3 WORKING PRINCIPLE OF SOCKET AND DESIGN REQUIREMENTS

The residual limb is subjected to a critical environment within a prosthetic socket as stated in [15]. As shown in Fig. 2, soft tissues of stump are elastically deformed by the internal socket surface so generating the pressures and the consequent shear stresses that are required to support the external loads during gait. However, it is worth to remark that the biological tissues are not conceived to support these actions and abrasion can appear if excessive slippage occurs between skin and socket, giving rise to physiological damages. Therefore, the socket shape must fit with the stump of patient in a tightness way in order to make the prosthesis comfortable, without causing intolerable concentrated peaks of pressure during gait and standing position. Moreover, it should allow an easy wearing by minimizing skin and tissues distortion during the donning phase.

The above performed considerations highlight that contact pressures and friction are relevant factors which impact the comfort requirements, as already observed also by several scholars [20, 21]. Indeed, low values of the friction coefficient are required to minimize tissue distortion, but such a condition may require high pressures at the socket-stump interface to support the external loads without slippage. On the other hand, too high contact pressures are always unadvised since they may exceed the pain threshold tolerance that in literature is defined as the pressure value giving rise to discomfort and damages. Furthermore, the recalled threshold is strongly dependent on the anatomy of the residual limb hence significant differences of this parameter may exist on different regions of the patient stump [11]. These evidences lead to the trivial conclusion that not all the areas of the residual limb are able to support the same loads.

By summarizing the above considerations, it can be inferred that high contact pressures positively affect the socket stability but they may cause discomfort if exceeding the pain threshold tolerance. On the contrary, low pressures may result insufficient to support the limb during standing position and walking, even if they beneficially impact on the comfort. Besides these aspects, the prosthesis socket should minimize the patient efforts during walking and should result safe. Such evidences bring to specific design criteria that can be conveniently worded as in the following:

1. lightweight socket;
2. avoiding pressure peaks on the stump according to the pain pressure tolerance of the patient;
3. avoiding the slippage of the stump;
4. structural safety.

As outlined, the mentioned requirements highlight some significant conflicting issues which make the socket design task particularly difficult. In such context, the authors believe that SO can represent an aid in identifying the best "compromise" solution capable to satisfy the recalled design criteria.

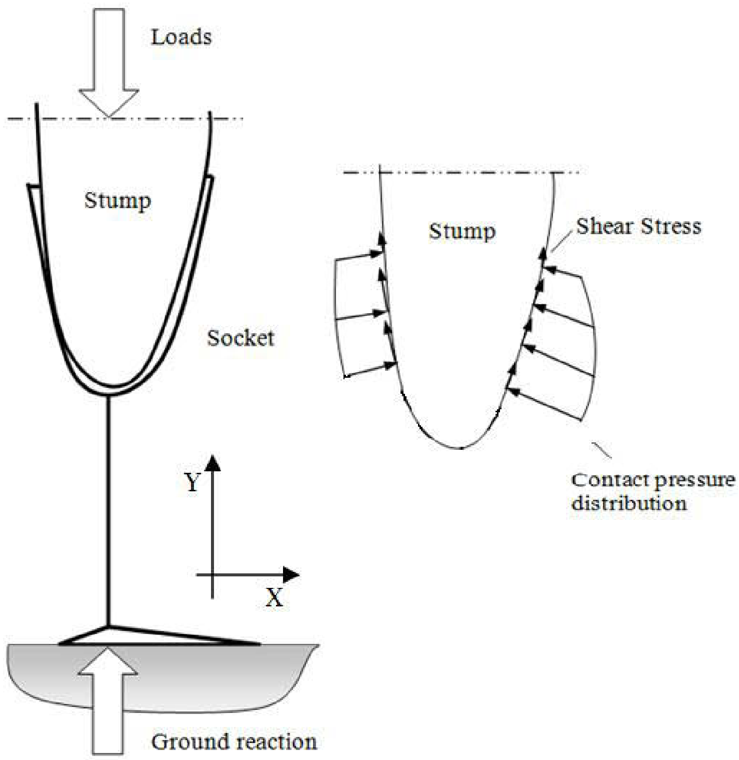

Fig. 2: Simplified schema of the biomechanical behavior of the socket-stump interface.

4 SOCKET OPTIMIZATION

The main aspects related to the definition of the optimization task and its implementation are hereinafter described in detail.

4.1 Objective Functions, Constraints and Design Variables

The analysis of socket requirements, performed in the previous section, allows the identification of specific properties to be evaluated by simulations and adopted as optimization drivers. Considering the need of lightweight socket, it suggests the attainment of a solution having the minimum weight, therefore such a performance clearly represents the optimization objective. Furthermore, the other design criteria specify some necessary features that the solution should ensure for its acceptance regardless the weight, hence they can be considered as optimization constraints.

Whereas the socket weight is a parameter that can be easily evaluated through any simulation tool, the definition of suitable metrics to assess the properties constituting the optimization constraints is less trivial.

The criterion that recommends to avoid pressure peaks exceeding the pain threshold tolerance of the patient can be easily translated into the following constraint condition:

$$p < ppt \qquad (4.1)$$

where:

- p represents the contact pressure acting on the stump, that is generated by the elastic deformation of the soft tissues caused by the socket;
- ppt is the pressure associated to the pain threshold tolerance which depends on patient and sometimes may differ for different regions of the stump.

According to this evidence, it is clear that an accurate determination of ppt is required in order to set a meaningful optimization constraint. Such a task can be carried out through dedicated indentation tests that are well acknowledged practices in literature to assess the mechanical properties of soft biological tissues constituting the residual limb. To this aim, a system has been suggested also by the authors in [3].

Besides uncomfortable situations, the contact pressures generated by the deformation of soft tissues, together with friction, play also a beneficial role in avoiding excessive slippage of the socket during the gait cycle and in providing the needed support. Indeed, as explained in the previous section, pressures and friction give rise to shear stresses capable to seize the socket upon the stump surface. The translation of such a condition into an optimization constraint brings to affirm that the overall action of shear stresses evaluated along the Y direction, as shown in Fig. 2, should have a magnitude greater than, or equal to, the maximum external load applied to the prosthesis. In a mathematical form, this condition can be expressed as it follows:

$$P = \int_S pf\vec{n} \cdot \vec{v} dS \geq W \qquad (4.2)$$

where:

- P is the overall action along Y direction generated by shear stresses;
- W represents the maximum external load applied to the prosthesis along Y direction;
- p points out the contact pressure at the socket-stump interface;
- f is the friction coefficient among skin and socket surface;
- n is the norm vector tangent to the socket surface;
- v is the norm vector along the Y direction;
- S represents the stump surface affected by the contact pressure.

The last constraint of optimization regards the structural behavior of the socket that has to work safely and without damages when the component experiences the above mentioned loads. This constraint involves the necessary condition that the overall stress status within the socket should result lower than the safety value pointed out by the material specifications. A common parameter to evaluate the overall stress within a component is the Von Mises equivalent stress which is a criterion accepted for a wide range of materials. According to this criterion, the structural constraint can be wrote as it follows:

$$\sigma \leq \sigma_{al} \qquad (4.3)$$

where:

- σ represents the Von Mises equivalent stress;
- σ_{al} is the material stress pointed out by specifications.

The final considerations of this section concern the design parameters selected as optimization variables. According to the expected outcomes, the optimization process should provide as output the shape of the surface hosting the stump and its thickness. Since FEM has been adopted for the physics based modeling of the socket-stump assembly, the design variables considered for optimization are represented by the coordinates of the nodes and the thickness of the finite elements constituting the mesh of the socket surface.

4.2 Implementation of the Optimization Task and Preliminary Verification

SO has been applied to a case study with the aim to preliminarily verify its potential impact on the socket design process. This experience has allowed the identification of the main issues to deal with, for an efficient implementation of SO and for its integration with the computer-aided tools adopted in the socket design process.

The considered case study concerns the optimization of a socket for transfemoral amputee, that has been kindly suggested by Prof. Caterina Rizzi from University of Bergamo (Italy). The colleague has provided the virtual model of patient stump and the virtual prototype of a preliminary socket shape. The latter refers to a design derived by orthopedic technicians through a cast of the patient residual limb thus the considered prototype corresponds to that adopted at the beginning of the socket development process, according to the scopes of this investigation. Virtual models of preliminary socket and stump are respectively depicted in Fig. 3a and 3b, it is worth of noting that the model of the stump includes soft tissues and internal bones.

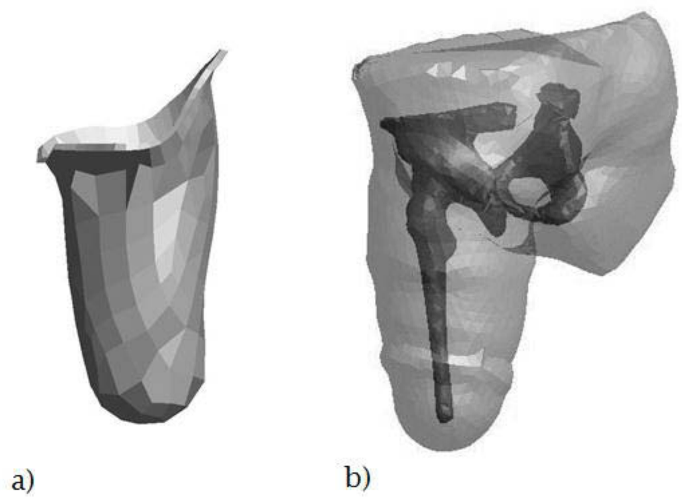

Fig. 3: The virtual models of preliminary socket (a) and of patient stump (constituted by soft tissues and internal bones) (b).

The implementation of SO involves two main activities that consist in building the physics-based model of socket-stump assembly and planning the optimization process within the computer-aided environment adopted for simulation.

The physics-based model of socket-stump assembly has been obtained making use of FEM, as already explained in the previous section. More in particular, the authors adopted Hyperworks rev. 9.0, developed by Altair Engineering (www.altair.com), as pre- and post-processor, while the explicit code LS-DYNA rev. 9.7 (www.lsdyna.com) has been selected as solver. The decision to choose an explicit solution strategy is justified by the acknowledged capability of explicit codes to manage non-linear simulation problems [3], as the case of socket-stump interaction where large deformations and critical contact conditions occur. The considerations carried out in the previous section highlight the key role played by contact pressure in the optimization, recommending a reliable assessment of this parameter to obtain an outcome compliant with the comfort requirement. Such a need is another important aspect that pushed the authors towards the adoption of an explicit solver, since it allows to use contact models that do not require the definition of the contact surfaces. In fact, explicit codes are able to deal with simulations where the contact surfaces are a priori unknown, as in the case of the socket donning where, due to the large deformations of soft tissues, the contact surfaces experience significant changes. Moreover, in terms of computational efforts, the explicit code is more efficient and faster than other solution strategies.

Besides the recalled aspects, it is worthwhile to provide further information about the other modeling issues.

The stump has been meshed through 3D solid elements while the surface of socket has been discretized by 3D shell elements having an initial thickness of 5 mm. The algorithm selected for managing the contact among stump and socket is the “surface to surface automatic one way” which is available within LS-DYNA, while the friction coefficient at the interface has been derived from literature [20].

The material adopted for socket is polyurethane, whose mechanical behavior has been considered linear elastic with a Young modulus of about 1500 MPa and a Tensile Strength of 16 MPa; the values of these parameters have been gathered from material database. The soft tissues of stump present a weak behavior with respect to the socket material that scholars identify as visco-elastic, moreover their biomechanical characteristics are subjective since each patient presents a specific anatomy. According to these considerations, the modeling of soft tissues represents a not negligible aspect for the reliable design of socket inasmuch any approximation of their behavior involves errors in the evaluation of contact pressures upon stump. However, it is not in the aims of the paper to investigate the effects that the material model may produce on the outcomes of design process, given that the interest is in verifying impact and applicability of SO. In consideration of the paper scopes, the authors believe that the adoption of an accurate material model for soft tissues is unnecessary, being aware, on the contrary, that the investigation of more reliable models represents an essential need for real design cases. According to this statement, they decided to approximate the behavior of soft tissues as linear elastic with Young modulus of 0.2 GPa and to employ a similar model also for internal bones considering a Young modulus of 10 GPa, these values have been obtained from literature [12]. The finite element model of the socket-stump assembly is presented in Fig. 4.

The remaining issues, related to the physics-based modeling activities, concern the boundary conditions that are considered for simulation. In real situations, the feeling of patient is probed by means of donning tests which serve to technicians for identifying socket drawbacks and consequent potential improvements. The design of socket assisted by SO tries to implement the same approach but in a virtual way, indeed the feedbacks of patient are represented through physical quantities that are used as drivers of optimization. According to this assertion, it is obvious that the simulation of socket-stump interaction has to faithfully emulate the donning of socket. This task is accomplished by assigning a displacement to the socket model along the Y direction (see Fig. 4) moving it up to the donning position pointed out by technicians. On the contrary, the stump is totally constrained at the top side in order to hinder any motion. The identification of the correct alignment between socket and stump is an important issue since a wrong initial position may involve a virtual donning that may give rise to unrealistic deformations of tissues and, consequently, incorrect contact pressures.

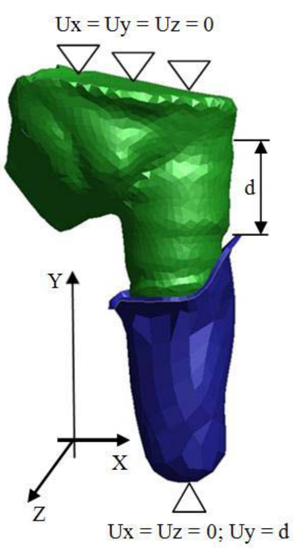

Fig. 4: Finite Element model of the socket-stump assembly and boundary conditions for simulation. Ux, Uy, Uz are the displacements along x, y, z directions. The stump is totally constrained at the top side while a displacement “d” is applied to the socket model along the y direction to simulate the donning.

The implementation of the optimization process has been carried out by HyperStudy which is a module of Hyperworks suite integrated in the simulation environment. Nowadays, several systems are available that provide advanced functionalities for design optimization, some software allow also the combination of different responses to build multi-objective functions for multi-goal optimization. Notwithstanding these features, the implementation of the considered optimization task can involve some practical difficulties. For instance, whereas weight, contact pressure and Von Mises equivalent stress are responses directly calculated by the employed computer aided tool, the overall component of shear stresses at the interface along the required direction is not available in the set of standard results. Therefore, the implementation of the constraint expressed by relation (4.2) represented a troublesome problem for the authors. To the purpose of this work, the authors decided to adopt an indirect approach to assess the recalled physical quantity, consisting in the use of the reaction force along the Y direction as an approximated measure of the friction resistance. It is clear that the recalled difficulty doesn't depend on deficiencies of SO but it is due to limitations of the adopted computer aided system.

Afterwards these considerations, some hypotheses and further assumptions to set the constraints are hereinafter described. As claimed in section 4.1, different regions of the stump present different tolerances to the contact pressure hence the definition of a meaningful pressure constraint requires an accurate measurement of the pain threshold tolerances. However, these data were not available for the considered patient, thus the authors decided to assume a unique pain pressure tolerance for the whole stump. The literature suggests that realistic values for this parameter range from 40-50 to 90-100 kPa [10], then an average of about 75 kPa has been considered as constraint for the entire surface of stump. Furthermore, the maximum load considered in the constraint (4.2) has been assumed equal to half weight of the patient, so about 400 N. This assumption cannot be accepted in a real design case since the maximum load experienced by socket is the weight affected also by inertial effects generated during gait. However, it is worth to remark that for the aim of this investigation the performed hypotheses do not invalidate the results, while for real cases an accurate determination of pain threshold tolerance and maximum acting load is mandatory to attain a reliable socket design. All the above implemented constraints have been summarized in Table 1.

Response		*Constraints*
Contact pressure	P	< 75+5% kPa
Maximum supported load	W	> 400–5% N
Equivalent stress	σ	< 5.3 +5% MPa

Tab. 1: Implemented constraints for the socket optimization.

The definition of design variables within the employed optimization environment is a very simple task since the code allows to handle any parameters characterizing the discretized model. The user can select any node of the mesh and/or other parameters, such as characteristics of materials, thickness of shell elements, etc., and specify which one to consider as design variable. As recalled in section 4.1, the design variables used for the optimization are the x, y and z coordinates of all nodes constituting the mesh of socket and the thickness of shell elements.

Eventually, the employed software offers several optimization algorithms belonging to Genetic Algorithms and mathematical methods. Due to the high number of design variables involved in the optimization task, the authors adopted the Adaptive Response Surface Method (ARSM) [16] which falls in the category of mathematical algorithms. ARSM results one of the less expensive algorithms in terms of required computational resources furthermore, since the optimization objective in this case is a convex function, problems of local minima do not exist. Finally, a convergence tolerance has been imposed to objective and constraints, equal to an allowed value of 5%.

4.3 Results

Here in the following the outcomes of optimization are presented. The output thickness of socket results 4.2 mm, starting from an initial value of 5 mm. The optimized shape of surface hosting the stump is presented in Fig. 5, where three sections at different depths are shown. The sections depict the optimized profiles which have been overlapped with the initial ones.

The optimization process has converged complying with the imposed constraints and according to the assigned tolerances. The mass of optimized socket resulted 2.30 kg starting from an initial value of about 2.40 kg. The contact pressure peak is 77 kPa while the maximum Von Mises equivalent stress is 5,53 MPa. The constraint on the maximum supported load has been satisfied with a value of 880 N. Fig. 6 shows the map of contact pressure distribution on the stump before and after the optimization process. Fig. 7 presents the Von Mises equivalent stress in the socket for initial and optimized design. From a computational point of view, the optimization process has converged after 27 iterations taking 7 hours.

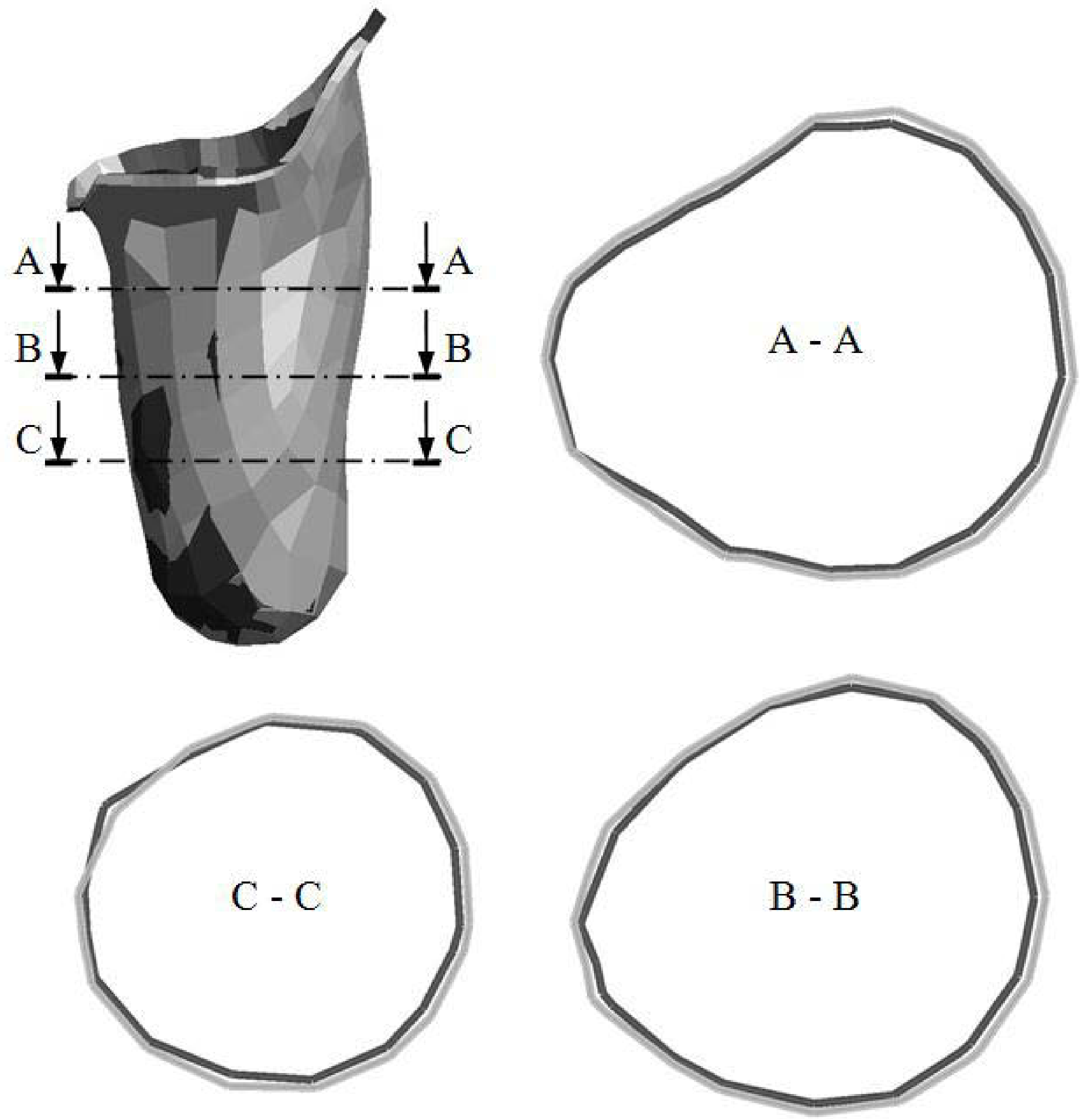

Fig. 5: Three sections at different depths of socket before (heavy grey) and after (light grey) the optimization process. The change of the shape is evident.

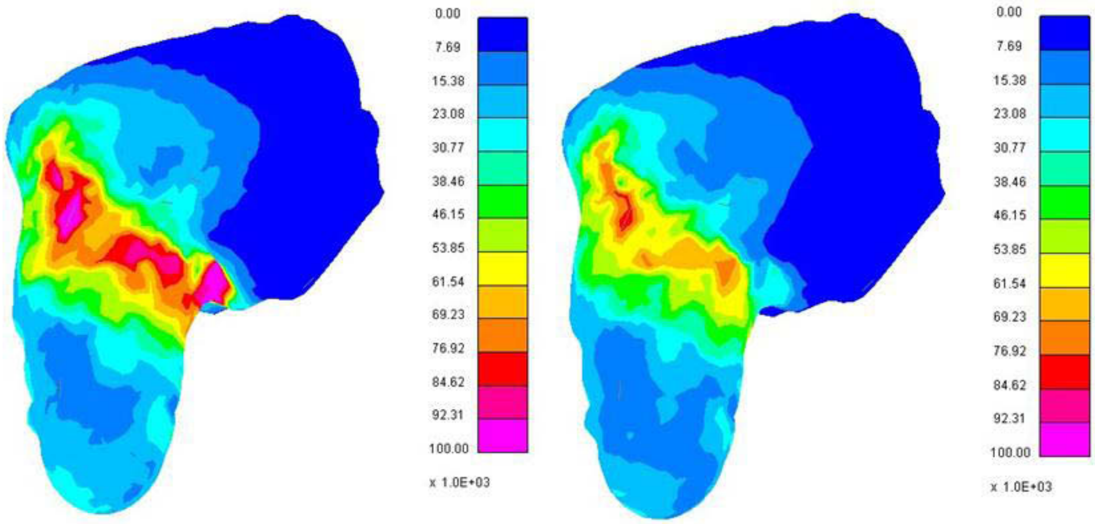

Fig. 6: Pressure (kPa) upon the stump before (left) and after (right) the optimization process. The maximum pressure after optimization comply with the constraint, it decreased of about 23%.

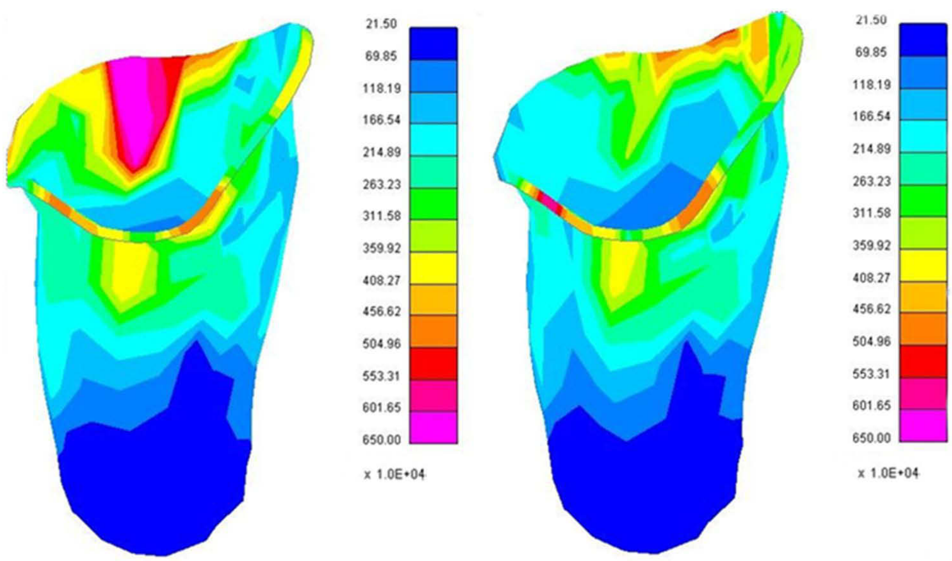

Fig. 7: Von Mises equivalent stress (Pa) before (left) and after optimization. It decreased of about 15%.

5 DISCUSSION AND CONCLUSION

Altogether, the results showed in the previous section point out that the proposed approach is capable to deal with the optimization task of socket. The sections at different depths, depicted in Fig. 5, highlight that the modifications performed by SO to the initial design of socket seem coherent with the overall decrease of contact pressure on the stump showed in Fig. 6. In fact, shape optimization has suggested to enlarge the socket just in correspondence of the regions generating pressure peaks not allowed by the optimization constraint. Accordingly, also the Von Mises equivalent stress within the material decreased as depicted in Fig. 7. Moreover, the final mass of socket complies with the current standards, even though the considered material is one of those presenting the highest density for this kind of applications.

According to the attained outcomes, a question arises which can be formulated as it follows: is this experience sufficient to claim that SO can be adopted as a valid aid in socket design? The authors believe that the results are encouraging and provide some important hints that witness the potential goodness of the proposed approach. However, they are conscious that it has been tested through a realistic but not real case study, thus an experimental activity swiveled on a real design case could represent the unique opportunity to dispel any doubt. Once the validity of the suggested approach will be proved, technicians can use shape optimization to speed up the socket design since they can define a preliminary design of socket, perform its development through automatic optimization and obtain a socket design very close to the optimum, that just requires a fine tuning involving few further time resources.

The analysis of the arisen outcomes brings to further considerations about implementation and usability of shape optimization to assist socket design. The proposed framework can be implemented within any simulation environment having modules and algorithms capable to manage optimization tasks, which nowadays are included in the most common computer aided engineering systems. This feature allows an easy integration of the proposed optimization procedure within the assisted prosthesis development process, since it can deal with any method and computer aided tool reviewed in the introduction section. Besides these aspects, one of the most pressing implementation issues to deepen concerns the identification of the right balance between computational efficiency and reliability of design procedure. As highlighted in section 4.1, contact pressure is the parameter having major impact on the optimization process, hence it requires a careful evaluation to provide reliable design outcomes. This need involves the usage of accurate models of stump and socket since the higher is the number of finite elements, the lower is the numerical error affecting the simulation results. However, although “heavy” finite element models give rise to benefits in terms of accuracy, they negatively impacts on the optimization process, whose computational efficiency strongly depends on the number of design variables. In fact, it is worthwhile to remind that the coordinates of nodes constituting the mesh of socket, together with the thickness of shell elements, are the design variables of optimization. One possible solution that may provide a positive impact on both accuracy of results and computational efficiency is to apply optimization only whereas it is necessary. In fact, looking to Fig. 6, the identification of critical regions on the initial design of socket can be easily carried out by technicians, therefore the shape optimization could be performed only for those regions with the possibility to use more accurate finite element models.

In conclusion, the paper deals with the problem to support optimization activities within socket design and investigates the feasibility of an approach based on SO. Suitable objective, constraints and design variables have been proposed to translate socket requirements into drivers guiding the optimization process. The proposed method has been applied to an illustrative example with the aim of verifying implementation issues and usability. The outcomes provided by this experience are encouraging and highlight positive features that could have a not negligible impact on the prosthesis development process, however future experimental activities involving real case studies are required to verify effectiveness and efficiency. Moreover, the investigation of relationships between required computational resources and accuracy of physics-based model is mandatory to understand the impact on outcomes. Eventually, the suggested optimization procedure can be implemented through common computer aided engineering systems and can be easily integrated with the other computer aided tools adopted in the socket design process. Moreover, it can be also embedded in design environments specifically dedicated to the design of socket.

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