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Development of a Generic Numerical Transtibial Model for Limb–Prosthesis System Evaluation

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Abstract: The well-established finite element method (FEM) has been used successfully to evaluate and develop medical devices for lower-limb prosthetics over recent decades. Most numerical models are based on a specific 3D geometry, which, although allowing for an accurate analysis of a specific case, may differ significantly from the target group that is often geometrically closer to the average residual limb. In order to address this issue, a generic numerical transtibial model was developed with the corresponding definitive socket and silicone liner. Three load cases were performed to analyse the applicability of the model: donning, single-leg stance, and the static P5 test according to ISO 10328. While the first two cases were used commonly in previous studies, the ISO test was only used in physical tests and not in a numerical environment. The results of the simulations in terms of contact pressure, as well as the relative deformation of the socket, fit into the range reported in the literature for similar boundary conditions, thus verifying the model in biomechanical terms. The generic transtibial model serves as a numerical tool for the relative comparison of different socket-liner designs prior to the fabrication, providing insights into results that are otherwise difficult to obtain.

Keywords: transtibial limb; prosthetic socket; numerical model; finite element method; generic model; prosthetic liner

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1. Introduction

An estimated 30 major lower limb amputations per 100,000 people are performed in Europe, most of which are transtibial (below the knee) [1]. It is predicted that the number of amputations will increase in the coming years due to increasing life expectancy and the associated increase in vascular disease and diabetes [2]. After lower limb amputation, patients are usually provided with prostheses to restore mobility and for their successful reintegration into social life. Prostheses are designed and manufactured in hospitals and rehabilitation centres by orthopaedic technicians according to the patient's abilities and the condition of the residual limb [3].

One of the most important parts of the prosthesis is the socket (with or without a liner), allowing the user to move as normally as possible and ensuring adequate safety. A challenging task is to rectify the socket to provide a comfortable fit between the limb and the socket. The residual limb is not designed for the stresses that occur during standing and walking. Therefore, designing and producing a socket that distributes the load optimally, providing stability and safety, is a significant challenge. The current process for socket manufacturing is time-consuming and relies on prosthetists' knowledge, experience, and skills to shape a socket properly [3]. During the first year after the amputation, the user has to visit the prosthetist on average nine times to modify the prosthesis for an improved fit [4]. The predominant approaches to socket design are the total surface bearing (TSB) and specific surface bearing (SSB) methods, with the patella tendon bearing (PTB) predominating [2]. The main difference between the above approaches is that, in the case of SSB, the aim is to transfer loads to the less sensitive sites that can withstand higher stresses, such as the patellar tendon in the case of PTB. On the other hand, TSB sockets aim to distribute the load as evenly as possible over the entire surface of the limb. The TSB method has become widespread in recent years, with the advent of silicone liners that distribute contact pressure over larger areas and help reduce stress concentrations in the residual limb. Silicone liners also adhere to the skin and provide a high coefficient of friction (CoF), which is beneficial for the load transfer between the limb and the prosthesis [5]. Usually, all socket variants are combined with either elastomeric or foam liners, which cushion the load further and provide sufficient friction between the skin and the socket.

The use of FEM in prosthetics has accelerated the development of the socket-liner system by analysing the results in terms of stresses, contact pressures, displacements, deformations, etc., effectively [6]. In vivo testing and measurement are time-consuming and costly, demanding a handful of physical prototypes. Therefore, virtual models are beneficial for initial design evaluation and provide insights into results that are otherwise difficult to obtain. Not only the design but also various materials can be compared for a better understanding of the outcome without the need to produce a physical prosthesis. Recent trends in computer-aided technologies led to a proliferation of numerical models in prosthetics [7,8]. Despite the complex geometry of the residual limb and nonlinear material properties of biological tissue, significant improvements have been made in recent decades [9]. Therefore, the numerical results should be used to analyse and evaluate socket-liner systems to further optimise fit, comfort, stability, and safety. However, the limitations of FEM should be considered when developing the numerical model and evaluating the results. The nonlinear models used to represent biological tissue are homogeneous and time-independent and therefore do not consider muscle activation or changes in soft tissue over time. In addition, the contact between soft tissue and the prosthesis is a complex interaction that depends on many factors, such as temperature, humidity, fit, etc., and is not constant as it is in a simulation. Due to all these limitations, numerical models are only an approximation of actual conditions, and the results should be treated accordingly.

A substantial number of specific lower limb FE models have been developed in attempts to analyse the donning of the socket, stance phase, or even gait cycle. Although this may be accurate for a particular case, we cannot generalise the model to all patients, as the geometry of the limb and the material properties of the biological tissue vary considerably from case to case. Using a specific geometry to design a prosthetic component may lead to a solution that is only suitable for a given case [10]. In order to gain a more general insight into the biomechanical behaviour of the limb–prosthesis system, a generic geometry of the residual limb would be beneficial. Such a model could be used to compare different results relatively, and could support the development of a socket-liner system more objectively for general groups of patients [11].

Accurately capturing all biological components in a numerical model is challenging and often results in an unstable numerical model. Hence, it is necessary to reduce the complexity of the model, to ensure convergence and minimise computational costs [10]. One way to obtain the average geometry of a given biological component is through statistical shape modelling (SSM), where measurements are taken on a given population and then averaged [12]. Such an approach requires a sufficient amount of data and an accurate acquisition method for the model to be adequate, which can be time-consuming and costly. The detailed shapes of bones obtained with SSM are advantageous when comparing morphological differences between race, sex, age, lifestyle, etc. [13]. On the other hand, the specific details increase the computational cost significantly and reduce the numerical convergence of a complex biomechanical system. In order to analyse the bulk interaction between the residual limb and the prosthesis sufficiently, the morphological details should be reduced to such an extent that the model still reflects a typical biomechanical response. Based on the previous point, the generic transtibial model should be simple enough to ensure numerical convergence but still provide valid results in terms of contact pressure at the limb surface and relative deformation of the socket and liner, allowing an objective evaluation of the prosthetic's components [14].

To date, only a limited number of generic lower limb models have been developed that are currently outdated or highly simplified, and for which the results, therefore, cannot compete with today's advanced computer-aided technologies [11,14–19]. B. Silver-Thorn et al. developed a generic numerical transtibial limb model consisting of basic geometric shapes representing an average-sized limb [11]. The model was also used in later studies, where it was compared with experimental measurements and results from the literature [14,15]. Due to the significant simplifications (linear elastic material models, basic geometric shapes, and simple boundary conditions), the overall biomechanical response of the model is questionable and can only be used as an initial assessment of the limb prosthesis system. On the contrary, the model developed in the current study uses nonlinear material models and complex boundary conditions, which represent more realistic scenarios; hence, more accurate biomechanical results could be obtained.

Simplified 2D axisymmetric numerical models have also been used to analyse specific properties, such as friction and contact pressure at the limb–socket interface [16–19]. Results have shown that such simplified and generic or quasigeneric models can be used to simulate specific biomechanical phenomena. In a recent study, a parametric model was created based on the population-driven residuum shape morphology, soft tissue compliance, and prosthetic socket design [8]. The model's geometry was based on a single MRI scan but could be morphed into different shapes using SSM. Further studies were conducted with this model [20,21] to create a numerical tool that enables real-time predictions and helps in the data-driven design of the socket. SSM was limited to the 30 surface scans of the rectified plaster casts and one specific internal structure of the knee joint provided by MRI.

With the exception of the outdated model consisting of simple geometric shapes, none of the numerical models represent an average transtibial limb of a general group that could be used for a limb–prosthesis system analysis and the relative comparison of different prosthetic components [11]. Numerous FEM simulations have been performed with a specific limb geometry and have yielded different results that are difficult to compare due to the complexity of the biomechanical system [10]. The generic model would, therefore, provide a virtual environment that allows for a more objective evaluation of the limb-prosthesis system. The aim of our research was to develop an average transtibial model for a general population that is numerically stable and allows for the effective simulation of the biomechanical interaction between the residual limb and the prosthesis in order to further assess and improve lower limb prostheses.

2. Materials & Methods

In order to develop a generic model of a transtibial limb, simplifications to the complex geometry, material models, and boundary conditions were incorporated with caution to ensure numerical convergence on the one hand and to preserve the critical features of the residual limb that influence the accuracy of the results on the other.

2.1. Geometry of the Residual Limb

The skeleton of the residual limb was subtracted from a subject-specific TLEM 2.1 lower extremity model, which was scaled to a standard size (50th percentile size for a European male) using the AnyBody Repository (Figure 1a) [22]. In clinical practice, it is vital that the bones are cut following the surgical guidelines; failure to do so may result in additional stress concentrations and increased pressure, leading to discomfort and pain [3]. Considering the previous point, the leg skeleton was sectioned in the virtual environment according to the guidelines for lower limb amputations in conjunction with the Traumatologist to create an average-size transtibial limb model [3]. The distance from the tibial plateau to the tibial end was 150 mm, which corresponds to the average transtibial limb size. According to the physiatrist's recommendations, the fibula was cut and bevelled 10 mm above the tibial end. The proximal part of the femur was also cut because it was not needed in the simulation and would only increase computational time. In addition, the surfaces of the bones were smoothed using the QuadRemesh function in Rhino 7 (Robert McNeel & Associates) to reduce the specific details that would increase numerical complexity but not affect the quality of the biomechanical behaviour. The final transtibial skeleton model includes the distal femur with the femoral shaft, the proximal tibia with cut and bevelled tibial shaft, the patella, and the fibular head with cut and bevelled fibular shaft (Figure 1b).

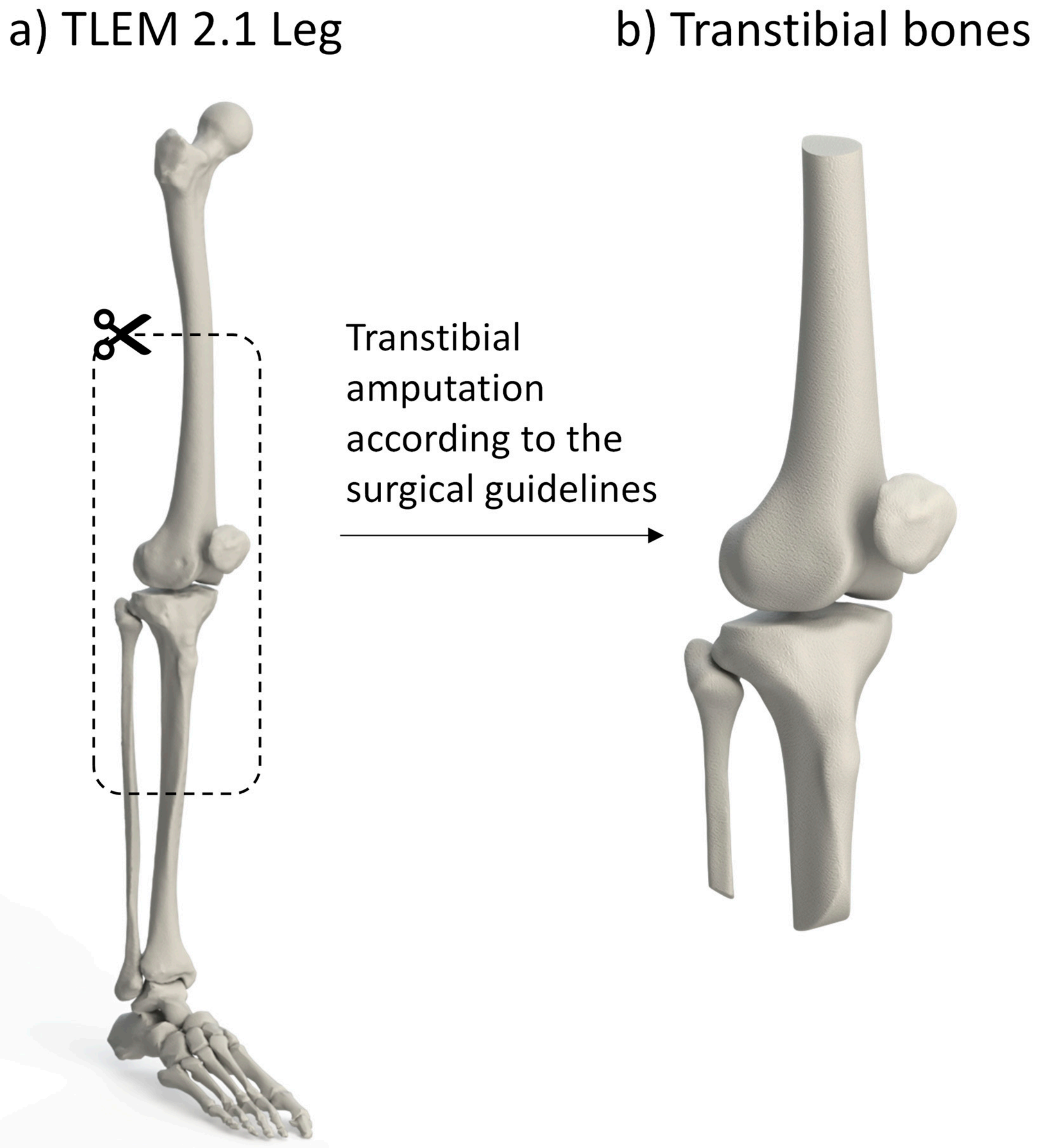

Figure 1. Scaled TLEM 2.1 leg model representing a size of the 50th percentile European male (**a**); transtibial bones truncated according to the surgical guidelines (**b**).

The muscles, ligaments, tendons and other biological tissues were combined to form a bulk soft tissue whose shape was governed by the average mid-thigh, mid-patella and calf circumferences (50th percentile male, 20 years and older) [23]. The transparent view of the limb's soft tissue with marked circumferences can be seen in Figure 2a. The shape was additionally modified according to The Physiology of the Joints—The Lower Limb by I.A. Kapandji, taking into account the position of the bones, and therefore a 4-degree flexion angle was added [24]. A 3D numerical model of the generic residual limb is shown in Figure 2b. The numerical values of the main design parameters used for the modelling are listed in Table 1.

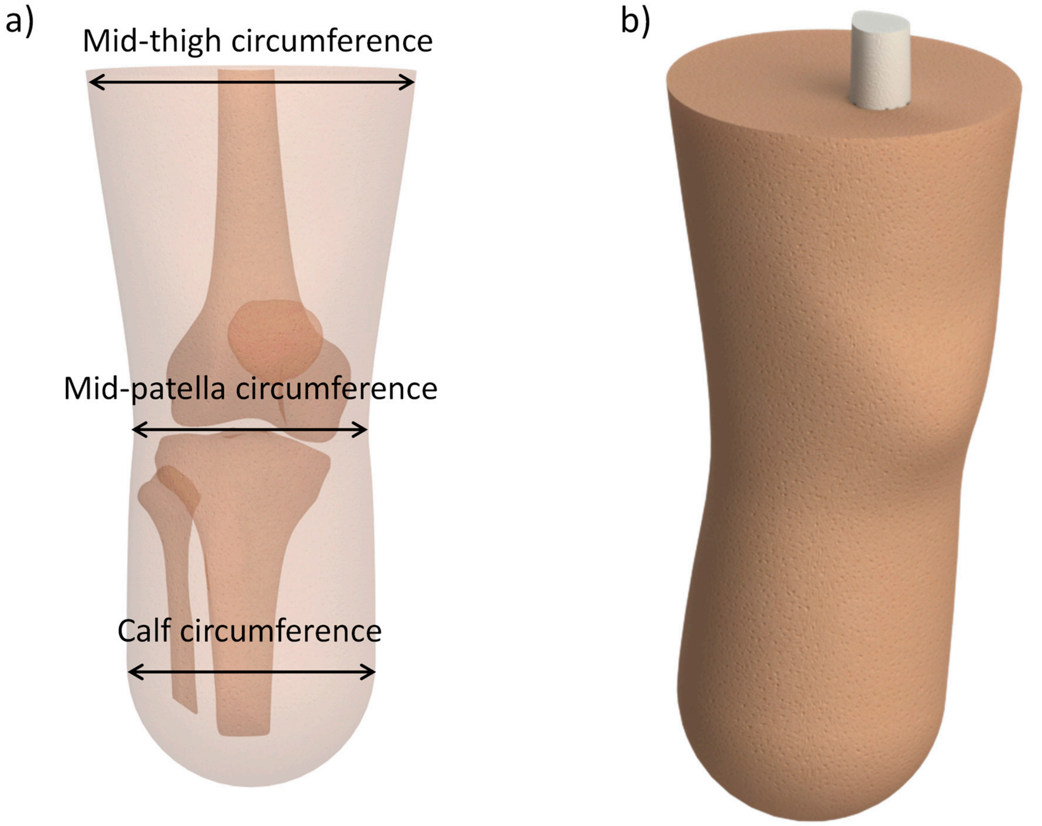

Figure 2. Transparent view of the bulk soft tissue with marked circumferences (**a**); a 3D view of the generic transtibial limb (**b**).

Table 1. Main design parameters used for the modelling of the generic residual limb.

Design Parameter	Value
Tibia length	150 mm
Fibula	cut 10 mm above the tibial end
Mid-thigh circumference	533 mm
Mid-patella circumference	368 mm
Calf circumference	392 mm
Knee bent angle	4 deg

2.2. Rectification of the Socket

The first step in modelling the socket was to incorporate the prosthetic liner. Therefore, a frequently used silicone liner was modelled by extruding the outer surface of the residual limb to a thickness of 6 mm. In practice, the silicone liner is rolled up like a sock and takes the form of the residual limb [25]. Following the modelling of the liner, the socket was reshaped according to the guidelines of two common rectification approaches. The first was the standard PTB method, which relieves pressure on sensitive areas, and stress areas that can withstand higher loads without causing discomfort or tissue damage. The second approach used was TSB, where the contact pressure is distributed as evenly as possible across the limb [2]. During the rectification process, the trim line of the socket was determined, and the edge was rounded to remove sharp edges that could damage the tissue. Once the suitable shape was achieved, the surface was extruded evenly to 3 mm, which is the approximate thickness of the definitive composite socket. Figure 3 shows a heat map depicting the socket's indented regions compared to the liner's outer surface. In the PTB, the patellar tendon region is the most indented, while in the TSB, it is the posterior region.

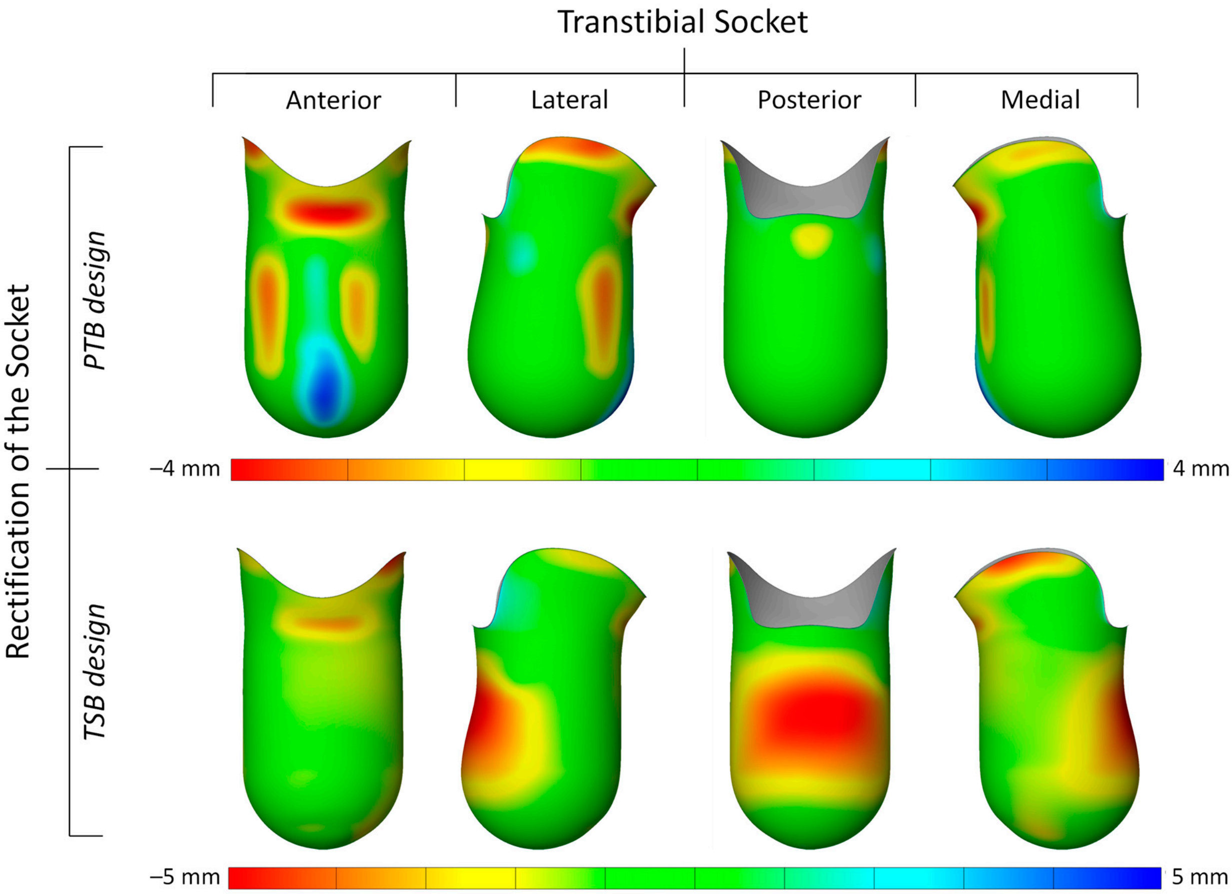

Figure 3. Heat map of rectified sockets. The red and blue colours represent concave and convex regions, respectively.

The final step was to design the distal part of the socket relative to the position of the leg skeleton to enable the attachment of the standard prosthetic adapter. Moreover, the distal part was reshaped to reduce the stress concentration and, thus, distribute the stresses more uniformly over the socket (Figure 4a). Rectification was performed in the prosthetic software Rodin 4D Neo (RODIN SAS, Merignac, France) with the assistance of Prosthetists from the University Rehabilitation Institute in Slovenia (URI Soča). The Prosthetists reshaped the sockets in a virtual environment according to the PTB and TSB rectification methods for transtibial prostheses. The geometry of the final virtual model consists of bones, bulk soft tissue, silicone liner and PTB or TSB socket. In Figure 4b, the socket overlaps with the silicone liner due to the rectification process. The overlap is resolved in the first step of the simulation using the interference fit and represents the donning of the prosthesis.

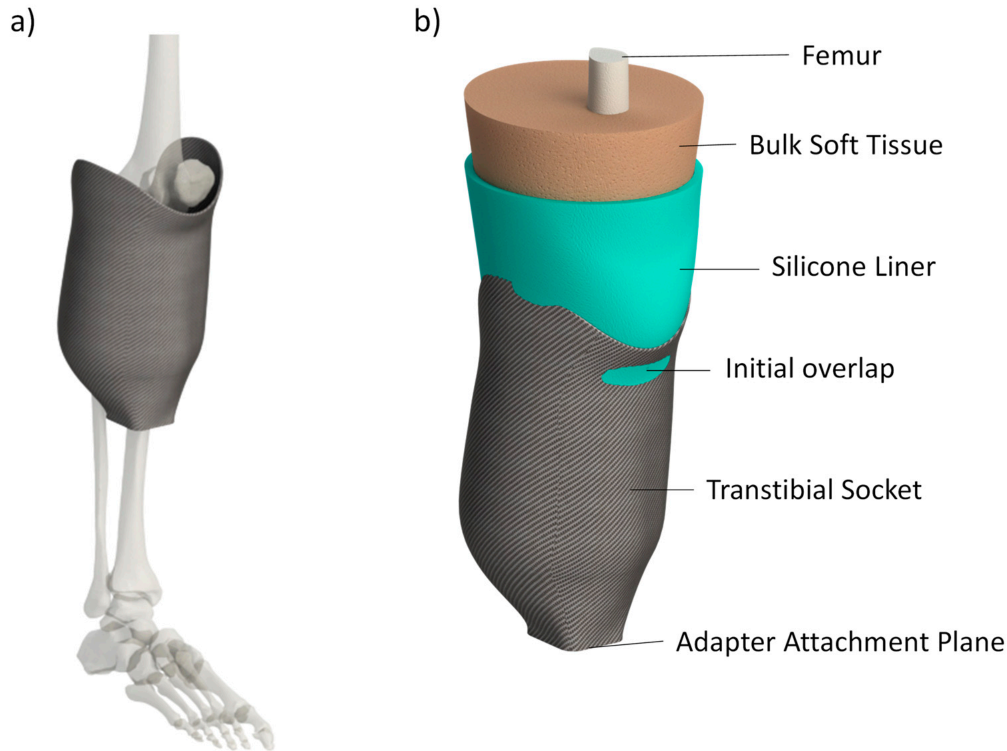

Figure 4. Rectified definitive socket, positioned with respect to the leg skeleton (**a**); final assembly of the residual limb model, silicone liner, and socket (**b**).

2.3. Material Properties

Determining the mechanical properties of biological tissue in vivo is challenging due to its nonlinear behaviour under load. The main characteristic of soft tissue is that it is almost incompressible and soft at low strains but becomes exponentially stiffer with increasing strains [26]. Since the main objects of the investigation were the contact pressure at the limb–liner interface and the relative deformation of the socket, the goal was to approximate a global response of the residual limb without focusing on a specific biological part within the limb, which was achieved with a hyperelastic material model. Specifically, the Ogden first-order nonlinear material model was used to represent the mechanical properties of the bulk soft tissue, including the skin [27]. Furthermore, the Yeoh third-order hyperelastic material model was used to define a silicone liner [28]. Both material models were derived from the literature, where they were also validated.

In order to reduce the number of elements and, thus, the computational time, the bones were modelled as rigid cavities in the residual limb, as they have a significantly higher stiffness compared to the soft tissue; hence, the rigid approximation is justified. In addition, auxiliary components, such as the prosthetic shaft and the foot, needed to build the desired load case were modelled as rigid connections between remote points. Finally, the composite socket was defined using the data from the experimental study conducted by URI Soča on the samples of the material used commonly in practice for the production of the definitive socket [29]. All material models used in the simulation are listed in Table 2.

Table 2. Material models and their parameters used in the simulation.

Component	Material Model	References	Parameters
Soft tissue	Ogden first order	Kallin et al. [27]	MU1 = 0.012 MPa A1 = 14 D1 = 1.67 MPa^{-1}
Silicone liner	Yeoh third order	Cagle et al. [28]	C10 = 0.2014 MPa C20 = −0.00115 MPa C30 = 0.00041 MPa D1 = 3 MPa^{-1}
Socket	Linear–elastic	Bombek et al. [29]	E = 4991 MPa ν = 0.3

2.4. Boundary Conditions

Three load cases were analysed in the simulation to cover the donning phase, single-leg stance and gait. The results of previous studies have shown that a numerical analysis of the prosthesis donning is necessary, as the initial stress affects the results in the following steps [30]. Due to the rectification of the socket, the contact pressure was distributed to the preferred areas after the donning. The first step in the simulation was carried out by solving the initial interference fit between the socket and the residual limb. The second load step was the commonly used vertical loading of the limb–prosthesis system, representing a single-leg stance. A vertical force of 850 N was applied to the rigid femoral cavity, approximating the 50th percentile weight for adult males of all races and ethnicities in the United States, which is 85.6 kg according to the 2008 National Health Statistic Reports [24]. Although the average European male weight, as stated in AnyBody Repository, is 77 kg, a higher weight was used to fit into the P5 loading level, which ranges from 80 kg to 100 kg according to ISO 10328 [31]. The reason for the higher weight was to test the applicability of the model at higher loads compared to the P3 (up to 60 kg) and P4 (from 60 kg to 80 kg) load levels.

The same loading level was also used for the static analysis of the gait. The simulated P5load case was developed based on the experimental tests, including all participants, some of whose body mass also exceeded 100 kg. The load case was divided into the P5 I and P5 II conditions, referring to the heel strike and push-off phases of gait, respectively. Each condition was simulated in two steps: (1) Settling test force—forces and moments occurring during the normal gait cycle, (2) Proof test force—a rare severe event where the loads and moments are much higher than in the previous step. To comply with the Standard, the prosthetic structures should remain undamaged and fully functional in both cases. All numerical load steps and their magnitude are listed in Table 3.

Table 3. Description of the loading steps with related magnitude.

Loading Step/Loading Condition		Magnitude [N]
Donning		Solving interference
Vertical force (single leg stance)		850
ISO P5 I (heel strike)	Settling test force	1024
	Proof test force	2240
ISO P5 II (push off)	Settling test force	920
	Proof test force	2013

As described in the previous subsection, the bones and other prosthetic components were rigid and connected via remote points. This results in the direct action of forces and moments on the distal part of the socket and the femoral cavity. The force line passes through the remote points Ft at the upper end and the Fb at the lower end. At Ft, translations were restricted in all directions, but all rotations were free. At Fb, however, the translation in the force vector direction and rotation in the z-direction was free to allow for deformation (Figure 5).

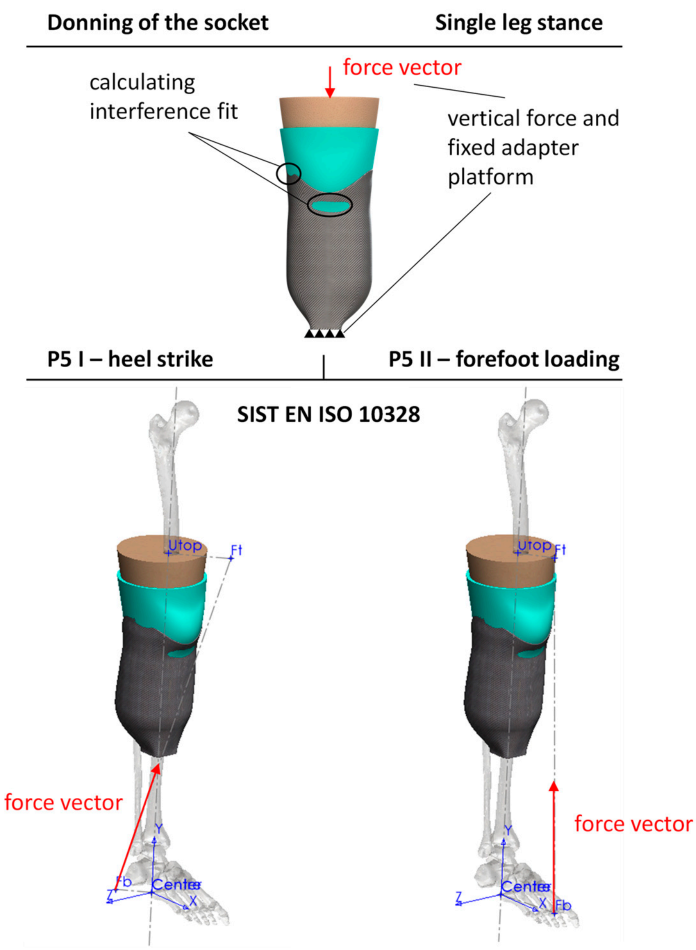

Figure 5. Load cases in the numerical simulation. Donning of the socket—the adapter platform and femur cavity are fixed via remote points. Single-leg stance—vertical force is applied to the femoral cavity. P5 I—heel strike load case according to ISO 10328. P5 II—push-off load case according to ISO 10328.

The silicone liner adheres to the skin and has a high CoF. A static CoF of 2 or more is reported in the literature and can be approximated by a rough contact that restricts tangential movement but still allows separation in the normal direction [5]. The backing material of the silicone liner is usually made of fabric and does not provide as high a CoF when in contact with the socket. Therefore, the frictional contact with 0.5 CoF defines the relative movement between the socket and liner [25].

2.5. Numerical Simulation and Validation of the Numerical Model

A multistep static FEM simulation was performed using the ANSYS Workbench 2021 R2 (ANSYS, Inc. Canonsburg, PA 15317 USA) on the HPC at the Faculty of Mechanical Engineering, University of Maribor. The duration of the simulations varied, depending on the load case and was approximately 2 h for the donning and single-leg stance load cases combined and 6 h for the simulation of all steps on an Intel Xeon CPU E5-2670 (2.60 GHz) processor with 16 cores. The contact pressure at the limb-liner interface and the deformation of the socket for all load cases and both rectification methods were simulated and analysed in the following sections.

In order to obtain mesh-independent numerical results, a mesh analysis was carried out for a single-leg stance load case following the donning of the socket. The complex geometry of the model, the nonlinear materials and the frictional contacts make it difficult for the model to converge. To overcome this problem, the size and resolution of the mesh were changed until the results did not improve with a finer mesh. The FE model was developed and analysed in ANSYS Mechanical, where the global mesh resolution is defined on a scale of 1 to 7 (the higher the number, the finer the mesh). In addition to the resolution, a size was set, starting with 7 mm and decreasing stepwise to 3 mm. Due to the complex geometry of the model, second-order 3D 10-node elements were used (SOLID187). The mesh was evaluated based on the average contact pressure at the limb-liner interface.

3. Results

The result of the mesh analysis is shown in Figure 6. It can be seen that the results did not change in the last three iterations. Therefore, the mesh with the fastest computation time was chosen for the final mesh (size 3 mm, resolution 3). The final model contained 217,985 quadratic tetrahedral elements with 377,810 nodes.

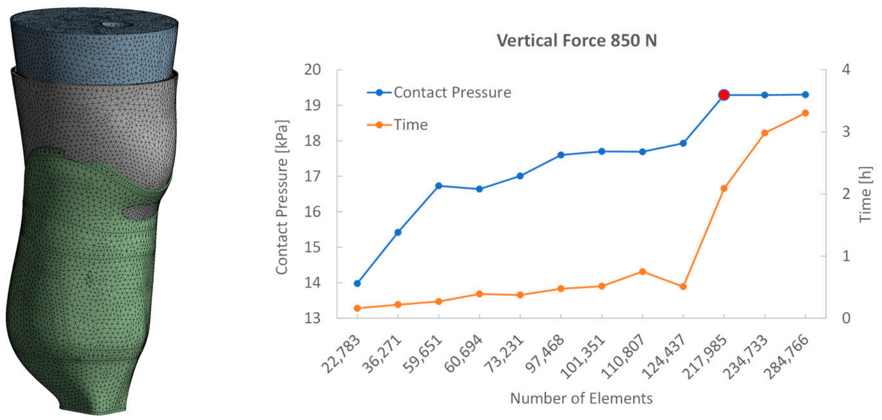

Figure 6. Meshed numerical model of a transtibial limb-prosthesis system and graphical representation of the convergence study evaluated by average contact pressure at the limb-liner interface. The red dot indicates the final mesh.

3.1. Contact Pressure

The maximum contact pressure at the limb–liner interface was determined for both the TSB and PTB sockets and for all load cases. The numerical values of the peak pressure are shown in Figure 7.

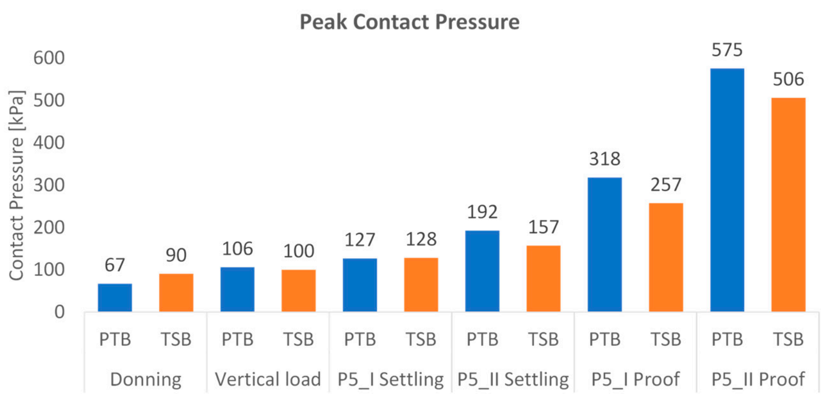

Figure 7. Peak contact pressure between the silicone liner and residual limb for the PTB (blue) and TSB (orange) sockets and all load cases.

A pressure distribution was also considered in addition to the maximum contact pressure. A significant difference can be observed between the PTB and TSB sockets, as well as between the load cases. Figure 8 shows the pressure distribution for donning and the single-leg stance load step. Similarly, Figure 9 shows the pressure distribution for the P5 I and P5 II load steps at the settling test force. Note that the scale is different for each load step, ranging from 0 to 90 kPa for donning and 0 to 106 kPa for the single-leg stance, while a higher contact pressure of 0 to 128 kPa and 0 to 192 kPa can be observed for P5 I and P5 II, respectively.

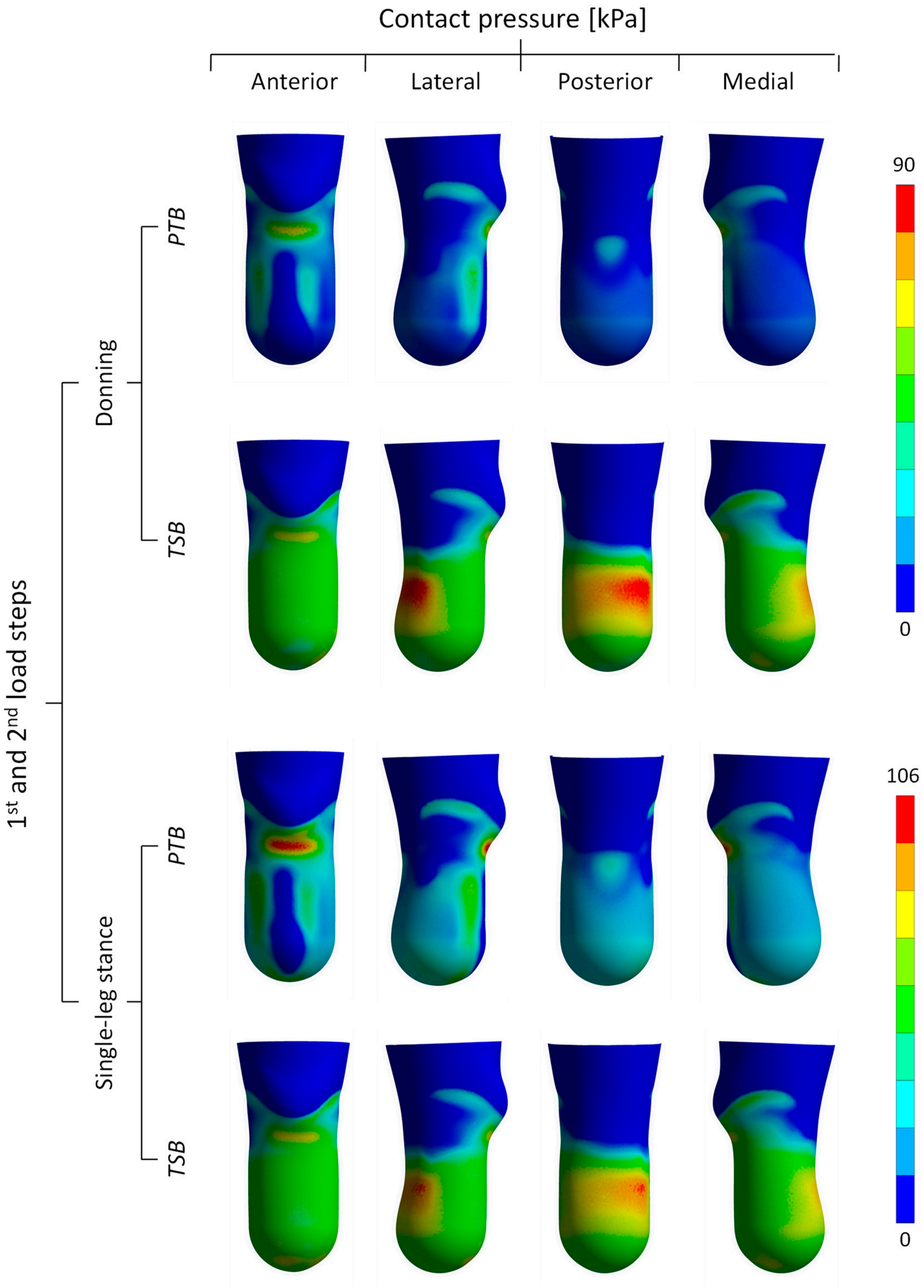

Figure 8. Contact pressure distribution for donning and the single-leg stance load steps.

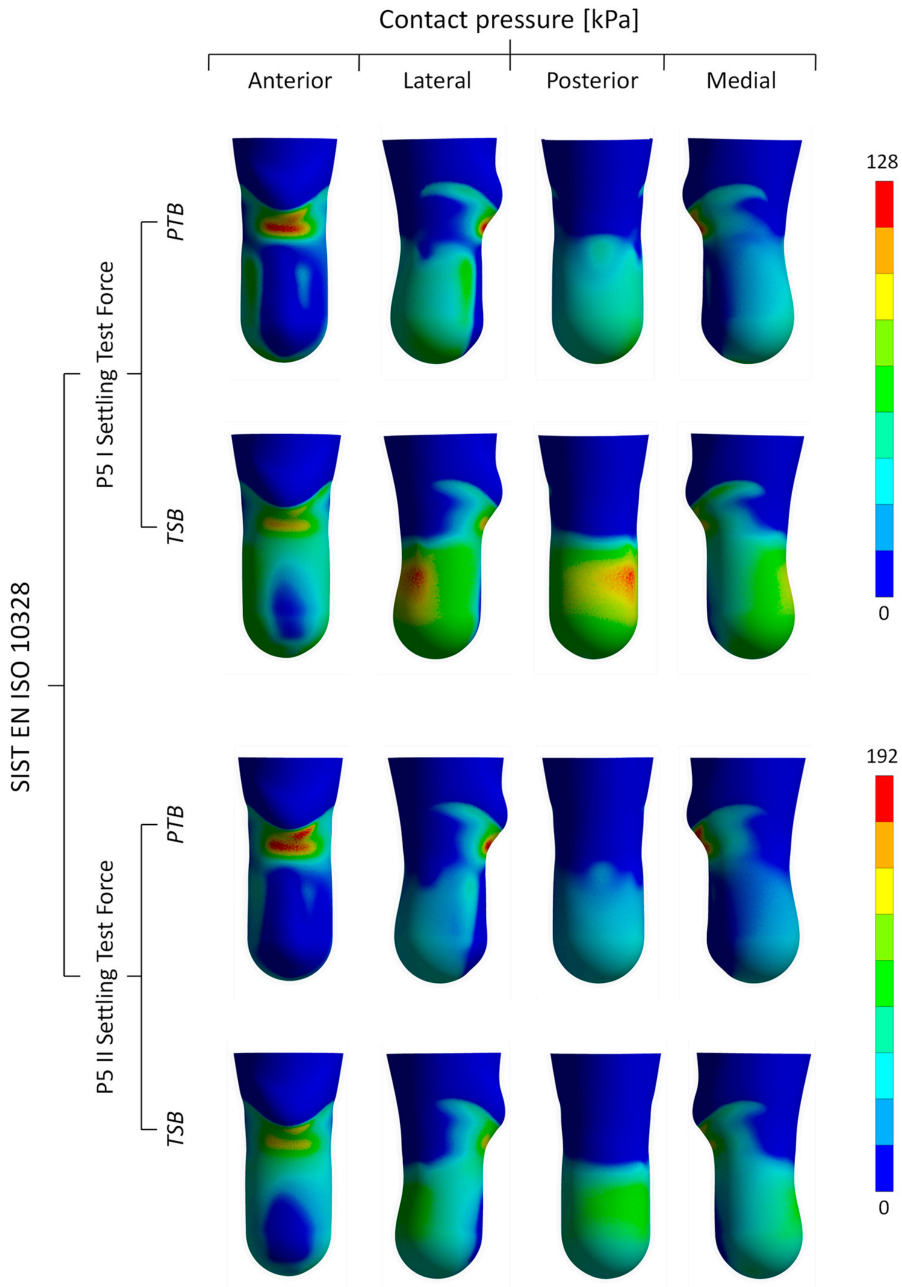

Figure 9. Contact pressure distribution for the P5 I and P5 II load steps.

3.2. Deformation of the Socket

The deformation of the outer surface of the socket was analysed to assess the relative displacement of the residual limb within the socket and, hence, the stability of the prosthesis. The numerical results of the relative deformation without the rigid translation and rotation for the TSB and PTB socket and all load cases are shown in Figure 10.

In addition, the deformation results are presented graphically with labelled maximum and minimum values in Figure 11. Note that the range of the heat map is different for each load step. The graphical comparison was made using GOM Inspect 4.0.1305.0 ZEISS Quality Suite (Carl Zeiss GOM Metrology GmbH, Braunschweig, Germany), comparing the original surface to the deformed surface. Negative values mean that the deformed surface moves inwards in relation to the original shape and vice versa.

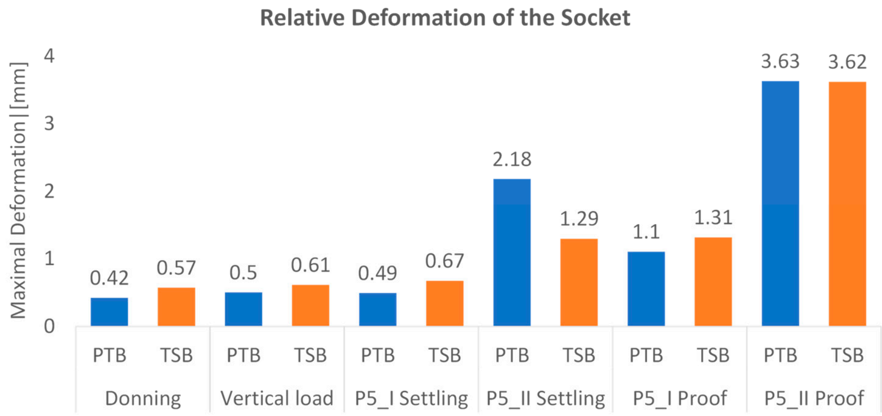

Figure 10. Deformation of the socket's outer surface relative to the initial shape of the socket. Deformation does exclude rigid body movement. Blue represents a PTB socket, while orange represents TSB socket results.

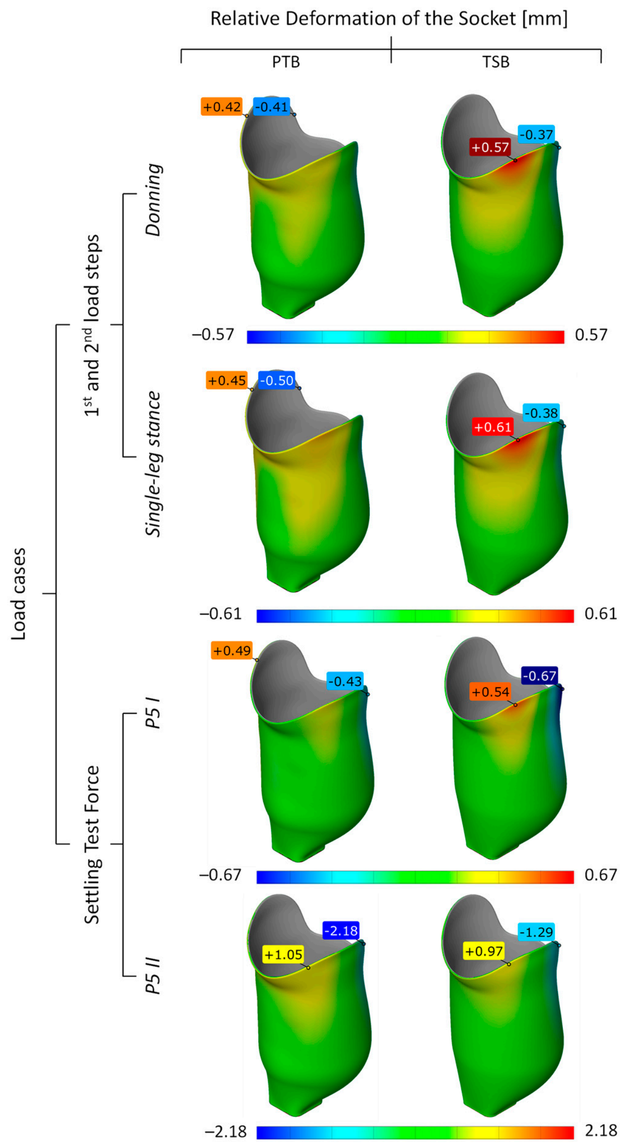

Figure 11. Relative deformation of the socket's outer surface. The heat map range depends on the given load case.

3.3. Comparison of the Contact Pressure Results

The FE results reported in the literature for lower limb amputees were analysed and categorised into groups based on the boundary conditions: donning of the prosthesis, stance, or gait. The peak contact pressure of the most commonly loaded regions on the surface of the limb, namely, the patellar tendon (PT) and the posterior area (PA), were compared to the results obtained with the generic FE model developed in the current study. The gait analysis results were divided into heel strike and push-off conditions for our model. Figure 12 shows the bar chart of the peak contact pressure, where the bars with the pattern fill correspond to the results reported in the literature, while the blue and orange bars show the results of the current study for the PTB and TSB sockets, respectively.

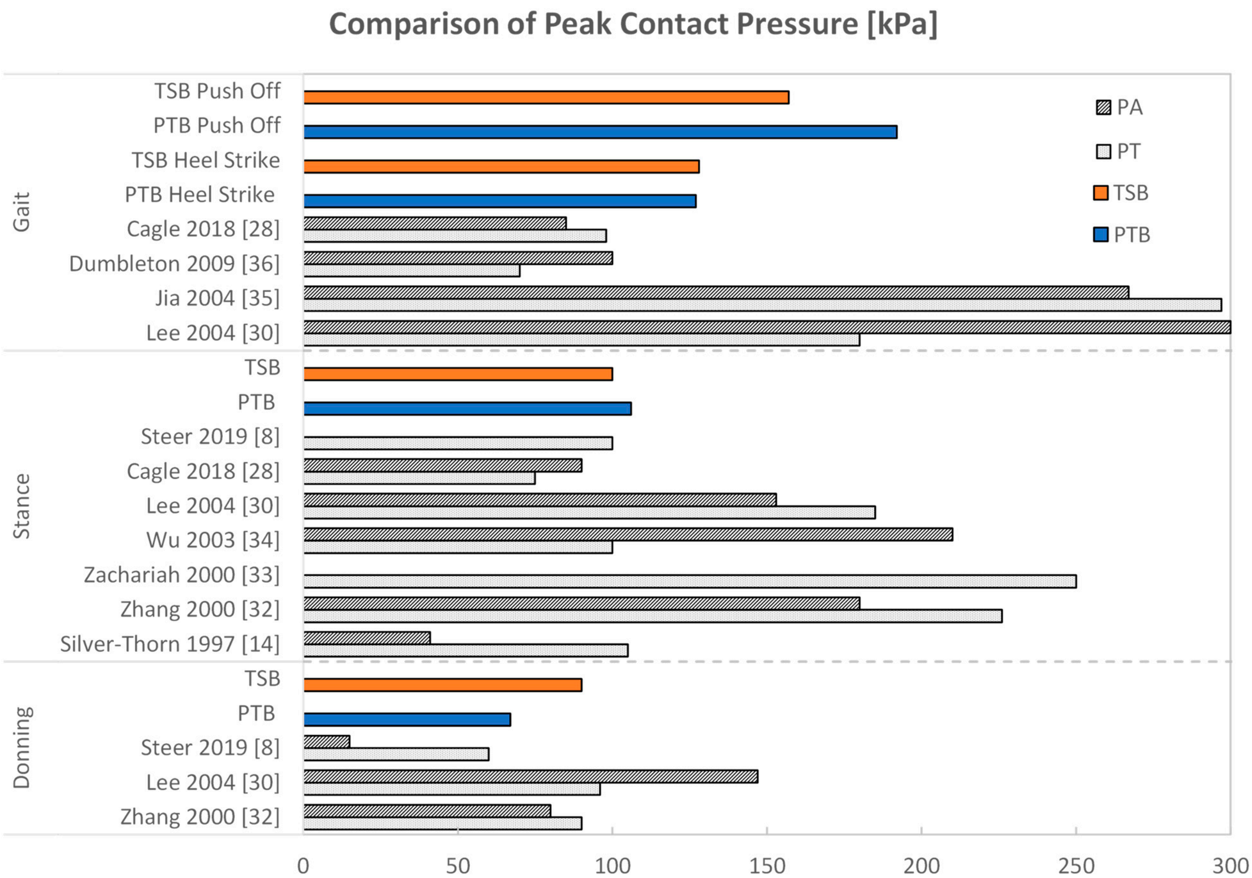

Figure 12. Comparison of peak contact pressure results from the FEA to those reported in the literature for the donning, stance, and gait boundary conditions at the patellar tendon (PT) and posterior area (PA) [8,14,28,30,32–36].

4. Discussion

The aim of the present study was to develop a generic 3D transtibial model that could be used to evaluate different socket-liner systems numerically. Such a model provides a virtual environment in which the biomechanical response of the residual limb is simulated and, hence, could help to design and assess lower limb prostheses before a physical prototype is manufactured. Various mechanical properties, such as stresses, strains, contact pressures, deformations, etc., can be analysed to improve the interaction between the residual limb and the prosthesis in the virtual environment using the developed transtibial model. The generic numerical model developed in this study provides a valid biomechanical response, as shown by comparison with the literature discussed in the following subsection and can therefore be used for a relative comparison of different prosthesis designs.

4.1. Biomechanical Validation

A validation of the numerical model of the residual limb in the sense of traditional verification, as is known from classical mechanics, is currently not possible due to the complex geometry and the rate-dependent, nonlinear material properties, which can vary from site to site and also from day-to-day [26]. The material models of biological tissue determined in vitro are only time-independent approximations and do not define the actual biomechanical properties of the tissue fully. Another challenge is controlling the boundary conditions of the in vivo tests so that they are repeatable. In order to extend the point further, anatomical structures and their topological characteristics vary significantly between lower limb amputees, which influences the results in terms of contact pressure, stresses, strains, and deformations. All the above factors should be taken into account, and therefore numerical results should only be evaluated in relative context to each other.

In order to validate the generic numerical model in biomechanical terms, we used material models from the literature that have been shown to provide valid numerical results for bulk soft tissue, silicone liners, and composite sockets [27–29]. The geometry of the numerical model was developed using the verified TLEM 2.1 skeleton, and this was scaled and modified further following the surgical guidelines for lower limb amputation [3]. In addition, the CoF between the limb-liner and liner-socket was specified based on previous studies [5,25]. A mesh analysis of the model was performed to obtain mesh-independent results and ensure numerical convergence. With the exception of the static gait analysis according to ISO 10328, the frequently used loading conditions of donning and single-leg standing were used, allowing for relative comparison to the previous results with similar load cases. In light of the aforementioned points, the numerical model should be considered validated in the biomechanical sense.

In order to validate the numerical results further, the peak contact pressures reported in previous studies were compared with the results of the generic model developed in the current study (Figure 12). Only studies with similar definitions were considered due to the wide range of reported results, which can be attributed to differences in prosthesis design, loading levels, the definition of boundary conditions, and the use of material models. Two commonly stressed regions on the residual limb were analysed, namely, the patellar tendon (PT) and the posterior area (PA). For the donning load case, the contact pressure ranged from 60 to 96 kPa and 15 to 147 kPa for PT and PA, respectively. The results of the current study for the PTB socket provide a peak contact pressure of 67 kPa at the PT region, while the TSB socket gives a 90 kPa at the PA region. Although the contact pressure is higher for the TSB socket compared to the PTB, both results were in line with those found in the literature. The influence of the socket rectification is notable in this step and determines how the pressure is distributed over the residual limb, as seen in Figure 8.

The most frequently analysed load case is the single- or double-legged stance (middle sector in Figure 12). In the current study, the single-leg stance generated a maximum pressure of 106 kPa and 100 kPa for the PTB and TSB sockets, respectively. The reported results can be divided into older and newer studies due to the significant differences in peak contact pressure. The results from older studies ranged from 100 to 250 kPa for PT and 41 to 210 kPa for PA. More recent studies reported a range of 75 to 100 kPa, which fits better with the results obtained in the current study [8,28]. The higher peak pressure reported in older studies can be attributed to the fact that a foam liner or even no liner was used to alleviate the pressure between the limb and socket [14,30,32–34]. The widespread use of silicone liners has only been introduced in recent years, resulting in lower pressure peaks. This is due to the features of silicone that help to alleviate contact pressure by flowing from high-pressure to low-pressure areas [8,28].

Finally, the gait conditions reported in the literature were compared to the P5 load steps at the settling test force corresponding to gait conditions; both heel strike and push-off were evaluated. A note of caution is due here since the reported studies vary regarding the boundary conditions describing the gait cycle. The upper part of Figure 12 shows a wide range of peak contact pressure results, indicating different loading conditions. The results from our study for heel strike were 127 kPa and 128 kPa for the PTB and TSB sockets, respectively. A significantly higher maximum contact pressure was observed in the push-off condition of the P5 load step, specifically 192 kPa and 157 kPa for the PTB and TSB sockets, respectively. The numerical results indicate that the push-off instant is more intense and generates higher contact pressures. A limited number of studies from other authors report a wide span of peak pressures, starting at 70 kPa for PT and reaching a maximum of 300 kPa for PA. Similar to the single-leg case, older studies tend to produce a higher peak pressure because no silicone liner was used.

4.2. Numerical Analysis of the Generic Transtibial Model

Currently, the model represents the size of a 50th percentile male transtibial limb but could easily be scaled and remodelled using the AnyBody Model Repository to provide sizes for various age, gender, weight, or ethnicity groups. Additionally, the size and shape of the limb could be modified by cutting the bones at different lengths and reshaping the soft tissue according to the anthropometric measurements of a given target group of patients. The same approach can be applied to transfemoral limbs. In this study, a PTB and a TSB socket were analysed, which gave significantly different results in terms of pressure distribution and pressure intensity (Figures 8 and 9). The Prosthetist can use the contact pressure results on the limb surface to understand better the effects of the different rectification methods. The definitive composite socket is much stiffer than the soft tissue; hence, the residual limb takes the form of the socket when donned, while the deformation of the socket remains negligible (maximum deformation of 0.42 mm for the PTB and 0.57 mm for the TSB socket). The rectification of the socket has a significant impact on the level and distribution of the initial contact pressure. As intended, after donning, a PTB socket produced the maximum contact pressure at the PT and a TSB socket at PA, which are the regions that can withstand higher loads. The preloading of the limb in this step gives the user a sensation of stability and security. However, on the other hand, the loads must be distributed to the preferred areas to avoid discomfort, or even pain.

Following the donning, a single-leg stance was simulated by applying an equal-weight vertical force to the femoral cavity and fixing the attachment plane of the adapter. Similar loading conditions have been used frequently in previous numerical and experimental studies and are, therefore, a fruitful source for validating the model. This step generated a peak contact pressure of 106 kPa and 100 kPa for the PTB and TSB sockets, respectively. In contrast to the initial stress state, a higher contact pressure occurred for the PTB socket, indicating that TSB rectification distributes the pressure more evenly over the limb surface. The locations where the maximum pressure occurred were similar to the donning load case for both rectification methods, as shown in Figure 8.

While the loading cases of donning and single- or double-leg stance are easy to interpret and standardise, this is not the case with gait analysis due to the complex boundary conditions that occur during walking. In the static simulation of the gait cycle, a particular instance, e.g., heel strike or heel-off, is evaluated, and these conditions can vary significantly from case to case. One of the main objectives of our study was to establish and define a standard numerical loading case of a gait and a severe event for the evaluation of prostheses. Therefore, the boundary conditions for FE analysis were proposed according to ISO 10328. The standard is essentially intended for the physical testing of various prosthetic components, except the prosthetic socket. However, since there is no specific standard for socket evaluation, the above standard has also been used for testing the socket physically in previous studies [6,37–40]. A major drawback of this standard for the experimental evaluation of prosthetic sockets is that a foam or sponge filling and plaster of Paris or various polymers are typically used to replace a residual limb in the socket, which hardly reflects the biomechanical response of the tissue [41,42]. While this is not problematic for other prosthetic components, the nonlinear behaviour of biological tissue affects the stress–strain results significantly by deforming and, thus, mitigating stress concentrations. Hence, more realistic conditions can be achieved using a generic numerical limb model and an approximation of the bulk soft tissue response. The introduction of ISO 10328 into the virtual environment, in combination with the generic model, enables a numerical evaluation of the socket–liner system in more complex and realistic loading conditions than simulating only a stance. The proposed approach allows a static numerical simulation of a gait and, thus, unifies the boundary conditions so that different studies can compare results relative to each other.

In order to present the usability of the results from the realistic gait cycle, the heel strike (P5 I) and the push-off (P5 II) were analysed regarding the settling and proof test force. From the results, it can be seen that, under push-off conditions, a higher maximum contact pressure occurred for both rectification methods (Figure 7). A rare severe event, such as a trip or fall, was represented by the proof test force. This loading condition resulted in a significantly higher contact pressure: 318 kPa and 257 kPa for the PTB and TSB sockets at heel strike and 575 kPa and 506 kPa for PTB and TSB sockets at push-off. The pressure distribution also varied depending on the load case and rectification method, as shown in Figure 9. Such high contact pressures could cause damage to the biological tissue and should therefore be avoided, or, if not possible, minimised by providing a stable prosthesis. It is challenging to relate the biomechanical results to the subjective sensation. According to a previous study, contact pressure can be a parameter for evaluating a pain pressure threshold and pain pressure tolerance [34]. The stability of the prosthesis can be assessed by analysing the relative deformation of the socket. Until the pain pressure threshold is reached, minimal deformation of the socket is desirable to ensure maximum stability. On the other hand, controlled deformation could reduce the pressure concentration and, hence, increase the comfort of the socket. The numerical results show that the composite socket proves to be very stiff, deforming only 2.18 mm at the settling test force and thus providing stability during gait (Figure 11). Due to the high stiffness of the socket, most of the deformation occurs in the soft tissue and silicone liner, which helps to alleviate stress concentrations in the residual limb that could lead to pain or discomfort. Since we cannot change the material properties of the biological tissue, the liner is the main component that can be designed to mitigate contact pressure further.

Although the numerical model provides a realistic biomechanical response, some limitations should be addressed. The geometry of the model is generic, and the simulation results cannot be extrapolated to a specific case but rather serve as a relative comparison of the different socket and liner designs. Additionally, the material models are simplified and are time-independent, so muscle activation is not taken into account. All load cases were static, regardless of the fact that walking is a dynamic process and that inertia has an influence on the results. All simplifications have been introduced in order to ensure numerical convergence and minimise computational costs. In addition to the already performed validation presented in this paper, the developed numerical model should also be validated by experimental tests. A possible solution is to design an experiment with the 3D-printed or moulded silicone stump to approximate a bulk soft tissue behaviour. A dynamic simulation should be considered to analyse the entire gait cycle according to ISO 10328. A more detailed residual limb model should be investigated, including muscle activation, tendons, skin, meniscus, etc. Using the developed model, different socket and liner designs should be analysed considering different materials. Future efforts should be made to link biomechanical parameters with subjective sensations.

5. Conclusions

A generic 3D numerical model of a transtibial limb with a combination of PTB or TSB socket and silicone liner was developed in the present study. The model provides high-quality numerical results in terms of stresses, strains, contact pressure, displacement, etc., and can therefore be used successfully to improve the socket–liner system in the virtual environment. A comparison with previous numerical or experimental studies in terms of contact pressure confirms the valid biomechanical response of the model. In contrast to the numerical models based on the specific geometry, the generic model corresponds to the 50th percentile male size and can also be scaled to fit different groups of patients. A loading condition was developed according to ISO 10328 to create a standardised test procedure for gait analysis in a virtual environment. The generic model enables the virtual testing of various socket and liner designs prior to physical testing, thus assisting in the development of new prosthetic components that can improve fit, stability, and comfort for prosthesis wearers.

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References

1. Kolossváry, E.; Björck, M.; Behrendt, C.-A. Lower Limb Major Amputation Data as a Signal of an East/West Health Divide Across Europe. *Eur. J. Vasc. Endovasc. Surg.* **2020**, *60*, 645–646. [CrossRef]
2. Paterno, L.; Ibrahimi, M.; Gruppioni, E.; Menciassi, A.; Ricotti, L. Sockets for Limb Prostheses: A Review of Existing Technologies and Open Challenges. *IEEE Trans. Biomed. Eng.* **2018**, *65*, 1996–2010. [CrossRef]
3. Krajbich, J.I.; Pinzur, M.S.; Potter, B.K.; Stevens, P.M. (Eds.) *Atlas of Amputations and Limb Deficiencies: Surgical, Prosthetic, and Rehabilitation Principles*, 4th ed.; Lippincott Williams & Wilkins: Rosemont, IL, USA, 2016.
4. Pezzin, L.E.; Dillingham, T.R.; MacKenzie, E.J.; Ephraim, P.; Rossbach, P. Use and satisfaction with prosthetic limb devices and related services. *Arch. Phys. Med. Rehabil.* **2004**, *85*, 723–729. [CrossRef]
5. Cagle, J. A Computational Tool to Enhance Clinical Selection of Prosthetic Liners for People with Lower Limb Amputation. Ph.D. Thesis, University of Washington, Seattle, WA, USA, 2016.
6. Colombo, G.; Rizzi, C.; Regazzoni, D.; Vitali, A. 3D interactive environment for the design of medical devices. *Int. J. Interact. Des. Manuf.* **2018**, *12*, 699–715. [CrossRef]
7. Meng, Z.; Wong, D.W.-C.; Zhang, M.; Leung, A.K.-L. Analysis of compression/release stabilized transfemoral prosthetic socket by finite element modelling method. *Med. Eng. Phys.* **2020**, *83*, 123–129. [CrossRef]
8. Steer, J.W.; Worsley, P.R.; Browne, M.; Dickinson, A.S. Predictive prosthetic socket design: Part 1—Population-based evaluation of transtibial prosthetic sockets by FEA-driven surrogate modelling. *Biomech. Model. Mechanobiol.* **2019**, *19*, 1331–1346. [CrossRef] [PubMed]
9. Moerman, K.; Sengeh, D.; Herr, H. Automated and Data-driven Computational Design of Patient-Specific Biomechanical Interfaces. Germany, Europe. *engrXiv* **2016**. [CrossRef]
10. Dickinson, A.S.; Steer, J.W.; Worsley, P.R. Finite element analysis of the amputated lower limb: A systematic review and recommendations. *Med. Eng. Phys.* **2017**, *43*, 1–18. [CrossRef] [PubMed]
11. Silver-Thorn, M.B. Prediction and Experimental Verification of Residual Limb/Prosthetic Socket Interface Pressures for Below-Knee Amputees. Ph.D. Thesis, Northwestern University, Ann Arbor, MI, USA, 1991.
12. Cerveri, P.; Belfatto, A.; Manzotti, A. Predicting Knee Joint Instability Using a Tibio-Femoral Statistical Shape Model. *Front. Bioeng. Biotechnol* **2020**, *8*, 253–264. [CrossRef] [PubMed]
13. Mahfouz, M.; Abdel Fatah, E.E.; Bowers, L.S.; Scuderi, G. Three-dimensional Morphology of the Knee Reveals Ethnic Differences. *Clin. Orthop. Relat. Res* **2012**, *470*, 172–185. [CrossRef]
14. Silver-Thorn, M.B.; Childress, D.S. Generic, geometric finite element analysis of the transtibial residual limb and prosthetic socket. *J. Rehabil. Res. Dev.* **1997**, *34*, 171–186.
15. Silver-Thorn, M.B.; Childress, D.S. Parametric analysis using the finite element method to investigate prosthetic interface stresses for persons with trans-tibial amputation. *J. Rehabil. Res. Dev.* **1996**, *33*, 227–238. [PubMed]
16. Tanaka, M.; Akazawa, Y.; Nakagawa, A.; Kitayama, I. Identification of pressure distribution at the socket interface of an above-knee prosthesis. *Adv. Eng. Softw.* **1997**, *28*, 379–384. [CrossRef]
17. Tönük, E.; Silver-Thorn, M.B. Nonlinear Elastic Material Property Estimation of Lower Extremity Residual Limb Tissues. *IEEE Trans. Neural Syst. Rehabil. Eng.* **2003**, *11*, 43–53. [CrossRef] [PubMed]
18. Portnoy, S.; Yarnitzky, G.; Yizhar, Z.; Kristal, A.; Oppenheim, U.; Siev-Ner, I.; Gefen, A. Real-time patient-specific finite element analysis of internal stresses in the soft tissues of a residual limb: A new tool for prosthetic fitting. *Ann. Biomed. Eng.* **2007**, *35*, 120–135. [CrossRef]
19. Ramalho, A.; Ferraz, M.; Gaspar, M.; Capela, C. Development of a preliminary finite element model to assess the effects of friction on the residual limb of a transfemoral amputee. *Mater. Today Proc.* **2020**, *33*, 1859–1863. [CrossRef]

20. Steer, J.W.; Grudniewski, P.A.; Browne, M.; Worsley, P.R.; Sobey, A.J.; Dickinson, A.S. Predictive prosthetic socket design: Part 2—Generating person-specific candidate designs using multi-objective genetic algorithms. *Biomech. Model. Mechanobiol.* **2019**, *19*, 1347–1360. [CrossRef]
21. Dickinson, A.; Diment, L.; Morris, R.; Pearson, E.; Hannett, D.; Steer, J. Characterising Residual Limb Morphology and Prosthetic Socket Design Based on Expert Clinician Practice. *Prosthesis* **2021**, *3*, 280–299. [CrossRef]
22. Carbone, V.; Fluit, R.; Pellikaan, P.; Van Der Krogt, M.M.; Janssen, D.; Damsgaard, M.; Vigneron, L.; Feilkas, T.; Koopman, H.F.; Verdonschot, N. TLEM 2.0–A comprehensive musculoskeletal geometry dataset for subject-specific modeling of lower extremity. *J. Biomech.* **2015**, *48*, 734–741. [CrossRef]
23. McDowell, M.A.; Fryar, C.D.; Ogden, C.L.; Flegal, K.M. Anthropometric reference data for children and adults: United States, 2003. *Natl. Health Stat. Rep.* **2008**, *10*, 5.
24. Kapandji, I.A. *The Physiology of the Joints: Lower Limb*; Churchill Livingstone: London, UK, 1987; Volume 2.
25. Cagle, J.C.; Hafner, B.J.; Taflin, N.; Sanders, J.E. Characterization of prosthetic liner products for people with transtibial amputation. *J. Prosthet. Orthot.* **2018**, *30*, 187–199. [CrossRef]
26. Silver-Thorn, M.B.; Tonuk, E.; Kemp, J. In vivo indentation of lower extremity limb soft tissues. In Proceedings of the Annual International Conference of the IEEE Engineering in Medicine and Biology, Atlanta, GA, USA, 13–16 October 1999.
27. Kallin, S.; Rashid, A.; Salomonsson, K.; Hansbo, P. Comparison of mechanical conditions in a lower leg model with 5 or 6 tissue types while exposed to prosthetic sockets applying finite element analysis. *arXiv* **2019**, arXiv:190713340. [CrossRef]
28. Cagle, J.C.; Reinhall, P.G.; Allyn, K.J.; McLean, J.; Hinrichs, P.; Hafner, B.J.; Sanders, J.E. A finite element model to assess transtibial prosthetic sockets with elastomeric liners. *Med. Biol. Eng. Comput.* **2018**, *56*, 1227–1240. [CrossRef]
29. Bombek, M.; Vesenjak, U.; Pisek, M.; Vidmar, G.; Knez, S.; Medved, S. Mechanical testing of laminated composite materials for prosthetic sockets. *Mater. Technol.* **2021**, *55*, 655–661. [CrossRef]
30. Lee, W.C.C.; Zhang, M.; Jia, X.; Cheung, J.T.M. Finite element modeling of the contact interface between trans-tibial residual limb and prosthetic socket. *Med. Eng. Phys.* **2004**, *26*, 655–662. [CrossRef]
31. *EN ISO 10328:2016 E*; Prosthetics—Structural testing of lower -limb prostheses—Requirements and test methods (ISO 10328:2016). European Committee for Standardization: Brussels, Belgium, 2016.
32. Zhang, M.; Roberts, C. Comparison of computational analysis with clinical measurement of stresses on below-knee residual limb in a prosthetic socket. *Med. Eng. Phys.* **2000**, *22*, 607–612. [CrossRef] [PubMed]
33. Zachariah, S.G.; Sanders, J.E. Finite element estimates of interface stress in the trans-tibial prosthesis using gap elements are different from those using automated contact. *J. Biomech.* **2000**, *33*, 895–899. [CrossRef] [PubMed]
34. Wu, C.L.; Chang, C.H.; Hsu, A.T.; Lin, C.C.; Chen, S.I.; Chang, G.L. A proposal for the pre-evaluation protocol of below-knee socket design—Integration pain tolerance with finite element analysis. *J. Chin. Inst. Eng.* **2003**, *26*, 853–860. [CrossRef]
35. Jia, X.; Zhang, M.; Lee, W.C.C. Load transfer mechanics between trans-tibial prosthetic socket and residual limb—Dynamic effects. *J. Biomech.* **2004**, *9*, 1371–1377. [CrossRef]
36. Dumbleton, T.; Buis, A.W.P.; McFadyen, A.; McHugh, B.F.; McKay, G.; Murray, K.D.; Sexton, S. Dynamic interface pressure distributions of two transtibial prosthetic socket concepts. *J. Rehabil. Res. Dev.* **2009**, *46*, 405–415. [CrossRef]
37. Campbell, A.I.; Sexton, S.; Schaschke, C.J.; Kinsman, H.; McLaughlin, B.; Boyle, M. Prosthetic limb sockets from plant-based composite materials. *Prosthet. Orthot. Int.* **2012**, *36*, 181–189. [CrossRef] [PubMed]
38. Goh, J.; Lee, P.; Ng, P. Structural integrity of polypropylene prosthetic sockets manufactured using the polymer deposition technique. *Proc. Inst. Mech. Eng. Part H J. Eng. Med.* **2002**, *216*, 359–368. [CrossRef]
39. van der Stelt, M.; Grobusch, M.P.; Koroma, A.R.; Papenburg, M.; Kebbie, I.; Slump, C.H.; Maal, T.J.; Brouwers, L. Pioneering low-cost 3D-printed transtibial prosthetics to serve a rural population in Sierra Leone—An observational cohort study. *E Clin. Med.* **2021**, *35*, 100874. [CrossRef] [PubMed]
40. Vitali, A.; Regazzoni, D.; Rizzi, C.; Colombo, G. Design and Additive Manufacturing of Lower Limb Prosthetic Socket. In Proceedings of the ASME International Mechanical Engineering Congress and Exposition, Tampa, FL, USA, 3–9 November 2017; American Society of Mechanical Engineers: New York, NY, USA, 2017.
41. Neo, L.; Lee, P.; Goh, J. Principal structural testing of trans–tibial prosthetic assemblies: Specimen preparation. *Prosthet. Orthot. Int.* **2000**, *24*, 241–245. [CrossRef] [PubMed]
42. Current, T.; Kogler, G.; Earth, D. Static structural testing of trans-tibial composite sockets. *Prosthet. Orthot. Int.* **1999**, *23*, 113–122. [CrossRef] [PubMed]