Influence of Gait Cycle Loads on Stress Distribution at The Residual Limb/Socket Interface of Transfemoral Amputees: A Finite Element Analysis

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A Finite Element Analysis (FEA) was performed to evaluate the interaction between residual limb and socket when considering the dynamic loads of the gait cycle. Fourteen transfemoral amputees participated in this study, where their residual limbs (i.e., soft tissues and bone), and their sockets were reconstructed. The socket and the femur were defined as elastic materials, while the bulk soft tissues were defined as a hyperelastic material. Each model included the donning, standing, and gait cycle phase, with load and boundary conditions applied accordingly. The influence of adding the dynamic loads related to the gait cycle were compared against the modelling of the static load equivalent to the standing position resulting in changes of 23% ± 19% in the maximum values and in an increase in the size of the regions where they were located. Additionally, the possible correspondence between comfort and the location of peak loadbearing at the residual-limb/socket interface was explored. Consequently, the comfort perceived by the patient could be estimated based on the locations of the maximum stresses (i.e., if they coincide with the pressure tolerant or sensitive regions of the residual limb).

In lower limb amputees, specifically for limb amputations above knee level, the prosthetic system consists mainly of a prosthetic foot, a prosthetic knee and a socket. Since the attachment between the residual limb and the prosthesis occurs through the socket, its coupling is critical for patients looking to regain their functional mobility and perceiving comfort1,2. Among others, the main task of the socket is to distribute the loads applied on the residual-limb/socket interface. By doing this, the stresses generated at the residual limb in sensitive areas are reduced, and gait becomes stable by allowing adequate proprioception and movement of the residual limb muscles3–5 (all of this during a prolonged loading time6). Thus, the residual-limb/socket interface is a key factor in the successful performance of the patient during his/her rehabilitation7.

When wearing a prosthesis, both normal (i.e., perpendicular to the skin) and shear stresses (i.e., tangential to the skin) are applied to the soft tissues of the residual limb, which are not accustomed to bear such elevated loads, inducing the risk of skin problems and chronic pain1,2,6. Recommendations for transtibial socket design based on Pain Pressure Thresholds (PPT) have been defined by other authors since pressure beyond certain limit triggers pain18 and pressure is the condition that most critically increases skin problem and chronic pain risks at the residual-limb/socket interface19. Moreover, the existence of algometers as reliable medical devices for measuring PPT20,21 can lead to easier implementation of new protocols for socket design where pressure tolerant and sensitive regions at the residual limb are defined according to the PPT that patients can endure based on their perception22,13,14. These thresholds are established when critical stresses and strains states exceed tolerable values. However, these thresholds may increase with larger contact areas or when the load is applied intermittently. In addition to these pain thresholds, pressure values have been reported at which capillary vessels are unable to conduct blood (from 30 mmHg (4 kPa)16 to 60 mmHg (8 kPa)17), being these pressure values critical for muscle tissues due to their greater vascularity and their metabolic demands (it should be noted that this injury pressure levels are...
substantially smaller than the pressure tolerance levels reported in this research). A successful socket design must
relieve pressure from sensitive regions and exert pressure on tolerant ones. Nevertheless, current socket design and
manufacture are based on the prosthetist’s ability and professional experience rather than on quantitative data.

FEA has been used as an instrument for evaluating a wide range of aspects of lower limb amputees. FEA allows
a less subjective analysis of factors that are difficult to study analytically or measure experimentally, including
strains and stresses generated at the residual-limb/socket interface during the use of the prosthesis.

Although FEA on transfemoral amputees have been studied before, there is a need to evaluate the behaviour of
the interface under dynamic loads. This will allow to analyse higher precision models for residual-limb load
and boundary conditions that do not ignore changes in the coupling between the socket and the lower limb
due to relative angular movements or axial displacements, or changes of variations in velocity and acceleration.
These dynamic conditions are present during the gait cycle, which is affected by the endogenous state of the
amputee given that the asymmetry of the gait during ambulation radically differs from healthy gait parameters.
Additionally, when individuals try to return to their dynamic stability, various compensations in forces and
moments are generated that result in specific pathologies affecting the load distribution on the residual limb.
Dynamic models that successfully include these compensated forces and moments could lead to more precise
simulations. The aforementioned will not be evident in models that only take into account the static loads caused
by the amputee’s weight, which, to the best of the knowledge of the authors, are the only loads currently
reported for transfemoral amputees.

This study aims to analyse the stress distribution of the residual limb of 14 transfemoral amputees, evaluating
which zones are highly exposed to pressure and shear stresses based on FE results. Additionally, the maximum
stresses values and their location, obtained during the gait cycle, are compared with those of a static-load sim-
ulation (i.e., standing) to identify additional information from numerical models. Further, the study compares the perception of comfort and the location of the peak loads (i.e., feeling comfortable when the peak
loads are located at pressure tolerant regions or feeling uncomfortable when they are located at pressure-sensitive
regions).

Methods

Fourteen unilateral transfemoral amputees participated in a series of experiments. Before the procedure, they
all signed an informed consent bearing all pertaining information and written in accordance with the guidelines
set by the Ethics Committee. All experimental protocols were approved by the Ethics Committee of Universidad
Nacional de Colombia (CEMED-145-10) and the experiments were carried out in observance of the World
Medical Association’s Code of Ethics and the Declaration of Helsinki.

Table 1 shows the general amputation-related information of each subject and the data and variables used to
analyse the results. Most participants used their prosthesis throughout the day and lived a fairly active lifestyle.
They had no other physical, vascular, neurological, or psychological condition that may alter or modify the results
of the numerical model simulation.

Regarding BMI, the method created by Mozumdar and Roy was used to calculate the estimated weight
\(W'_e\). This method infers the \(W'_e\) from the current body weight, and its reduction as a consequence of the ampu-
tation \(\Delta W\). The fraction of weight lost due to the missing limb was defined according to the values reported by
Osterkamp for different body parts, and the proportion of the thigh that was amputated, which was calculated
during the experiments. The information used for the calculation and the BMI results for each patient are shown
in Table 1.

Figure 1 shows the simulation process. The load and boundary conditions of each phase were applied accord-
ingly to faithfully simulate the use of the socket from the donning to the gait cycle. The numerical model was
carried out in three stages: socket donning (a), a period of stabilization (b) and the load phase. This final phase
includes the model of the static condition (i.e., standing position) (c) and the dynamic condition (i.e., complete
gait cycle) (d).

Geometry. During socket design, as a general rule, the prosthetist aims to achieve an adequate load distribu-
tion by compressing tolerant regions in the residual limb and relieving pressure from intolerant regions to make
the socket more comfortable for the amputee. In this study, the socket and the residual limb were digitally
reconstructed as separate elements using a 3D laser scanner (NextEngine Inc., Santa Monica, USA). The socket
was obtained by scanning a rectified positive plaster while the external surface of the residuum soft tissue was
generated from a direct positive plaster cast of the residual limb. Although surgical scars played an important
role in numerical models, they were purposely excluded in this study because the main objective was to simulate
the interaction between the socket and the residual limb. Additionally, including the surgical scars would complicate
the solution of the FEM model without adding valuable information to the volumetric response of the residual
limb. The femur of the amputee was also included in the 3D reconstruction of the residual limb using information
from a computerized axial tomography (CT) to define its geometry and relative position to the soft tissues. To
appropriately define the relative position of the three elements, marks were made to indicate the location of the
greater trochanter and the ischial tuberosity in the 3D scanned parts. Finally, the CT information was used to
align the residual femur with the soft tissues and the socket.

Detailed information on the tomography parameters, geometry reconstruction, and assembly and donning
procedures followed in this study can be found in Lacroix and Ramirez.

Materials. The material’s mechanical properties (i.e., soft tissue, bone and polypropylene) were not
custom-tailored for each patient. All sockets and bones were considered a linear elastic homogeneous isotropic
material and all soft tissues, a hyperelastic material. The properties were in the same order of magnitude as those
used by other authors, although those studies mainly focused on the socket/residual-limb interaction for transtibial amputees19,25,27–33. For the bone, Young’s modulus was set to 15 GPa, Poisson’s ratio to 0.3 and density to 2000 kg/m³34. As for the socket, which was made out of polypropylene, Young’s modulus was set to 1.5 GPa, Poisson’s

| Patient | Time since amputation [years] | Socket type                  | Weight without Prosthesis [Kg] | Prosthesis Weight [Kg] | Estimated Weight [Kg] | Height [cm] | Leg Length [cm] | Residual limb length [cm] | Body mass index BMI [kg/m²] |
|---------|-------------------------------|------------------------------|--------------------------------|------------------------|-----------------------|-------------|-----------------|---------------------------|-----------------------------|
| P01     | 9                             | Quadrilateral               | 72                             | 5                      | 82.5                  | 176         | 86.5            | 28                        | 26.6                        |
| P02     | 2                             | Quadrilateral               | 57                             | 4.1                    | 65.8                  | 172         | 80.5            | 21                        | 22.2                        |
| P03     | 7                             | Quadrilateral               | 91.5                           | 4.9                    | 105.5                 | 177         | 86              | 23                        | 33.7                        |
| P04     | 1                             | Quadrilateral               | 83.8                           | 4.9                    | 94.5                  | 165         | 74              | 34                        | 34.7                        |
| P05     | 2                             | Semi ischial-containment    | 75.3                           | 2.9                    | 84.8                  | 168         | 76.5            | 36.5                      | 30.0                        |
| P06     | 4                             | Semi ischial-containment    | 67.9                           | 3.2                    | 77.5                  | 175         | 85              | 30                        | 25.3                        |
| P07     | 24                            | Exomodular                   | 73.6                           | 6.2                    | 85.0                  | 167         | 79              | 20                        | 30.5                        |
| P08     | 13                            | Semi ischial-containment    | 49.1                           | 4.1                    | 56.5                  | 153         | 69.5            | 20.5                      | 24.1                        |
| P09     | 6                             | Quadrilateral               | 72                             | 4.1                    | 83.3                  | 167         | 80              | 19                        | 29.9                        |
| P10     | 42                            | Semi ischial-containment    | 64.5                           | 3.7                    | 75.6                  | 161         | 77              | 10                        | 29.2                        |
| P11     | 23                            | Quadrilateral               | 64.7                           | 2.8                    | 74.0                  | 164         | 83              | 28                        | 27.5                        |
| P12     | 4                             | Quadrilateral               | 81                             | 6.6                    | 92.4                  | 171         | 85              | 31                        | 31.6                        |
| P13     | 3                             | Quadrilateral               | 59                             | 4.6                    | 68.4                  | 162         | 78              | 17                        | 26.1                        |
| P14     | 5                             | Semi ischial-containment    | 59                             | 4                      | 67.9                  | 168         | 83              | 24                        | 24.1                        |

Table 1. Amputees’ general information.

Figure 1. Numerical simulation sequence: (a) Socket donning: displacement of the socket to its final position and solution of initial overclosure; (b) Stabilization: created to mitigate the effects of the socket donning and to allow the soft tissues to acquire their final position; (c) Static load condition: simulation of the standing position; and (d) Dynamic load condition: simulation of the complete gait cycle. Where BC stands for the representation of the hip joint action restricting all degrees of freedom relative to displacement; RP is the zone where all the loads are applied, coinciding with the coupling of the prosthetic device and the socket; and each arrow represents the anatomical direction of the Forces (F) and Moments (M) simulating the corresponding load condition.
ratio to 0.3 and density to 800 kg/m$^3$\textsuperscript{27,28,37}. The software's defined default values for linear and quadratic bulk viscosity parameters were used (0.06 and 1.2, respectively).

Due to the large strains to which the soft tissues were subjected, a hyperelastic model was selected for its simulation. The behaviour was defined using the following generalized Neo-Hookean strain energy potential equation:

$$W = C_{10} \left( I_1 - 3 \right) + \frac{1}{D_1} (J - 1)^2$$

(1)

where the invariants of the principal stretch ratios were $I_1 = \lambda_1^2 + \lambda_2^{-2} + \lambda_3^{-2}$. The relative volume change was $J$, and $C_{10}$ and $D_1$ were the constitutive parameters. For this study, $C_{10} = 11.6$ kPa and $D_1 = 11.9$ MPa$^{-1}$ were identified from an inverse method developed by Affagard et al. when assessing a displacement field measurement\textsuperscript{36}. Finally, the soft tissues density was set to 1000 kg/m$^3$.

**Boundary conditions.** For all the phases, the interaction between the bone and the bulk representation of the residual soft tissues were modelled using a tie condition that simulates perfect bonding between these two elements. The interaction between the socket and the residual limb was modelled using a surface to surface contact condition in ABAQUS V6.12-3 (Dassault Systèmes SolidWorks Corp., Waltham, USA), which prevents the residual limb nodes (\emph{i.e.}, slave nodes) from penetrating the socket (\emph{i.e.}, master surface) during their relative displacement. The hip joint state was recreated with a restriction on all degrees of freedom relative to the displacements of the femoral head, specifically over the zone where the acetabulum encloses the femur. Additionally, the pressure and shear stresses at the residual-limb/socket interface were calculated.

A dynamic model was developed. Due to the complexity of its geometry, tetrahedral elements were used for all parts. The approximated global sizes of the elements (intern-nodal spacing) were determined after a mesh sensitivity analysis and defined as 5 mm for the residual limb and 3 mm for the bone and the socket. The number of elements varied between approximately 300,000 and 480,000, depending on the size of the residual limb.

Depending on the patient, the routine lasted between 9 to 18 hours using a Xeon E5-1650 v2 Processor with 64GB RAM on a 64-Bit Windows 10.

**Socket donning.** Considering that during donning there is hair but no sweat at the residual-limb/socket interface, a 0.37 coefficient of friction was assigned to the interaction between the two surfaces\textsuperscript{37}. In the simulation, a displacement vector was applied on the distal end of the socket. The value of each vector was equivalent to the displacement needed to situate the residual limb on its actual final position inside the socket from a non-contact position. This usually implied a displacement vector with components in the three axes. Vectors were different for each subject and calculated according to the CT information and the marks on the socket and the residual-limb positive cast. The donning procedure was stopped at the matching of the marks. The condition of displacement was applied to the socket in a quasi-static step requiring the lowest possible velocity to minimize dynamic effects but reasonable time for calculation. As a consequence, although amputees needed only a short time to set their residual limb inside the socket according to the actual donning procedure, the duration of the model for this study was set to 15 s and, depending on the condition of socket displacement for each amputee, the velocities varied from 6 to 9 mm/s.

**Stabilization.** In this intermediate step, no additional stimulus was applied. The dynamic effects of the socket donning were mitigated, and the soft tissues reached their final position. A stabilization time of 5 s was set to let the soft tissues adjust to the socket’s interior and reach a position of greater equilibrium.

**Standing position.** The stress states obtained from the previous step were maintained the same while applying a force representing the standing load’s condition. The load was vertically applied to the socket with an equivalent magnitude of half the weight of the amputee. Regarding the coefficient of friction, a change in the dryness of the interface (since sweat was expected to be present) resulted in a new value, 0.23 at the residual-limb/socket interface\textsuperscript{37}.

**Gait cycle.** A previous study\textsuperscript{38} was carried out to predict the loads generated at the base of the socket during gait in transfemoral amputees. The data was generated by recording the subject’s whole gait cycle in a motion capture laboratory, using a force plate on a flat surface at natural stride speed. The forces and moments at the joint between the socket and the femoral extension were calculated based on a Multibody System Inverse Dynamics (MSID) approach. This study provided the forces and moment curves at the socket distal end of a reference amputee without major difficulties to walk using an aluminium articulated foot and a pneumatic knee.

Since carrying out the gait analysis for all of the subjects was not possible due to the availability of resources and the time and willingness of the subjects, the 14 amputee’s gait curves were approximated. The gait force and moment curves of the reference amputee were scaled for each of the 13 remaining subjects taking into account the ground reaction forces and its increment are proportional to the Body Mass Index (BMI) during the gait cycle, and that the joint kinematics remain similar\textsuperscript{39}. Due to the specific condition of the amputees’ anatomy, the BMI\textsubscript{F} (instead of the BMI) of each subject was used as the scale parameter for each curve since it accounts for the missing limb length (the BMI\textsubscript{F} calculation procedure and the value for each subject are provided in the Methods section). Although the curve magnitudes were scaled, the shape of the curves was the same for all amputees. Further, it was assumed that the BMI\textsubscript{F} takes into account the residual limb length effect at the moments applied at the distal end of the socket, since it is included in the calculation and the lengths do not vary greatly among the subjects (level of amputation of 34% ± 15% and BMI\textsubscript{F} = 28.3 ± 3.7).
The values of forces and moments obtained for each patient were applied at the base of the socket as dynamic loads simulating the complete gait cycle during a time-lapse of 5.26 s (which was the actual duration of the movement gesture). Figure 2 shows an example of the gait forces for the reference patient. Each line represents the magnitude of the force in an anatomical direction (anterior-posterior, medial-lateral and proximal-distal) for the femoral extension segment.

Figure 3 shows the example of the gait moments for the reference individual. Each line represents the magnitude of the moments that were applied and corresponds to the anatomical direction considered for the femoral extension segment: the rotations in the direction of intro-extra rotation, abduction-adduction and flexo-extension.

The explicit dynamic analysis procedure in ABAQUS was used for the gait cycle. Damping was calculated using the default bulk viscosity values, mass scaling was modified until the model converged, and incrementation time was set as automatic.

To analyse the stress distribution, seven zones were obtained with the support of the patients and an experienced prosthetist. The zones are presented in Fig. 4. These zones represent pressure-tolerant and pressure-sensitive areas after the amputation. It is known that a correct fitting, leading to a comfortable prosthesis, depends on the how weight bearing and pressure loads are distributed over pressure-tolerant zones. Peak values of stresses in the residual-limb/socket interaction, and the regions in which they were exhibited were compared for both dynamic and static loading cases.

Additionally, during the acquisition of data for the construction of the numerical models, a comfort test was carried out to learn whether patients felt comfortable with the use of their prostheses or whether they did not adapt to it completely, hindering their daily life. This test specifically evaluates the comfort sensation on transfemoral amputees, and consist of 30 questions (divided by topic: appearance, well-being, pain, function, psychological factor, and social factor) and, according to a final score, defines if the subject feels or not comfort while wearing...
the prosthesis. Their responses were analysed according to the location of maximum stresses in the numerical models and the identified zones (i.e., pressure tolerant and pressure sensitive regions as shown in Fig. 4). It was expected that amputees would feel comfortable wearing their prostheses if the maximum stresses were located in pressure tolerant regions.

Results
The analysis focused on the residual-limb/socket interaction. The reaction force magnitude at the acetabulum, at the end of the donning phase, was stated in Table 2. The contact pressure (CPRESS) reported in Table 2 represents the maximum pressure value found at the residual limb's surface in each phase. For the gait cycle, the maximum value was selected after analysing the results during the whole phase simulation. Regarding the identification of the peak pressure, extreme caution was taken to identify the maximum value within the region supporting highest pressure to prevent false data caused by a compromised element (e.g., an element located at the proximal border of the residual-limb reconstruction that does not resemble the actual condition since the residual limb is attached to the rest of the body. This situation increases the stresses values due to concentration factors. Or single elements reporting high stresses without surrounding elements having similar values suggesting meshing problems instead of a true stress distribution). Circumferential (CSHEAR1) and longitudinal peak shear (CSHEAR2) stresses at the time of maximum pressure value were established and are shown in Table 2 (in the table, NN refers to non-needed data because the stabilization phase was not required).

By adding the dynamic load to the model, an increase of up to 23% ± 19% was observed in the value of the maximum pressure that occurs at the interaction of the socket and the residual limb. Figure 5 shows the results for reference patient (P7) and how the zones and stress distribution changed during the gait cycle.

Although it was expected to find higher stresses at the proximal regions (i.e., the edge of the soft tissues reconstruction) as a result of the socket design, there were also stress concentrators due to the partial modelling of the residual limb. When a stress concentrator was causing the maximum stress value rather than what was physically expected due to socket design, the maximum limit value was reduced until reaching a reasonable stress distribution. The reset magnitude was the peak stress value reported in this study. For the patient shown in Fig. 5, there was no need to reset the maximum stress limit.

Table 3 shows the areas where each patient's model exhibited the greatest pressures (according to Fig. 4) for the standing loading condition and the time during the gait cycle where the peak pressure was identified (columns two and three respectively). The table also indicates what changed from one loading condition to the other based on visual inspection (e.g., if the area where the maximum values were located enlarges or contracts) in column four. Column five indicates the moment of the gait cycle at which peak pressure was identified.

The maximum values and their locations were compared to the outcomes of a comfort test carried out during the experiments. The responses in the test indicate whether the patient feels comfortable or not using the prosthesis. In the simulation, if the largest pressure is located in a sensitive area (defined in Fig. 4), it could be assumed that the patient did not feel comfortable. On the contrary, if the largest pressure was located in a tolerant zone (defined in Fig. 4), the patient might feel comfortable with the prosthesis. The comfort test results are presented in Table 3 (column nine). Columns seven and eight indicate whether the maximum stresses are located at a tolerant zone or not during the standing and gait cycle phases respectively.

It should be pointed out that there was variation not only among the geometry of the 14 residual limbs, but also in the distance between the greater trochanter and the proximal surface of the soft tissues used in the models. For some patients, the reconstruction of the soft tissues was performed up to the lesser trochanter of the femur. However, for others, the reconstruction was conducted only until the proximal third of the residual femur or even lower (see column six, Table 3). Furthermore, the length of the residual bone for each individual varied significantly.
Table 2. Reaction forces for the 14 patients present at the acetabulum in the end of the donning phase. Peak values of CPRESS, CSHEAR1 and CSHEAR2 stresses in the stabilization, standing and gait phase. Difference between the Stabilizing and the Gait Cycle (GC-S) values for CPRESS.

| Patient | Donning RF [N] | CPRESS [kPa] | CSHEAR1 [kPa] | CSHEAR2 [kPa] | Standing CPRESS [kPa] | CSHEAR1 [kPa] | CSHEAR2 [kPa] | Gait cycle CPRESS [kPa] | CSHEAR1 [kPa] | CSHEAR2 [kPa] | Difference GC-S [kPa] |
|---------|----------------|--------------|---------------|---------------|-----------------------|---------------|---------------|------------------------|---------------|---------------|-----------------------|
| P1      | 144            | 54           | -14           | -20           | 120                   | -14           | -23           | 130                    | 43            | 36            | 200                    |
| P2      | 365            | 140          | 28            | -48           | 150                   | 14            | 20            | 110                    | 25            | 38            | 110                    |
| P3      | 159            | 5            | 0             | -1            | 140                   | -18           | -46           | 180                    | 51            | 56            | 190                    |
| P4      | 237            | 110          | 24            | -35           | 405                   | -77           | -99           | 500                    | 180           | 86            | 560                    |
| P5      | 458            | 120          | 23            | 46            | NN                    | NN            | NN            | NN                     | 190           | 51            | 300                    |
| P6      | 308            | 120          | 23            | -24           | 110                   | 39            | 16            | 130                    | 48            | 20            | 150                    |
| P7      | 97             | 76           | 1             | 16            | 73                    | 25            | 19            | 73                     | -10           | -10          | 88                     |
| P8      | 76             | 110          | 11            | 41            | 150                   | 54            | -29           | 180                    | 62            | 480          | 190                    |
| P9      | 67             | 57           | -15           | -21           | 65                    | -19           | 16            | 100                    | 33            | 23            | 110                    |
| P10     | 10             | 51           | -12           | 25            | 27                    | -6            | -8            | 63                     | -9            | -7            | 96                     |
| P11     | 451            | 110          | 5             | -15           | 40                    | 210           | 410           | 290                    | 160           | 47            | 200                    |
| P12     | 185            | 99           | -15           | 36            | 110                   | 25            | -25           | 110                    | 25            | 24            | 130                    |
| P13     | 176            | 130          | 10            | -49           | 537                   | -131          | -58           | 350                    | 130           | 61            | 710                    |
| P14     | 165            | 205          | 82            | 52            | 56                    | 47            | 48            | 170                    | 58            | 48            | 200                    |

Table 2. Reaction forces for the 14 patients present at the acetabulum in the end of the donning phase. Peak values of CPRESS, CSHEAR1 and CSHEAR2 stresses in the stabilization, standing and gait phase. Difference between the Stabilizing and the Gait Cycle (GC-S) values for CPRESS.

Discussion

This study focused on the differences in residual-limb stress distribution, when different types of loads are applied (static vs dynamic) to a FEA of transfemoral amputees, especially on maximum pressure distribution. The study is based on the fact that excessive pressure causes multiple inconveniences that delay the rehabilitation of patients and prevent them from feeling comfortable with their prosthesis. Most common inconveniences include pain, local blood circulation disruption, erosion of the distal residual limb followed by ulceration, residual edema syndrome, intertrigo, chronic ulcers and skin breakdown. The study included 14 patients and included the evaluation of the effect of geometrical differences and amputation characteristics on the stress distribution by adding dynamic loads.

As reported in Dickinson et al., there are not many studies using dynamic models with transfemoral amputees so the comparison with other authors is not extensive. However, the peak pressure values obtained in this study (ranging from 88 to 710 kPa) correspond in order of magnitude with those reported in Zhang et al., who also added dynamics loads due to gait cycle (i.e., heel strike, midstance, terminal stance in their simulation). Their maximum pressure value was 119 kPa at the ischial bearing area. Also, Mu et al. developed a 3D FEA model whose results were compared to MFlex Sensor Distributing System measurements. The maximum stress in the FEA model — with a value of 258 kPa — was found at the distal end of the residual limb and it was compared to the maximum stress of 259 kPa measured by the sensor system. Nonetheless, it is important to note that peak pressures in these studies were located at the distal end of the residual limb instead of closer to the ischium, as expected in an ischial containment socket and found in this study. Additionally, when looking at the reaction force magnitudes at the acetabulum, at the end of the donning phase, values are in agreement with the order of magnitude of the loads applied at the socket base and the ones reported by other authors, which supports the accuracy of the simulations.

Although the lack of the pelvis bone does not accurately reflect what is happening at the ischial containment socket by supporting the loads at this region, when comparing the model proposed by van Heesewijk et al. with this model, this dynamic model can compensate to some extent by an adequate reconstruction of the residual limb (i.e., no supine position of the subject which implies compressed soft tissues close to the pelvis) and the socket (i.e., rectified geometry, not sharing the internal geometry with the external geometry of the soft tissues). The correct positioning of the parts using the trochanter bone as a reference led to a model closer to the real condition from the start (i.e., donning phase). This can be observed in the cation of the peak stresses close to the ischium and not the distal end of the residual limb. Nonetheless, future work including the pelvis is proposed, i.e., in the pathologic gait. Its variability, since the curves are affected by the individual particularities (i.e., pathologic gait). It will introduce misleading results by increasing its variability, since the curves are affected by the individual particularities (i.e., pathologic gait).

Except for patient P2, all amputees showed greater magnitudes of the maximum value when modelling the loads corresponding to the gait cycle versus the standing phase values. All of them had an increase or redistribution of the areas affected by the maximum pressure values. Besides, excluding patient P3, the maximum pressure values occurred during the stance phase of the gait cycle. This is consistent with the large flexion moment created.
during the initial contact, due to the location of the ground reaction force anterior to the hip joint. However, no explanation was found for the behaviour of $P_3$ stress distribution based on the variables included in the study.

The maximum values encountered during the whole gait cycle were compared against the standing phase for each type of stress. At the moment of maximum pressure, both circumferential and longitudinal peak shear stresses did not match the peak pressure behaviour, which was always greater during the gait cycle (as can be seen in the reported data, the shear stresses were greater during the standing phase). Additionally, when analysing the shear stresses present during the gait cycle, the maximum circumferential shear stresses were lower for 10 subjects, while seven subjects also presented lower longitudinal shear stresses at this phase. This behaviour could be explained by the gait cycle relieving the shear strains due to the application of forces and moments in all three axes, liberating the pre-stressed condition created during the donning phase. Physically, this can be interpreted as pistoning happening between the socket and the residual limb. Consistently, during the standing phase, this condition is intensified due to the load applied.

All amputees that presented a change of more than 20% between the standing and walking phase had a BMI$_x$ that exceeded 25 (i.e., they were overweight or obese). However, five amputees showed a differen between 5%
### Table 3. Zones distribution, changes and period of maximum pressure at the standing and gait cycle phases, comfort perception and models’ interpretation.

| Patient | Standing | Gait cycle | Variations between standing and gait cycle | Gait cycle phase | Soft tissues height | Are the maximum stresses located at a tolerant zone? | Does the amputee feel comfortable wearing his/her prosthesis? |
|---------|----------|------------|---------------------------------------------|------------------|--------------------|-----------------------------------------------|-----------------------------------------------|
| P1      | 1 (proximal), 5 and 6 (posterior) | 1 (proximal), 5 and 6 (posterior) | The area enlarges and the stresses distribution remain similar | Midstance | Near the minor trochanter | YES | YES | YES |
| P2      | 1 (proximal), 2 and 6 (lateral) | 1 (proximal), 2 and 6 (lateral) | The area enlarges | Initial contact | Near the minor trochanter | NO | NO | NO |
| P3      | 1 (above the bone) and 6 (posterior) | 1 (above the bone) and 6 (posterior) | Both area and stresses distribution remain similar | Terminal swing | Near the minor trochanter | YES | YES | YES |
| P4      | 1 (above the bone) and 6 (lateral) | 1 (above the bone) and 6 (lateral) | The area enlarges | Initial contact | Second femoral third | YES | YES | NO |
| P5      | 1 (above the bone) and 6 (lateral) | 1 (above the bone) and 6 (lateral) | The area enlarges and the stresses distribution remain similar | Midstance | Second femoral third | YES | YES | YES |
| P6      | 1, 2 and 6 lateral | 1, 2 and 6 lateral | The area enlarges | Terminal stance | Near the minor trochanter | NO | NO | NO |
| P7      | 1 (above the bone) and 6 (posterior) | 1 (above the bone) and 6 (posterior) | The area enlarges | Initial contact | Second femoral third | YES | YES | YES |
| P8      | 1 (above the bone) and 6 (posterior) | 1 (above the bone) and 6 (posterior) | The area enlarges | Initial contact | Near the minor trochanter | YES | YES | YES |
| P9      | 1 (proximal), 2 and 6 (posterior) | 2 and 6 posterior | The area enlarges, especially over zone 2 | Midstance | First femoral third | NO | NO | NO |
| P10     | 1 proximal | 1 proximal | Both area and stresses distribution remain similar | Pre-swing | Second femoral third | YES | YES | YES |
| P11     | 1 (above the bone) and 6 (posterior) | 1 (above the bone) and 6 (posterior) | The area enlarges | Initial contact | Near the minor trochanter | YES | YES | YES |
| P12     | 6 (posterior) | 1 and 6 (posterior) | The area enlarges | Initial contact | Second femoral third | YES | YES | YES |
| P13     | 1 (above the bone) and 6 (posterior) | 1 (above the bone) and 6 (posterior) | Both area and stresses distribution remain similar | Loading response | Near the minor trochanter | YES | YES | YES |
| P14     | 1 (proximal), 2 and 6 (lateral) | 2, 6 (lateral) and 7 | The area enlarges | Initial contact | Near the minor trochanter | NO | NO | NO |

and 20%, in the maximum pressure value while having a \( BMI_f \) higher than 25. Conversely, amputees with a \( BMI_f \) lower than 25 did not have a difference of more than 20% in stresses values. Hence, it can be presumed that \( BMI_f \) is one of the variables influencing the maximum stresses magnitudes. Further research, including other variables, is required to explore when the force and moment curves used during the gait cycle are not dependant.

For the comparison with the comfort perceived by the patients, except for patient P4, the hypothesis was fulfilled. When the highest pressure was located at the sensitive areas, it would indicate that the patient does not feel comfortable. If it is located in the tolerant zone, the patient might feel comfortable with the prosthesis. Apart from these regions, the pressure comfort threshold for each patient should also be taken into account during the comfort analysis. This threshold may indicate how much pressure the person can stand and may be independent of the region of application. This could explain the disparities in patient P4.

It should be noted that for regions 3, 4, 5 and 7 described in Table 3, it was not possible to conduct a complete analysis. For region 3, due to the bonded interaction used between the bone and the residual limb, it was not possible to obtain the value of the pressure on the distal end of the bone. However, this interface is recognized as one of the places where great stresses are present, coinciding with other authors. For region 4, the scar was not reconstructed, so it was not considered. Only regions 5 and 7 were taken into consideration for patients whose residual limb was modelled close to or above the lesser trochanter.

For the atypical results that either did not coincide with the hypothesis or were not in line with what was observed in most amputees, no explanation could be found beyond the marked geometrical differences, or based on the variables involved in this study. By including dynamic loads in the FEA for transfemoral amputees, specifically the complete gait cycle, it was possible to provide a complete view of how stresses and the areas affected at each moment change, giving practical values that will support better decisions in patients’ rehabilitation. Especially, FEA could provide quantitative tools to consider factors such as comfort, which are subjective and difficult to measure. For example, the development of a valid and reliable model that can relate comfort perception to the stresses generated at the residual limb by the strains created through socket design. The model could lead to the quantitative definition of the amount of rectification that amputees can bear according to their comfort threshold.

Likewise, it has been shown that specific solutions are required for numerical models to benefit the quality of life of patients. Computational tools can cover those particularities. For example, in the case of transfemoral
amputees, whether it is conservative or not to consider only static loads, the areas in which the greatest stresses are located, and the deviations due to compensation that are present in the different phases of their gait cycle.

Finally, the study concludes that the magnitudes of the maximum values of stresses generally increase in dynamic models. Usually, these values appear during the stance phase and the locations remain the same when changing from static to dynamic conditions. However, the peak pressure region can increase in size only or can increase in both magnitude and size. Hence, the residual-limb initial stresses state that is established at the time of designing and manufacturing the socket is crucial, since the location of the maximum stresses induced by the external loads do not change significantly. Although these locations may give evidence about the comfort perceived by the patient, direct measurements should be taken to establish a real comfort pressure threshold.

Data availability
Data is available from the corresponding author on reasonable request.

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Author contributions
Sofía C. Henao and Camila Orozco contributed in developing the dynamic models, analyzing the data, and writing the main manuscript text. Furthermore, Sofía C. Henao was in charge of the conception and design of the work, while Camila Orozco made contributions in the acquisition of the data, besides preparing the figures. Finally, Juan Ramírez, PhD, developed the models until the standing phase (static models), participated in the conception of the work, and reviewed the final version of the document. Lastly, all authors approved the submitted version and agreed both to be personally accountable for their own contribution and to ensure that questions related to the accuracy or integrity of any part of the work are appropriately investigated, resolved, and the resolution documented in literature.

Competing interests
The authors declare no competing interests.

Additional information
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