Numerical Study of a Customized Transtibial Prosthesis Based on an Analytical Design under a Flex-Foot® Variflex® Architecture

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Featured Application: A potential application of this work is an ergonomic method for designing personalized hiking and jogging prostheses for use in rehabilitation after amputation.

Abstract: This work addresses the design, analysis, and validation of a transtibial custom prosthesis. The methodology consists of the usage of videometry to analyze angular relationships between joints, moments, and reaction forces in the human gait cycle. The customized geometric model of the proposed prosthesis was defined by considering healthy feet for the initial design. The prosthesis model was developed by considering the Flex-Foot® Variflex® architecture on a design basis. By means of the analytical method, the size and material of the final model were calculated. The behavior of the prosthesis was evaluated analytically by a curved elements analysis and the Castigliano theorem, and numerically by the Finite Element Method (FEM). The outcome shows the differences between the analytical and numerical methods for the final prosthesis design, with an error rate no greater than 6.5%.

Keywords: biomechanics; prosthesis design; gait cycle; videometry; Castigliano theorem; numerical simulation

1. Introduction

The main cause of lower limb amputations is car accidents, followed by diabetes and related vascular diseases. According to the National Health and Nutrition Examination Survey (NHANES) 2012, about 6.4 million people have diabetes in Mexico [1]. Mexico currently ranks eighth worldwide in terms of the prevalence of diabetes [2], and Projections of International Reports estimate that, by 2025, Mexico will rank sixth or seventh, with 11.9 million Mexicans with diabetes. Prostheses, together with the amputee, present a complex biomechanical system whose behavior is influenced by various design factors. To determine the operating conditions to which the prosthesis will be subjected, it is necessary to analyze the gait cycle [3]. The operating conditions are the reaction times and forces, as well as the angles between each joint during the running cycle. In terms of biomechanical design, the main factors to consider are the mechanical properties [4], the length of the prosthesis [5,6], and the weight of the prosthetic components [7]. Most studies in the literature have focused on assessments...
of the kinematic and kinetic gait [8] and foot plantar pressure [9]. The kinematic method [10,11] describes body movements and the relative movements of body parts during different gait phases; for instance, the study of the angular relationships between lower limb segments during the gait cycle is a kinematic method.

In recent decades, numerical methods have gained popularity, especially when it is necessary to obtain detailed and complex information about the behavior of the prosthesis or the interaction between an amputee and the prosthesis [12–14]. Through the Finite Element Method (FEM), the stress and strain distribution in a prosthesis can be determined, which is non-viable using experimental or analytical methods. Despite the many articles dealing with modeling by FEM and the interaction of limbs, only a few have explored the behavior of the components of lower limb prostheses [15–17]. FEM modeling of a SACH®-type foot was performed to treat the effect of the viscoelastic heel performance [18]. Additionally, [19] presents a complete analysis of a prosthetic foot, validating it through FEM and an experimental analysis to improve footwear testing.

Nevertheless, to the best of the knowledge of the authors at the time of the writing of this paper, there are no published works describing the behavior of the entire prosthesis. Some approaches can be found in studies examining the mono limb® prosthesis model [20]. In cases where a prosthetic foot is included, the ground reaction force (GRF) is considered as a load for FEM analyses. However, GRF has usually been directly applied to model nodes of the prosthetic foot or surfaces, despite geometric nonlinearity in the prosthesis design [18–20]. This assumption has been reported as the most likely source of error, so the incorporation of elements of a contact and friction floor-standing model in future works could sensibly reduce such error [18].

This work has three main goals: to define the operating conditions of lower limbs during a human gait cycle at a medium–high speed; to design a transtibial prosthesis for medium–high impact activities, through an analytical method, supported by a well-defined methodology; and, finally, to validate the obtained results through analytical methods and numerical simulations.

2. Materials and Methods

This work heavily relies on the guidelines of the general method for solving biomechanical problems, proposed by Özkaya and Nordin [21]. It proposes the construction of a transtibial prosthesis with a Flex-Foot® prosthesis architecture using the methodology shown in Figure 1. These prostheses are designed for persons engaged in medium–high impact activities, because they allow vertical shock absorption, reducing the trauma in the residual limb, joints, and lower back during daily activities. In addition, they provide energy storage and return. The weight exerted on the heel becomes energy that drives the step, imitating the driving force of a normal foot, offering a greater flexibility and a design that is easy to cover and adapt aesthetically.

![Figure 1. Flowchart of the methodology used for prosthesis development and analysis.](image-url)
2.1. Biomechanical and Anatomical Considerations

The most important parameters employed to determine the gait cycle behavior in a patient are the age, weight, and height. Table 1 shows the physiological characteristics of the patient and test subject, which shall allow the videometric analyses.

Table 1. Anatomical data of the patient and test subject.

| Patient | Subject of Study |
|---------|------------------|
| Age 23 years | Age 24 years |
| Weight 70.5 kg | Weight 73 kg |
| Total height 173 m | Total height 174 m |
| Hip to knee length 44.8 cm | Hip to knee length 45 cm |
| Knee to ankle length 37.4 cm | Knee to ankle length 37.5 cm |
| Ankle to heel length 8.5 cm | Ankle to heel length 8.5 cm |
| Hip to heel length 90.7 cm | Hip to heel length 91 cm |
| Type of amputation Transtibial Burgess |

2.2. Conditions of the Lower Limbs during the Gait Cycle

The method used for the gait test was videometry analysis. One of the most important parameters to be taken into consideration for the study of the human gait cycle is the speed. As the design of the custom prosthesis ought to be geared towards daily activities, gait speeds ought to be chosen within the parameters in the ranges of medium and fast motion. A half speed of 2.4 m/s was chosen. For the videometry analysis, a single camera in a transversal position in relation to the test subject was used. Circular indicators for the video capture system were employed, in order to recognize specific points in the gait cycle to determine angles formed with the hip, knee, and ankle. The employed camera has a video capture resolution of 50 fps (frames per second), and it always remained at the same distance from the subject. In Figure 2, a complete cycle of motion is observed, relative to the sagittal plane. This work only takes into consideration two joints as points of study for gait analysis.

![Full gait cycle for the test subject.](image)

2.2.1. Kinematics

The information obtained from videometry analysis was processed using Tracker® software, which allows the coordinates of reference points, as well as the elapsed time from a sequence of frames obtained from a video, to be acquired.

To obtain relationships between reference points (joints), it is necessary to calibrate the distances between such points. In Figure 3, calibration in Tracker® was performed for the test subject from the anatomical data.
To determine the angular relationships between joints, we used the geometric triangular relationships formed in the leg joints, in order to be able to apply the law of cosines to obtain the subtended angles for each phase of the gait cycle (Figure 4).

\[ D = \sqrt{(X2 - X1)^2 + (Y2 - Y1)^2} \]  

An example of this calculation is shown in the following section: in order to obtain the distance between the hip joint and knee joint, \( X1 \) and \( Y1 \) values are considered as fixed joints and \( X2 \) and \( Y2 \) represent the values of movable joints.

2.2.2. Kinetics

Moments and reaction forces are important parameters for the march, as these indicate the loads to be applied in prosthesis modeling. In order to obtain the resulting moments of mass centers, Dempster diagrams were employed [22]. In Figure 5, the percentage ratios of the mass centers are shown.

In Figure 5, \( W_a = 61,247 \) kg is the total weight of the body to the hip, \( W_b = 7,227 \) kg is the thigh’s weight, \( W_c = 68,474 \) kg is the total weight of the body to the knee, and \( W_d = 3,431 \) kg is the weight of the leg.
2.3. Approximation of the Geometric Model of the Prosthesis

The Flex-Foot® system with a Variflex® architecture is the basis for the customized design model of the transtibial prosthesis. Such a prosthesis consists of four essential components: a foot module, heel module, male pyramid adapter, and clamping elements. The architecture of the Flex-Foot® Variflex® system mainly consists of two fundamental elements: foot and heel modules. To define the prosthesis architecture and dimensions, a healthy foot was taken as a starting point. In Figure 6, the first approximation of the geometric model of the prosthesis is shown, from which two main modules were taken: Module Foot (MF) and Module Heel (MH).

2.4. Analogy between the Human Body Parts and Mechanical Elements

The first geometric model approach (Figure 7) allowed us to define the longitudinal dimensions, so it was then necessary to define the proper thickness for each section of the prosthesis. The initial model consisted of curved sections with different dimensions, which could be related to the concept of curved beams, simplifying the analysis. In the first stage, the theory of Timoshenko and Goodier was used to obtain stresses; then, the energy method through the Castigliano theorem allowed us to obtain the strains [23]. The proper thickness of each section of the prosthesis model was determined through four study cases. The initial conditions are represented in red and the boundary conditions are represented in gray. The stress on curved beams was determined by an analysis of each case of study. The ideal thickness of each prosthesis module was obtained through Equation (2), which allowed us to determine the circumferential stress distributions:

\[
\sigma = \frac{N}{A} + \frac{M_x (A - rA_m)}{Ar(RA_m - A)}
\]

where \(\sigma\) is the circumferential stress, \(A\) is the cross-sectional area, \(r\) is the beam radius, \(N\) represents the axial forces, \(M_x\) represents the bending moments, and \(L_{\text{max}}\) is the length of the lever arm. The expressions for \(A\), \(R\), and \(A\) are
\[ A = \left( \frac{b_1 + b_2}{c - a} \right); R = \left( \frac{a(2b_1 + b_2) + c(b_1 + 2b_2)}{3(b_1 + b_2)} \right) = \left( \frac{b_1c + b_2a}{c - a} \right) \ln \left( \frac{c - b_1 + b_2}{a} \right) \] (3)

It should be noted that the international system of units was adopted to carry out all calculations. The units used in all of our calculations and simulations were Newtons (N), Pascals (Pa), meters (m), and kilograms (kg).

Figure 7. Study cases of prosthesis modules for the analytical method.

Taking study case 1 for MF, different thicknesses were analyzed, producing their stresses in different fibers. The maximum stresses in the cross section of the curved zone on MF (Figure 8) were determined by Equation (5), which permitted us to determine the circumferential stress distribution on curved beams. In Figure 8, an example of the application of Equation (5) for study case 1, by the analytical method, can be observed.

Case 1: Summation of forces and moments on the foot module.

\[ \sum Fr = V + F \sin \theta = 0 \]
\[ \sum F\theta = N + F \cos \theta = 0 \]
\[ \sum M_0 = PR(1 - \cos \theta) - M = 0 \]
\[ V = -F \sin \theta \]
\[ N = -F \cos \theta M = F \times r \times L_{max1}(1 - \cos \theta) \] (4)

The maximum stress in sections of the curved beam with respect to its angle can be calculated as follows:
\[
\sigma = \frac{-F \cos \theta}{\left(\frac{b_1 + b_2}{c-a}\right)} + \frac{-F \cdot r \cdot L_{max} \cdot 1}{\left(\frac{b_1 + b_2}{c-a}\right)} \left(\frac{b \cdot c + b \cdot d}{c-a}\right) \ln\left(\frac{\frac{b}{a} - b_1 + b_2}{\frac{b}{a} - b_1 + b_2}\right)
\]

where \(\Sigma Fr\) is the sum of radial forces, \(\Sigma F\theta\) is the sum of circumferential forces, \(\sigma\) is the circumferential stress, \(\Sigma M_0\) is the sum of moments, \(N\) is the axial force, \(V\) is the shear force, and \(M_x\) represents the bending moments.

Material Selection

With the acquaintance of the main stress, \(\sigma_1\), Equation (2) is easy to determine by the von Mises criterion. For the MH in the case of study 1, the maximum tension stress was 936.355 Mpa, while the maximum compression stress was \(-898.998\) MPa. Therefore, the von Mises stress result was 1.589 GPa. Using a safety factor of two, the elastic limit was calculated with the stress of 3.2 GPa. A carbon fiber was selected because its elastic limit was within the calculated values, which allowed a greater deformation of the prosthetic element. In addition, a High Resistance (HR) carbon fiber allows for greater energy storage.

2.5. Analytical Behavior of the Prosthesis

To illustrate the analytical applied method, we will present its application to study case 1 (sum of forces and moments shown in Figure 9). As the Castigliano theorem determines the total deformation of an element from the strain energy in each element independently, it is necessary to determine the independent sections. In Figure 9, the division of independent elements for MF is shown, for study case 1.

![Figure 9. Forces and moments sum. Free body diagram of curved sections of MH under analysis.](image)

It is necessary to analyze the energy generated in MF to determine the energy to be taken by the articulated area. Therefore, a strain energy analysis from the Castigliano theorem and free body diagram for MF was performed.

2.5.1. Case 1: Summation of Forces on the Foot Module

It is necessary to analyze the energy generated in the foot module to determine the energy to be taken into an articulated area. This is achieved through the analysis of strain energy from the Castigliano theorem and free body diagram foot module.
Case 1: Summation of forces on the foot module.

\[ V = 0; N = F; M = Fz; \frac{\partial N}{\partial F} = 1; \frac{\partial M}{\partial F} = z \]

Case 1: Curved foot section of the module.

\[
\begin{align*}
\sum F_r &= V + F \sin \theta = 0 \\
\sum F\theta &= N + F \cos \theta = 0 \\
\bigcirc + \sum M0 &= PR (1 - \cos \theta) - M = 0
\end{align*}
\]  

Calculation of the strain energy generated in the curved zone, through the deformation of equations defined by the strain energy, produces the Castigliano theorem:

\[
U = \int \frac{N^2}{2EA} \, dx + \int \frac{M_x^2}{2EI} \, dx + \int \frac{KV^2R}{2AG} \, d\theta + \int \frac{N^2R}{2AE} \, d\theta + \int \frac{AmM_x^2}{2A(AR_m - A)E} \, d\theta
\]

Straight foot section  
Curved foot section  

Using the first Castigliano theorem (Equation (7)):

\[
\delta U = \int \frac{N^2}{2EA} \frac{\partial N}{\partial F} \, dx + \int \frac{M_x^2}{2EI} \frac{\partial M_x}{\partial F} \, dx + \int \frac{KV^2R}{2AG} \frac{\partial V}{\partial F} \, d\theta + \int \frac{N^2R}{2AE} \frac{\partial N}{\partial F} \, d\theta + \int \frac{AmM_x^2}{2A(AR_m - A)E} \frac{\partial M_x}{\partial F} \, d\theta,
\]

where \( U \) is the deformation energy, \( F \) is the reaction force obtained from the analysis by videometry, \( A \) is the cross-sectional area, \( Am \) is the distance from the center of the circumference of the curved beams, \( r \) is the beam radius, \( N \) is the axial stress, \( V \) is the shear stress, \( M_x \) represents the bending moments, \( k \) is the correction coefficient, \( E \) is the young modulus, and \( g \) is the shear modulus.

2.5.2. Case 4: Articulated Section

The calculation of the articulated section is important because part of the energy generated in the module foot (MF) is accumulated and released in this area, and it is thus necessary to determine the right dimensions. In Figure 10 the articulated area is shown.

**Figure 10.** Case 4: Parameters of the articulated section.

Case 4: Summation of forces and moments on the foot module curve Section 1

\[
\begin{align*}
\sum F_r1 &= V1 + F \sin \theta = 0 \\
\sum F\theta1 &= N1 + F \cos \theta = 0 \\
\bigcirc + \sum M01 &= Fa1(Lmax2 + a1 (1 - \cos \theta)) - M1 = 0
\end{align*}
\]

Case 4: Summation of forces and moments on the foot module curve Section 2

\[
\begin{align*}
\sum F_r2 &= V2 + F \sin \theta = 0 \\
\sum F\theta2 &= N2 + F \cos \theta = 0 \\
\bigcirc + \sum M02 &= Fa2(Lmax3 + a2 (1 - \cos \theta)) - M2 = 0
\end{align*}
\]
where $\Sigma Fr_1$ and $\Sigma Fr_2$ are the sum of radial forces, $\Sigma F\theta_1$ and $\Sigma F\theta_2$ are the sum of circumferential forces, $\Sigma M_01$ and $\Sigma M_02$ are the sum of moments, $N_1$ and $N_2$ are the axial force, $V_1$ and $V_2$ are the shear force, and $M_x$ represents the bending moments. To calculate the strain energy generated in the curved zone, we used the strain energy equations, defined by the Castigliano theorem. Substituting the values of the straight section in the curved Sections 1 and 2 produces the total strain energy:

\[
U = \int \frac{N_1}{2A_1} \, dz + \int \frac{M_1^2}{2EI_1} \, dz + \int \frac{KV_1^2 a_1}{2A_1 G} \, d\theta_1 + \int \frac{N_1^2 a_1}{2A_1 E} \, d\theta_1 + \int \frac{A_{01} M_1^2}{2A_1 (a_1 - a_2) \epsilon} \, d\theta_1 + \int \frac{KV_2^2 a_2}{2A_2 G} \, d\theta_1 + \int \frac{N_2^2 a_2}{2A_2 E} \, d\theta_1 + \int \frac{A_{02} M_2^2}{2A_2 (a_2 - a_3) \epsilon} \, d\theta_1
\]

The maximum average energy generated in MF was then used to determine the variables of the articulated section. For this, the Castigliano theorem considers the energy $U$ generated by an item as the ratio in the stress–strain curve of material under linear loads.

2.6. Numerical Prosthesis Assessment

The final geometry of the transtibial prosthesis model based on the Flex-Foot® Variflex® architecture was drawn in AutoCAD® and exported to the ANSYS® program generator (Figure 11).

![Figure 11. Final geometric pattern exported in ANSYS®.](image-url)

To compare the analytical and numerical results, a prosthesis ought to be divided into two main modules, analogous to the division made for the analytical method. Then, three critical cases of study can be determined: MF, MH, and the complete prosthesis model. Figure 12 shows, in red, such critical cases.

![Figure 12. Study cases of prosthesis modules for numerical simulation.](image-url)
The properties of the HR carbon fiber employed for the numerical analyses were as follows:

Modulus of elasticity: \( E = 3.9 \times 10^5 \text{ N/mm}^2 \); yield stress: \( y = 3.5 \times 10^3 \text{ N/mm}^2 \); and Poisson’s ratio: \( \nu = 0.3 \). After exporting the prosthesis geometrical model into ANSYS®️, it was meshed as follows: The SOLID186 element was used because it has intermediate nodes, which yielded an increased numerical accuracy. Numerical loads applied to the MF model were taken from the kinetic analysis.

Case 3: Final Prosthesis Model

In order to assess the final prosthesis model, it ought to be divided into two subcases, because each sub-model (MF and MH) is exposed to two different forces, depending on the gait phase. Figure 13 shows each subcase to be analyzed:

- Case 3.1: Analysis in the gait subphase when the heel contacts the ground.
- Case 3.2: Analysis in the gait subphase when the heel does not contact the ground.

3. Results

3.1. Lower Limb Operating Conditions during a Gait Cycle at a Medium Speed

The angular relationships, angular velocities, resulting moments, and reaction forces of joints presented in the following figures are plotted vs. the cycle of human motion to determine the positions in the gait cycle where greater angular relationships, angular speeds, resulting moments, and reaction forces are achieved. Such values are considered for the analytical design of prostheses. Figure 14 shows the angular relationships in knee and ankle joints from triangular geometric relationships (law of cosines).

![Figure 13. Case 3: Critical support phases for ANSYS® prosthesis analysis.](image1)

![Figure 14. Analysis of knee flexion in the gait cycle using the Tracker® software. (A) Flexion angles of the knee joint. (B) Flexion angles of the ankle joint.](image2)
Figure 15 shows the vertical displacements obtained from coordinates and distances between joints; a maximum vertical displacement of 7.755 cm (hip), 7.476 cm (knee), and 12.009 cm (ankle) can be observed. Although the test subject mass center does not follow a straight line during the gait cycle, the mean point of this vertical displacement in the male adult is, on average, 8 cm, causing the center of gravity to have a very smooth movement without abrupt deflection changes, minimizing the spent energy.

Figure 15. Vertical displacements of foot joints during the gait cycle.

The parameters obtained from both knee and ankle flexion angles are shown in Figure 16. In this work, a knee joint flexion between 4.7° and 50.5° was determined, while, for the ankle joint, it lied between 10° and 19.7°. Furthermore, it ought to be remarked that the obtained graphical behavior of angles during the gait cycle is consistent with previous work [12–20]. The fact that the minimum flexion angle at the ankle joint is slightly above the average reported values might be because the employed camera has a lower resolution with respect to those used in other works. As for the moments of reaction and resulting forces, the literature reports that moments resulting from the knee have a maximum of 0.5–0.45 nm and a minimum of 0.01–0.05 nm [12–14], while, for the ankle, they have a maximum of 0.9–0.70 Nm and a minimum of 0.01–0.03 Nm [15–18]. In this work, the resulting moments for knee joint of 0.035 nm and 0.487 nm were obtained as minimum and maximum values, respectively, while for the ankle joint, values of 0.0164 nm and 0.703 nm were obtained analogously. These values are in good agreement with previously published results. With respect to the reaction forces, the knee joint was the only considered joint, because this work is focused on the design of a transtibial prosthesis. In Figure 8, the reaction forces, generated in the knee, can be particularly observed in the tibiofemoral joint. This is mainly because the prosthesis under design is focused on working during low-medium impact activities, such as climbing stairs, smooth jogging, or even a fall, which do not entail double support. Therefore, the values obtained due to reaction forces in this work and double values are published elsewhere. Figure 16 shows the resulting moments obtained from Equation (7), in knee and ankle joints, where the ankle angle is represented with a red line and the ankle reaction moment is represented with a blue line for Figure 16A,B, while Figure 17 shows the reaction forces in such joints.
3.2. Analytical Assessment of Prosthesis Behavior

In this section, stresses and associated deformations in different thicknesses of the cross section are analytically analyzed for the most critical points in the prosthesis. Stresses and deformations in flexion and compression were obtained for cross sections in cases 1, 2, and 3 (Table 2) by means of Equations (3)–(5). To assess the behavior of fibers in the cross section of the curved beam, the length of the thickness was divided. For stress analysis, the considered angles selected for each case of study are those in which the greatest stresses were achieved.
Table 2. Comparison of maximum stresses.

| Study Cases      | Maximum Stress Angle (Degrees) | Maximum Stress in Tension (N/m²) | Maximum Stress in Compression (N/m²) |
|------------------|-------------------------------|----------------------------------|-------------------------------------|
| Case 1: Foot Module | 54°                           | 357,984,296                     | −319,161,066                        |
| Case 2: Heel Module   | 27°                           | 675,166,712                     | −664,295,733                        |
| Case 3: Heel Module   | 31°                           | 936,355,844                     | −8989,98,77                         |

Once maximum deformations had been determined for each case, they were compared to determine the case that produced the maximum values, which turned out to be case 3 (see Table 3). Therefore, case 3 was the most critical point in the prosthesis. In this case, the HR carbon fiber had a maximum elongation of 2%.

Table 3. Maximum deformations.

| Prosthesis Section | Max. Deformation (Meters) |                  |                  |
|--------------------|---------------------------|-----------------|-----------------|
|                    | Cross Section Minimum     | Cross Section Maximum |                  |
| Case 1: Foot Module | 1.02 × 10⁻³               | 0.794 × 10⁻³     |                  |
| Case 2: Heel Module | 2.07 × 10⁻³               | 0.776 × 10⁻³     |                  |
| Case 3: Heel Module | 2.64 × 10⁻³               | 1.79 × 10⁻³      |                  |

In Figure 18, the deformation energy of the cross section of MF is shown for the case of study 3 (calculated from Equation (6)). Figure 18b shows the computed value of 3.925 cm for the base of the hinged section, for the final prosthesis model.

Figure 18. Case 3 results. (A) Deformation energy in the cross section of MF during the support phase of the walking cycle. (B) Final dimensions of the hinged section.

3.3. Numerical Assessment of Prosthesis Behavior

Numerical analysis of geometric models allows a realistic and efficient simulation of the working conditions, in order to assess the proposed Flex-Foot® prosthesis design. Figures 19 and 20 show the stresses and deformations obtained after analyzing the study cases 1 and 2 previously stated. Figure 19 shows case 1, where a maximum stress of 382.812 N/mm² and maximum deformation of 0.998 mm were obtained. Figure 20 shows case 2, where a maximum stress of 639.467 N/mm² and maximum deformation of 2.58192 mm were obtained. The loads applied to MF and MH were taken from the most critical reactions obtained from geometry analysis. For MF, the toe-off position was selected, while for MH, the heel strike condition was imposed (see Figure 13).
Figures 21 and 22 show the stresses and deformations obtained after analyzing study cases 3.1 and 3.2 with the initial and boundary conditions previously defined. Figure 21 shows case 3.1, where a maximum stress of 665.42 N/mm² and maximum deformation of 4.51728 mm were obtained. Figure 23 shows case 3.2, where a maximum stress of 675.236 N/mm² and maximum deformation of 7.27703 mm were obtained. The loads applied to MF and MH were taken from the most critical reactions obtained from videometry analysis. For case 3.1, the steps of heel strike were selected, while for case 3.2, the toe-off phase load was imposed (see Figure 13).
4. Discussion

The results obtained by the analytical method could be validated by comparing them with numerical results. Figure 23 compares the maximum stresses and deformations obtained in MF and MH. Tables 4 and 5 compare the most critical stresses and deformations obtained using both methods. Figure 24 compares the maximum numerical stresses and deformations obtained for the complete prosthesis model for cases 3.1 and 3.2, with respect to the maximum ones that can be borne by the selected material. It can be appreciated that the maximum stresses and deformations exhibited by the complete model do not exceed the material yield stress and its allowed deformations. Furthermore, the slippage suffered in the modules of the prosthesis due to the contact is very low, ensuring that the prosthesis does not undergo abrupt geometric changes, providing prosthesis integrity and patient safety.

Table 4. Comparison of numerically and analytically computed stress.

| Prosthesis Section | Stress in MPa | Analytical Method | Numerical Simulation | Error Rate  |
|--------------------|---------------|-------------------|----------------------|-------------|
| Foot module        | 357.984296    | 382.812           |                      | 6.4856%     |
| Heel module        | 675.166712    | 639.467           |                      | 5.2873%     |
Table 5. Comparison of analytically and numerically computed deformations.

| Prosthesis Section | Deformations in m | Analytical Method | Numerical Simulation | Error Rate |
|--------------------|-------------------|-------------------|----------------------|------------|
| Foot module        | 1.02 × 10^{-3}    | 9.9866 × 10^{-4}  | 2.0914%              |
| Heel module        | 2.64 × 10^{-3}    | 2.5819 × 10^{-3}  | 2.2%                 |

5. Conclusions

In this work, a methodology to design a personalized transtibial prosthesis using an analytical method was developed. Furthermore, the analytical results were validated by means of finite element analysis, obtaining errors no greater than 6.5%. The main difference between commercial and customized prostheses is the efficiency and comfort they provide to the patient. The methodology provided herein allows the geometric model of the prosthesis to be approximated, so as to be able to determine stresses and deformations associated with its operating conditions. Therefore, the selection of adequate construction materials is easier, achieving an operational design.

Furthermore, the usage of the videometry technique has been proven to be a successful method for studying the biomechanics of the human gait, simplifying the process due to the ease of implementation. Of interest is the analysis of the articulated area in the prosthesis design, which allows the impact produced in the foot during the contact phase of the walking cycle to be partially absorbed. The weight of the prosthesis is also considered in order to provide comfort and adaptation for the patient. In this sense, the designed prosthesis has a smaller weight than the patient’s healthy foot, which allows the weight in the socket to be adjusted, maintaining the stability of both lower limbs.

This paper presents limitations based on four important aspects. Firstly, in terms of methodological limitations, the sample size was only one test subject; however, the test subject had a 50th percentile anatomy. This allows us to estimate that 50% of the world’s population will be able to use this research to design a custom Flex-Foot® prosthesis. Secondly, the software used to capture the test subject’s gait could present errors due to shutter delay, so it is necessary to carry out many tests until the repeatability of the experiment is greater than 90%. Thirdly, the lack of previous research studies on this subject prevents a comparison of the results obtained. However, this research supports the use of an analytical method and numerical method for prosthesis design. Finally, one of the greatest limiting factors is the longitudinal effects that occur in the prosthesis when it is used by a patient with a lower limb amputation. The time available to investigate a problem and measure change or stability over time is, in most cases, very limited. This bias may reflect its dependence on research, since it is not possible to estimate data on the evolution of the anatomy of the subject using the implant. These limitations of our study may inspire other researchers to return to custom prosthesis design.
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References
1. International Diabetes Federation. Atlas de Diabetes, 5th ed.; International Diabetes Federation: Brussels, Belgium, 2012. Available online: https://www.idf.org/e-library/epidemiology-research/diabetes-atlas/20-atlas-5th-edition.html (accessed on 1 May 2020).
2. Hernández-Avila, M.; Gutiérrez, J.P.; Reynoso-Noverón, N. Diabetes Mellitus en México. El Estado de la Epidemia. Salud Pública de México 2013, 5, 129–136. Available online: http://www.scielo.org.mx/scielo.php?script=sci_arttext&pid=S0036-36342013000100009 (accessed on 1 May 2020). [CrossRef]
3. Su, P.-F.; Gard, S.A.; Lipshutz, R.D.; Kuiken, T.A. Gait characteristics of persons with bilateral transtibial amputations. J. Rehabil. Res. Dev. 2007, 44, 491–502. [CrossRef] [PubMed]
4. Wang, J.; Zielińska, T. Gait features analysis using artificial neural networks testing the footwear effect. Acta Bioeng. Biomech. 2017, 19. [CrossRef]
5. Bober, T.; Dziuba, A.; Kobel-Buys, K.; Kulig, K. Gait characteristics following Achilles tendon elongation: The foot rocker perspective. Acta Bioeng. Biomech. 2008, 10, 37. Available online: http://www.actabioeng.pwr.roc.pl/Vol10No1/Art_05.pdf (accessed on 1 May 2020).
6. Fridman, A.; Ona, I.; Isakov, E. The influence of prosthetic foot alignment on transtibial amputee gait. Prosthet. Orthot. Int. 2003, 27, 17–22. [CrossRef] [PubMed]
7. Lemaire, E.D.; Samadi, R.; Goudreau, L.; Kofman, J. Mechanical and biomechanical analysis of a linear piston design for angular-velocity-based orthotic control. J. Rehabil. Res. Dev. 2013, 50, 43–52. [CrossRef] [PubMed]
8. Umsberger, B.R.; Martin, P.E. Mechanical power and efficiency of level walking with different stride rates. J. Exp. Biol. 2007, 210, 3255–3265. [CrossRef] [PubMed]
9. Dorn, T.W.; Schache, A.G.; Pandy, M.G. Muscular strategy shift in the human running: Dependence of running speed on hip and ankle muscle performance. J. Exp. Biol. 2012, 215, 1944–1956. [CrossRef] [PubMed]
10. Noce-Kirkwood, R.; de Alencar-Gomes, H.; Ferreira-Sampaio, R.; Culham, E.; Costigan, P. Biomechanical analysis of hip and knee joints during gait in elderly subjects. Acta Ortop. Bras. 2007, 15, 267–271. [CrossRef]
11. Wolf, E.J.; Everding, V.Q.; Linberg, A.L.; Schnall, B.L.; Czernecki, J.M.; Gambel, J.M. Assessment of transfemoral amputees using C-Leg and Power Knee for ascending and descending inclines and steps. J. Rehabil. Res. Dev. 2012, 49, 831–842. [CrossRef] [PubMed]
12. McGibbon, C.A. A biomechanical model for encoding joint dynamics: Applications to transfemoral prosthesis control. J. Appl. Physiol. 2012, 112, 1600–1611. [CrossRef] [PubMed]
13. Zhang, M.; Mak, A.F.T.; Roberts, V.C. Finite element modelling of a residual lower limb in a prosthetic socket: A survey of the development in the first decade. Med. Eng. Phys. 1998, 20, 360–373. [CrossRef]
14. Silverthorn, 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. Available online: https://www.ncbi.nlm.nih.gov/pubmed/8823671 (accessed on 1 May 2020).
15. Zhang, M.; Lord, M.; Turner-Smith, A.R.; Roberts, V.C. Development of a nonlinear finite element modeling of the below-knee prosthetic socket interface. Med. Eng. Phys. 1995, 17, 559–566. [CrossRef]
16. Zachariah, S.G.; Sanders, J.E. Finite element estimates of interface stress in the transtibial prosthesis using gap elements are different from those using automated contact. J. Biomech. 2000, 33, 895–899. [CrossRef]
17. Lee, W.C.C.; Zhang, M.; Jia, X.; Cheung, J.T. Finite element modeling of the contact interface between transtibial residual limb and prosthetic socket. Med. Eng. Phys. 2004, 26, 655–662. [CrossRef] [PubMed]
18. Jia, X.; Zhang, M.; Lee, W.C.C. Load transfer mechanics between transtibial prosthetic socket and residual limb—Dynamic effects. *J. Biomech.* 2004, 37, 1371–1377. [CrossRef] [PubMed]

19. Saunders, M.M.; Schwentker, E.P.; Kay, D.B.; Bennett, G.; Jacobs, C.R.; Verstraete, M.C.; Njus, G.O. Finite element analysis as a tool for parametric prosthetic foot design and evaluation. Technique development in the solid ankle cushioned heel (SACH) foot. *Comput. Method Biomech. Biomed. Eng.* 2003, 6, 75–87. [CrossRef] [PubMed]

20. Mara, G.E.; Harland, A.R.; Mitchell, S.R. Virtual modelling of a prosthetic foot to improve footwear testing. Institution of Mechanical Engineers. *Part L J. Mater. Des. Appl.* 2006, 22, 207–213. [CrossRef]

21. Özkaya, N.; Nordin, M.; Goldsheyder, D.; Leger, D. *Fundamentals of Biomechanics: Equilibrium, Motion, and Deformation*, 3rd ed.; Springer-Verlag: New York, NY, USA, 2012. [CrossRef]

22. Voegeli, A.V. *Lecciones Básicas de Biomecánica del Aparato Locomotor*, 1st ed.; Springer-Verlag Iberica: Barcelona Spain, 2004; pp. 35–47, 67–74.

23. Boresi, P.A.; Schmidt, R.J. Advanced Mechanics of Materials, 6th ed.; John Wiley & Sons, New York, USA 2003. Available online: https://www.brijbedu.org/Brij%20Data/Advance%20Mechanics%20of%20Solids/Book/Advanced%20Mechanics%20of%20Solids%20By%20Arthur%20P%20Boresi%20%26%20Rudolph%20Schmidt%20%206%20Ed.pdf (accessed on 1 May 2020).

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