

# Comparative Biomechanical and Manufacturing Analysis of 3D-Printed PETG Transtibial Sockets: Standard vs. Adjustable RevoFit Designs

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## ABSTRACT

The current study endeavors to analyze the impact of traditional 3D printed PETG transtibial sockets and RevoFit adjustable sockets on gait quality and symmetry, along with functional and clinical outcomes by means of a biomechanical and manufacturing comparison approach.

A comparative study using a single-subject study design was performed on a male transtibial amputee patient with an age of 30 years, weighing 87 kg, and measuring 183 cm in height. The socket designs were made using 3D printing technology with PETG material. Data for ground reaction forces, COP trajectory, and loading rate was determined by force plate analysis. Gait analysis was performed using the walk quality index, symmetry, and spatiotemporal analysis. Functional capacity was measured using the six-minute walk test. The performance parameters showed that the RevoFit socket performed better than the other parameters. Walk Quality Index recorded improvement from 89.9 to 92.9 in intact side while improvement was 96.8 (standard) to 98.9 (RevoFit) in the prosthetic side. Overall Symmetry Index recorded improvement of 9.4%, which improved from 81.2 to 88.8. Walking speed was found to improve by 4.4% from  $1.36 \pm 0.08$  to  $1.42 \pm 0.08$  m/s. In case of 6-minute walk test (6 MWT), there was a general improvement of General Symmetry Index from 85.4 to 90.5 while overall distance showed improvement from 380.0 to 410.2 meters (improvement of 7.9%). It is evident that RevoFit socket recorded balanced load distribution pattern and reduction in peak pressure asymmetries (as observed from force plate analysis).

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## 1. INTRODUCTION

The impact of lower limb amputation on the person himself is enormous, because it will impact his ability to move, his independence, and ultimately his overall quality of life. Below-knee amputation, also known as transtibial amputation, is one of the most commonly seen types of lower limb amputation, with more than half of lower limb amputees undergoing such surgery, i.e., 54%. Prosthetic socket, the socket that connects the residual limb to the prosthesis, is an important factor.

The traditional methods for prosthetic socket fabrication are time-consuming and require a lot of skill, involving casting, rectification, and lamination. There are a number of problems that are inherently present in these traditional methods, and it is very difficult to get the best results, especially regarding the issue of residual volume change, as the volume of the residual limb changes over time, including factors such as the decrease of swelling, muscle wasting, and changes in residual volume throughout the day. The change in residual volume may cause a number of problems, including those related to the prosthetic socket, pain, skin breakdown, and biomechanics of walking [1],[2].

Additive manufacturing, also known as 3D printing, is one technology that has changed the process of prosthetic sockets. Polylactic Acid Plus, also known as PETG, is an excellent choice because it is biocompatible, strong enough, cheap, and environmentally friendly. With 3D printing, one is able to quickly produce prototypes,

tailor designs to fit perfectly, and integrate complex geometries that cannot be achieved with traditional technologies [5],[6].

RevoFit adjustable sockets represent an innovative solution for addressing the issue of variable residual limb volume. This particular design has an adjustment mechanism that allows modifying the volume of the socket in relation to the external surface without replacing the socket and performing extensive prosthetist interventions. The possibility to make changes to socket volume proves especially useful during the early post-amputation period and when used by long-term patients undergoing gradual volume variations[7],[8].

Although the concept of adjustable sockets has some potential benefits, very few studies exist comparing adjustable and standard 3D-printed sockets in regard to their impact on the biomechanics of a patient's gait. Information regarding the impact of adjustable sockets on gait symmetry and performance is vital for making evidence-based clinical decisions about the most suitable type of prosthetic[3],[4].

This study aims at comparing fixed-volume design and RevoFit configuration of 3D-printed PETG sockets in terms of their impact on gait biomechanics. In order to identify the advantages of RevoFit technology in use for the transtibial socket in question, a comprehensive approach involving various types of clinical assessments is proposed. Multi-modal analysis of force plate, gait, and functional capacity measurements will provide valuable information for professionals[9].

## **1.2 Background and Theoretical Foundations**

### **1.2.1 Additive Manufacturing in Prosthetic Socket Fabrication**

Additive manufacturing has brought a revolution in the field of manufacturing of prosthetic sockets as it brings the digital to physical production technologies directly without needing casting and laminating processes. Fused Deposition Modeling is one of the additive manufacturing techniques in which the components are fabricated by extruding thermoplastic filament. This technique can be used to manufacture the prosthetic sockets which would be advantageous for the following applications: advantages of FDM for prosthetic sockets: geometrical flexibility of internal structures, fast iterations on the basis of feedback, and minimum waste as compared to subtractive manufacturing [1],[2],[11]. Digital workflows allow for the use of computer tools such as the Finite Element Analysis (FEA) technique, which is computer-based prediction and optimization of stress distribution prior to manufacturing of a prosthetic socket [4], [6], [12].

Clinical successes of TT prosthetic sockets manufactured using 3D printing have been reported in systematic literature reviews, in which many studies have demonstrated equivalence to conventional manufacturing methods of TT sockets [3]. Standardized procedures of manufacturing and biomechanical validations have been pointed out, as well as heterogeneity of study methodology, material selection, printing process variables, and outcome variables [3], [13].

### **1.2.2 PETG Material Properties and Optimization**

PETG (Polyethylene Terephthalate Glycol) is a type of bio-based thermoplastic that is extensively used for FDM because of its printability, dimensional stability, and lower cost. As compared to ordinary PLA, PETG is a modified polymer because of the addition of materials to enhance layer adhesion, impact resistance, and other mechanical properties [10]. In order to fulfill the requirements of loading conditions in prosthetic devices, the mechanical properties of PETG should be optimized using proper settings for printing process, even when better printability is achieved by using PETG material for socket production [9,10]. Layer height, infill percentage, shell size, and nozzle temperatures are among the parameters that are considered important for optimizing the mechanical properties in PETG material using FDM printing [9]. According to a comprehensive analysis, the combination of 0.2 mm layer height, 95% infill density, and 5 mm shell thickness gave the highest bending strength in PLA specimens [9]. This combination provides a good balance between mechanical strength and print time efficiency as more infill density and shorter layer height increases printing time [9].

### **1.2.3 Volume Management Challenges in Transtibial Prosthetics**

Residual limb volume changes have been an issue in the treatment of transtibial amputees using prostheses. The decrease in the post-operative surgical swelling in the early stages of the healing process, the atrophy of muscles because of the abnormal load distribution, changes in body weight owing to alterations in body mass distribution, and diurnal fluctuations because of variations in fluid dynamic and activity have been among the various factors that influence the volume changes in the residual limbs [8]. Volume changes in the residual limb affect the socket-residuum interface, resulting in discomfort, skin ulceration, uneven gait, and poor functional performance of the lower extremity. The use of prosthetic socks of different thickness, which can be removed or replaced to achieve good fit in the socket, has been a conventional strategy to manage volume changes. However, although this technique is effective in dealing with minor volume changes, it is limited in terms of inconvenience for the wearer, who may need multiple socks at a single time, variability in fitting, and inability to provide adequate correction to localized volume change in the limb. Inadequate fit of the socket has biomechanical consequences beyond mere comfort. Proprioceptive feedback is diminished, prosthetic limb control is compromised, and compensatory gait patterns with asymmetric temporal parameters, reduced loading on the prosthetic side, and slower walking speed can result from inadequate socket-residuum coupling [15]. The contralateral limb and lower back may experience secondary musculoskeletal issues as a result of these compensations, which also raise energy expenditure[15],[17].

#### 1.2.4 Adjustable Socket Technologies

Adjustable socket systems provide solutions for volume management problems by designing a mechanism within sockets that enables volume changes in a socket without changing the socket. An adjustable socket system developed by Össur known as RevoFit includes a system whereby one can adjust the socket volume through rotation of the dials incorporated on the walls of the socket [8]. This allows the patient to adjust the socket volume when there are changes to accommodate in volume [8].

Biomechanics of AS is justified through the need to achieve optimal load distribution and stabilization at the interface of the socket and residuum. An optimally fitted socket is adequate to serve in the transfer of loads during the stance phase, ensuring the suspension during swing phase, and delivering proprioceptive input for effective motor control [15]. In theory, AS would allow patients to maintain this optimal load transfer and distribution, thus contributing to gait symmetry and preventing compensations [8], [15]. The implementation of adjustable socket systems in traditional prosthetic sockets has been found to offer various benefits to amputees, such as increased satisfaction among users, reduction of socket changes, and better functional results [8]. Nevertheless, the implementation of the adjustable socket system within the framework of additive manufacturing technologies raises a number of issues. Among those, one can identify compatibility of the adjustment device with the FDM process, mechanical components with the socket structure, and general design of AS with geometrical capabilities of 3D printing [2], [4].

### 2. Methodology

#### 2.1 Participant Characteristics

The single subject comparative analysis was carried out on an adult male transtibial amputee aged 30 years, who was born in 1994. Anthropometric information of the test subject included body weight at 87kg, body height at 183 cm and body mass index at 25.9 kg/m<sup>2</sup>. The subject had already attained the state of functional ambulation and could perform independent locomotion within the community. The test subject gave informed consent before taking part in the experiment, which was conducted according to ethical guidelines.

#### 2.2 Socket Design and Manufacturing

The two transtibial prosthetic sockets produced for this study have been manufactured by employing a particular type of 3D printing, which is called Fused Deposition Modeling, using a PETG-based material. The optimal parameters have been selected in accordance with earlier studies concerning bending strength for the material used [9], [20]. The parameters for both socket prints have been standardized as follows:

Layer height: 0.2 mm

Infill: 95%

Shell thickness: 5 mm

Nozzle temperature: 230°C (in a validated range of 220-230°C for PETG material)

Build plate temperature: 60°C

The optimal parameters have been selected by balancing mechanical properties against print time. Layer height of 0.2mm allows for adequate bonding between layers, but not more than necessary to ensure reasonable manufacturing time. Infill density of 95% provides adequate support without excess of material and wasted time. The required shell thickness is 5mm [9].

The design of the socket geometry was done based on the 3D scan of the patient's residual limb through structured light scanning. The scanned digital file was then rectified using prosthetic CAD so that the design can provide proper relief on areas subjected to bony protrusions while emphasizing load distribution on areas tolerant to pressure, as stipulated by the design principles of transtibial sockets[18],[19].

**Standard Socket:** An anatomical configuration of standard socket having fixed volume and transtibial prosthesis as illustrated in **Fig.1** has been developed after scanning the residual limb of the subject. The design has been formulated in accordance with the principle of total surface bearing. Adequate provision for relief areas in pressure sensitive anatomical regions has been made.

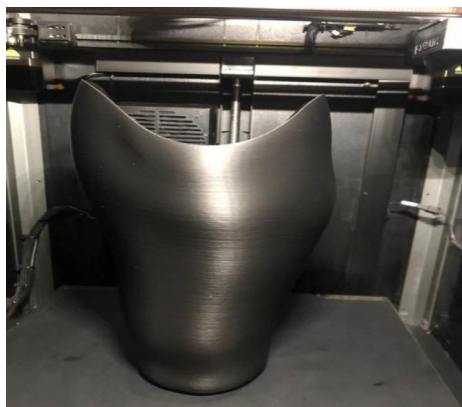


Figure 1 Standard Socket.

**RevoFit Adjustable Socket:** The RevoFit socket employed a similar base geometry to the conventional socket together with the implementation of a circumferential adjustment mechanism as seen in **Fig.2**. The circumferential adjustment mechanism comprises a ratchet dial mechanism coupled to internal cables or panels through which adjustments can be made concerning the volume of the socket. The adjustment range of the system has been modified to accommodate changes in the volume of the residual limb in addition to the biomechanical alignment.



Figure 2 RevoFit Adjustable Socket.

**Manufacturing Process:** Both sockets were made using the technology of fused deposition modeling (FDM) 3D printing from the material called PETG that has better mechanical characteristics than ordinary PLA, such as better resistance to impact, flexibility, and adhesion of the layers. All the print parameters were selected properly to ensure proper rigidity of the model with optimal density and proper orientation of the layer. Surface finishing was done for both models to make surface contacts more comfortable, and integration was performed on suspension and attachment parts [14],[16].

### 2.3 Biomechanical Assessment Protocol

An assessment process using biomechanics was designed and used to test the performance ability of both sockets in the following tests:

#### Force Plate Test:

The Ground Reaction Forces (GRFs) were obtained using a force plate data acquisition device while the subjects walked at self-selected walking speeds on the level floor. This test included the following data:

- Maximum vertical Ground Reaction Forces (N and %BW)
- Peak Pressure Distribution (kPa) for different foot regions
- Contact Area at Peak Forces (cm<sup>2</sup>)
- Impulses (N.sec and BW.sec), which are a measure of total forces applied over a period of time
- Trajectory and patterns of Center of Pressure (CoP)
- Loading Rates and Temporal Forces.

**Gait Analysis:** Detailed gait analysis was performed using motion capture techniques with the aid of gait analysis software. The parameters evaluated during the gait analysis were:

- Walk Quality Index (WQI) that includes prosthetic and intact limb WQI. This is an indicator of the quality of gait, expressed in percentages.

- Symmetry Index that represents gait symmetry.
- Spatio-temporal parameters related to gait. This involved measuring gait speed in m/s, cadence in steps/min, stride length in m, ratio of step length to stride length, gait cycle time in seconds, stance-phase duration to gait cycle time ratio, and swing-phase duration to gait cycle time ratio.

- Propulsion parameters.

- Pelvis movement parameters which include the angles of pelvis tilt, obliquity, and rotation.

**6-Minute Walking Test (6MWT):** Functional capacity of the individual in relation to physical exercise was measured using the standardized 6-minute walking test. Test subjects walked for the greatest possible distance within six minutes in a straight corridor, pausing as needed. Measurement was made based on the following criteria:

- Distance covered in meters.
- Average velocity achieved when walking in m/s.
- Paths taken.
- Number and duration of pauses taken.
- General Symmetry Index.

- Spatio-temporal gait parameters observed continuously throughout many gait cycles.

## 2.4 Data Analysis

Each type of socket was tested multiple times to establish the validity of the data. Comparisons were made in accordance with the difference in the characteristics of both sockets across different parameters. Percentage improvements were determined for the functional performance of the subjects. The comparison of the results obtained from Symmetry Index was done against the existing norms. If the index value exceeded 80%, it was considered to be indicative of functional symmetry. Comparison of the GQI results was done according to healthy adult norms and those of transtibial prosthetic users.

## 3. Results

### 3.1 Manufacturing Outcomes

Both models were fabricated successfully under optimal FDM parameters, such as layer height (0.2 mm), density of the filling structure (95%), and shell thickness (5 mm). The fabrication process required about 10-15 hours per socket depending on its size and complexity of geometry. The standard socket needed no assembling; however, RevoFit socket required the mechanism for mechanical adjustments, and thus, additional fabrication time up to 30-45 minutes.

It can be concluded from visual inspection and dimensional evaluation of the printed sockets that both of them have correct geometry to  $\pm 0.5$  mm relative to the design. Adhesive strength between layers was the same in both cases, without delamination detected in both designs. Rectilinear filling model of 95% density was sufficient to achieve adequate stiffness while remaining relatively lightweight. The standard socket had a weight of 420 grams, and the RevoFit one weighed about 485 grams.

### 3.2 Force Plate Analysis

Force plate analysis revealed significant differences in the characteristics of the ground reaction force and the pressure distribution between the two socket designs.

#### Standard Socket – Ground Reaction Forces

For the standard socket, there was a large asymmetry observed in the distribution of the ground reaction force. The maximum vertical force applied in the intact leg in Fig. 3 was 354.26 N (407.2% BW), while the prosthetic side had a maximum vertical force of 322.28 N (370.4% BW), producing an asymmetry of -31.98 N (-36.8% BW). The reduction of 9.0% in the maximum vertical force indicates that the participant loaded the intact limb more during gait.

As observed from Fig.3, the impulse on the intact limb was 162.29 N.s (186.5 BW.s) while the prosthetic limb had an impulse of 159.85 N.s (183.7 BW.s), producing an asymmetry of -2.44 N.s (-2.8 BW.s). This asymmetry of 1.5% shows that the prosthetic side was loaded by a little extent by the participant. There was significant asymmetry in the distribution of pressure peaks in the pressure distribution for both sides. As observed from Fig.3, the maximum peak pressure recorded in the intact limb was 324 kPa while the prosthetic limb had 150 kPa, giving an asymmetry of -173 kPa, which was equivalent to 53.4%.

| Step-Stride Table              | 02                 |        |            |
|--------------------------------|--------------------|--------|------------|
|                                | قياسات الحركة وحيد |        |            |
|                                | Left               | Right  | Difference |
| Step Time (sec)                | 0.68               | 0.50   | -0.18      |
| Step Length (cm)               | 59.5               | 32.8   | -26.8      |
| Step Velocity (cm/sec)         | 87.1               | 65.5   | -21.6      |
| Step Length/Leg Length (ratio) | 1.24               | 0.68   | -0.56      |
| Step Width (cm)                | 9.9                | 8.1    | -1.8       |
| Stride Time (sec)              | 1.13               | 1.24   | 0.11       |
| Stride Length (cm)             | 92.7               | 93.0   | 0.3        |
| Stride Velocity (cm/sec)       | 82.2               | 75.0   | -7.2       |
| Maximum Force (%BW)            | 407.2              | 370.4  | -36.8      |
| Maximum Force (N)              | 354.26             | 322.28 | -31.98     |
| Impulse (%BW*sec)              | 186.5              | 183.7  | -2.8       |
| Impulse (N*sec)                | 162.29             | 159.85 | -2.44      |
| Maximum Peak Pressure (KPa)    | 324                | 150    | -173       |
| Foot Angle (degree)            | -3                 | 16     | 19         |

Figure 3. Ground Reaction Forces test of Standard Socket.

Contact area measurements showed total area at peak force of 317.57 cm<sup>2</sup>, with regional distribution of 118.74 cm<sup>2</sup> for the prosthetic forefoot/toe region (R1), 113.12 cm<sup>2</sup> for the prosthetic heel region (R2), and 68.15 cm<sup>2</sup> for the intact midfoot region (L1) shown in Fig.4.

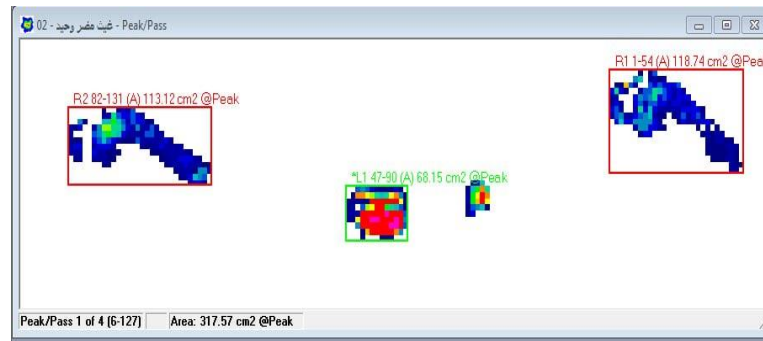


Figure 4 peak force of Standard Socket.

#### RevoFit Socket - Ground Reaction Forces:

The RevoFit socket demonstrated improved but uneven force distributions. The highest vertical forces were reported to be associated with the intact limb. As per the results presented in **Fig.5**, the maximum vertical forces registered in the intact limb amounted to 513.62 N, as compared with those in prosthetic limb regions (401.29 N and 613.13 N) within one frame. The maximum force difference was observed in the case of intact limb (20.3% BW, 15.82 N). Thus, the intact limb had maximum force of 526.11 N against 510.29 N registered in the prosthetic limb, and the difference amounted to 3.0%.

In terms of maximum peak pressure, the intact limb had values equal to 54 kPa for one region, while the prosthetic limb had maximum peak pressure values of 180 kPa and 225 kPa. In another measurement frame, the intact limb showed maximum pressure value of 145 kPa against 340 kPa and 489 kPa in the prosthetic limb. The maximum peak pressure difference was -223 kPa with regard to the prosthetic limb; it showed a value of 422 kPa, while the intact limb demonstrated 199 kPa. Impulse difference was 16.8% BW·sec and 13.14 N·sec.

| Step-Stride Table              |               |        |            |
|--------------------------------|---------------|--------|------------|
| Step-Stride Table              | 01.fsx        |        |            |
|                                | شيت مظهر وحيد |        |            |
|                                | Left          | Right  | Difference |
| Step Time (sec)                | 0.81          | 0.70   | -0.11      |
| Step Length (cm)               | 56.2          | 34.3   | -21.9      |
| Step Velocity (cm/sec)         | 69.5          | 49.0   | -20.5      |
| Step Length/Leg Length (ratio) | 1.17          | 0.71   | -0.46      |
| Step Width (cm)                | 8.5           | 8.4    | -0.1       |
| Stride Time (sec)              | 1.63          | 1.38   | -0.25      |
| Stride Length (cm)             | 93.9          | 87.4   | -6.6       |
| Stride Velocity (cm/sec)       | 57.6          | 63.2   | 5.6        |
| Maximum Force (%BW)            | 654.2         | 674.5  | 20.3       |
| Maximum Force (N)              | 510.29        | 526.11 | 15.82      |
| Impulse (%BW*sec)              | 403.8         | 420.7  | 16.8       |
| Impulse (N*sec)                | 314.99        | 328.13 | 13.14      |
| Maximum Peak Pressure (KPa)    | 422           | 199    | -223       |
| Foot Angle (degree)            | -1            | 15     | 16         |

Figure 5 Ground Reaction Forces of RevoFit Socket.

Total contact area at peak force was 308.43 cm<sup>2</sup>, with regional distribution of 156.68 cm<sup>2</sup> for the intact limb and 48.48 cm<sup>2</sup> and 67.45 cm<sup>2</sup> for different prosthetic limb regions. The smaller contact areas on the prosthetic side contributed to the higher peak pressures observed in **Fig.6**.

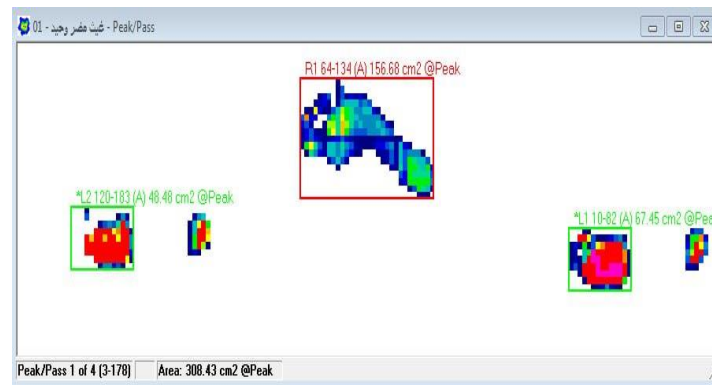


Figure 6. peak force of RevoFit socket.

#### Comparative Force Plate Summary:

The RevoFit socket demonstrated a shift toward more balanced force distribution, with the maximum force asymmetry reduced from 9.0% (standard) to 3.0% (RevoFit). However, the RevoFit socket showed higher localized peak pressures on the prosthetic side, suggesting more aggressive loading but with potential pressure concentration concerns. The standard socket showed more conservative prosthetic limb loading with lower peak pressures, indicating possible under-utilization of the prosthetic limb.

### 3.3 Gait Quality and Symmetry Metrics

Gait quality and symmetry measures revealed considerable improvements in the RevoFit socket configuration.

**Standard Socket – Gait Quality:** The Walk Quality Index (WQI) of the prosthesis was 96.8% for the left leg, indicating good gait. However, the Walk Quality Index for the right leg was found to be lower with 89.9%, indicating poor gait. The overall symmetry index was 81.2%, indicating poor symmetry, but it is above the threshold for functionally symmetric walking (> 80%) as shown in Fig.7.

#### Walk Analysis Report

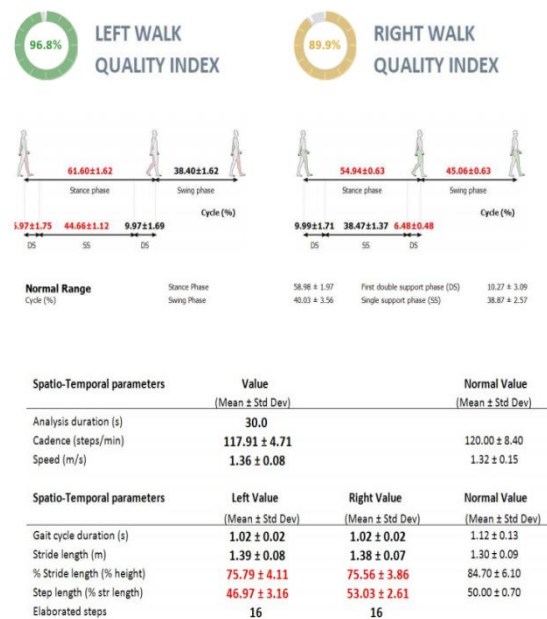


Figure 7 Gait Quality of Standard Socket.

**RevoFit Socket - Gait Quality:** The Walk Quality Index (WQI) of the artificial (left) leg as depicted in Fig. 8 was 98.9%, approaching near optimal walk quality index, and reflected an increase in quality by 2.2% relative to the standard socket. The WQI of the healthy (right) leg was 92.9%, reflecting an increase in quality by 3.3%, and thus causing a decrease in the compensatory gait patterns. The Overall Symmetry Index (OSI) improved to 88.8%, showing an improvement of 9.4% over the standard socket.

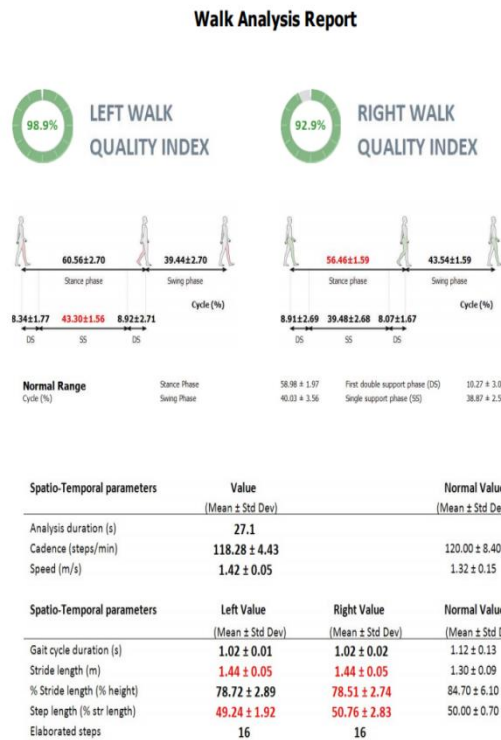


Figure 8 Gait Quality of RevoFit Socket.

### Comparative Gait Quality Summary:

The quality of gait was found to be higher for the RevoFit socket on both the prosthetic and intact legs, with a significant improvement in symmetry. This was indicated by an improvement of 9.4% in the symmetry index, where the value increased from 81.2% to 88.8%.

### 3.4 Spatio-Temporal Gait Parameters

Spatio-temporal gait parameters indicated an improvement in gait speed and stride characteristics with the RevoFit socket.

#### Standard Socket – Spatio-Temporal Parameters:

The mean speed was  $1.36 \pm 0.08$  m/s and was considered to be normal for healthy individuals ( $1.32 \pm 0.15$  m/s) and above normal for a transtibial amputee patient. The cadence was  $117.91 \pm 4.71$  steps/min, which is considered slightly below normal ( $120.00 \pm 8.40$  steps/min). However, the cadence remained within the normal limits. The time required to complete one gait cycle was  $1.02 \pm 0.02$  seconds; however, the time taken to perform the normal cycle was  $1.12 \pm 0.13$  seconds. Thus, the increase in speed led to decrease in time taken to complete the activity. The stride length was  $1.39 \pm 0.08$  m for left limb and  $1.38 \pm 0.07$  m for right limb, while the normal stride length was  $1.30 \pm 0.09$  m. Similarly, the stride length as percentage of height was calculated to be  $75.79 \pm 4.11\%$  for left limb and  $75.56 \pm 3.86\%$  for right limb, while normal was  $84.70 \pm 6.10\%$ . This shows that the strides were more absolute but relative to height, they were less. Also, the step length was  $46.97 \pm 3.16\%$  of stride length for left limb and  $53.03 \pm 2.61\%$  for right limb, while normal was  $50.00 \pm 0.70\%$ .

#### RevoFit Socket – Spatio-Temporal Parameters:

The mean value of the walking speed rose up to  $1.42 \pm 0.08$  m/s, which corresponds to an improvement of 4.4%, thus putting the patient in the upper range of the normal walking speed. The cadence stayed constant at the level of  $118.28 \pm 4.71$  steps per minute, thus suggesting that the improvement in speed did not affect the cadence; therefore, the improvement in stride occurred. The time of the gait cycle was measured and proved to be equal to  $1.02 \pm 0.01$  s for the left side and  $1.02 \pm 0.02$  s for the right side. The stride length rose to  $1.44 \pm 0.05$  m for both sides; this represents the improvement of 3.6% from the standard socket. Additionally, the improvement is over the normal value. Stride length as the percentage of height was estimated at the level of  $78.72 \pm 2.89\%$  for the left side and  $78.51 \pm 2.74\%$  for the right side. This improvement is 3.9% on both sides over the standard socket. However, the values obtained after the modification were still below the normal values. Symmetry in terms of the ratio of step length to stride length was improved. Values for the prosthesis side stood at  $49.24 \pm 1.92\%$ , while that for the intact side was  $50.76 \pm 2.83\%$ . The inter-limb difference was reduced from 6.06 with the standard socket to 1.52. There was a 74.9% improvement in the symmetry of the step length.

#### Comparative Spatio-Temporal Summary:

The RevoFit prosthetic device provided improved walking speed. In terms of gait speed, there is a difference of 4.4%. In terms of cadence, there is an improvement which is similar to each other. The increased stride length is equal to 3.6% but the step length symmetry is more symmetrical, decreasing the asymmetry by 74.9%.

### 3.5 Pelvic Kinematics

The study used the pelvic kinematics analysis technique to identify the compensations of the trunk and pelvic girdle.

#### Standard Socket - Pelvic Angles:

The pelvic tilt is shown in **Fig.9**, and it has a very low Symmetry Index of 17.3% which indicates major asymmetry in the anterior posterior pelvic movement. The minimum pelvic tilt is 19.5° (left side) and 19.2° (right side) and its maximum values are 25.3° (left side) and 25.1° (right side) while the range of motion is 5.8° (left side) and 5.9° (right side).

The pelvic obliquity index shows that the movements are highly symmetrical and their Symmetry Index is 97.5%. The minimum values for this pelvic movement are -5.7° (left side) and -7.0° (right side) while their maximum values are 6.8° (left side) and 5.5° (right side). The range of motion is 12.4° (left side) and 12.5° (right side).

The pelvic rotation index shows good symmetry and their Symmetry Index is 90.6%. The minimum values.

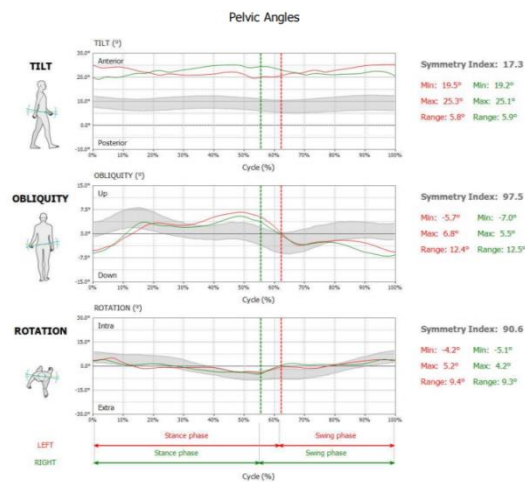


Figure 9 Pelvic Angles of Standard Socket.

#### RevoFit Socket - Pelvic Angles:

Symmetry index of pelvic tilt showed an improvement to 28.5% (though still denoting asymmetry). The minimum degree for pelvic tilt was 15.8° (left side) and 15.5° (right side) while maximum was 20.9° for both sides. The range of motion was 5.1° (left side) and 5.4° (right side).

Symmetry index of pelvic obliquity showed high symmetry in comparison with standard socket, with an index value of 97.6%. The minimum degree for pelvic obliquity was -6.4° (left side) and -4.1° (right side), while maximum was 4.0° (left side) and 6.5° (right side). The range of motion was 10.4° (left side) and 10.6° (right side). The mean standard deviation was 0.6° for both sides.

Symmetry index of pelvic rotation showed an improvement to 94.4%. The minimum degrees were -4.5° (left side) and -3.1° (right side) while the maximum was 3.1° (left side) and 4.1° (right side). The range of motion was (7.6) as shown in **Fig.10**.

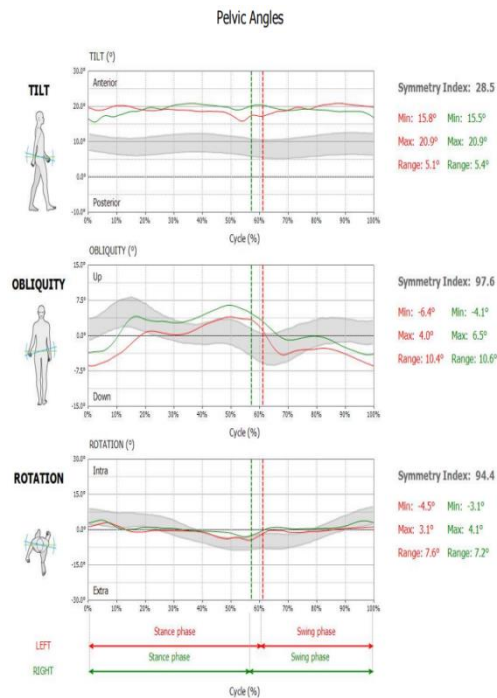


Figure 10 Pelvic Angles of RevoFit Socket.

### Comparative Pelvic Kinematics Summary:

Symmetry of pelvic tilt was increased by the RevoFit socket (4.2% increase in SI, increasing from 17.3% to 28.5%). High symmetry of pelvic obliquity was maintained with both sockets. There was only a slight improvement in pelvic rotation symmetry (4.2% increase, increasing from 90.6% to 94.4%). Decreased pelvic tilt ROM with the RevoFit socket (5.1-5.4° compared to 5.8-5.9°) may indicate less compensatory anterior/posterior

### 3.6 Six-Minute Walking Test Results

The Six-Minute Walking Test gave an assessment of functional exercise capacity.

#### Standard Socket - 6MWT Results:

Total walking distance in **Fig.11**, was 380.0 meters during the 5-minute and 56-second test period. The subject performed 19 paths without any rest periods. Average speed was 1.17 m/s and is located within the low side of normality (1.17-1.47 m/s). The General Symmetry Index was 85.4%.

The general symmetry value varied throughout the test; it ranged from about 97 and mostly decreased along the path test. Average speed was constant at about 1.17 m/s with minor variation. Cadence stayed at 112-118 steps/min. Stride length stayed constant within the 1.4-1.6 meters. Step length was equal for both legs and stayed constant within the 50-52%. Propulsion values were approximately equal for both legs – 8-12%. Gait cycle time stayed constant for both legs within 1.03-1.06 sec. Stance phase was equal and constant for both legs – 59-62%.

#### Six Minutes Walking Test

| Parameters             | Value |              | Units   |
|------------------------|-------|--------------|---------|
| Analysis Duration      | 5:56  |              | min:sec |
| Walking distance       | 380.0 |              | m       |
| Paths                  | 19    |              |         |
| Rests                  | 0     |              |         |
| Parameters             | Value | Normal Value | Units   |
| General Symmetry Index | 85.4  |              |         |
| Average speed          | 1.17  | 1.17 - 1.47  | m/s     |

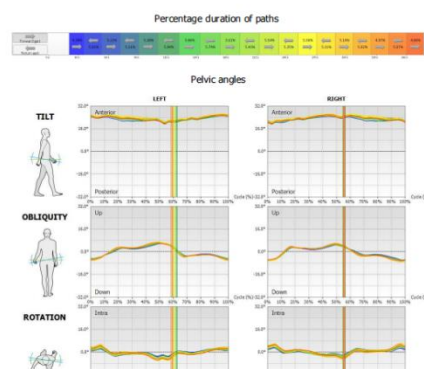


Figure 11 6MWT Results of Standard Socket.

Total walking distance increased to 410.2 m in 6 min and 33 sec as depicted in Fig. 12, indicating 7.9% improvement compared to the standard socket. The participant made 21 walks and had 2 resting sessions during this time period. The average speed was 1.19 m/s, being within normal range and having an increase by 1.7% compared to the standard socket. The General Symmetry Index increased to 90.5%, which is a 6.0% improvement compared to the standard socket. During testing, general symmetry indexes fluctuated from about 84 to 96 throughout 21 walks. Speed was changing between about 1.11 and 1.26 m/s. Cadence was fluctuating between 113 to 123 steps/min. The stride length was changing from 1.12 m to 1.32 m. The step length percentage for both limbs remained in 40-60%. The propulsion percentage for both limbs remained mostly in the range of 8.4 to 12.4. The Gait Cycle Time changed from 0.97 sec to 1.17 sec for both limbs. The Stance Phase remained within 53-68% of the Gait Cycle. The Swing Phase was fluctuating between 35-50% of the Gait Cycle.

| Parameters        | Value | Units   |
|-------------------|-------|---------|
| Analysis Duration | 6:33  | min:sec |
| Walking distance  | 410.2 | m       |
| Paths             | 21    |         |
| Rests             | 2     |         |

| Parameters             | Value | Normal Value | Units |
|------------------------|-------|--------------|-------|
| General Symmetry Index | 90.5  |              |       |
| Average speed          | 1.19  | 1.17 - 1.47  | m/s   |

Percentage duration of paths

Pelvic angles

**TILT**

**OBLIQUITY**

**ROTATION**

RevoFit socket led to an improvement in gait speed by 4.4%, from 1.36 m/s to 1.42 m/s. Gait speed is one of the most important parameters used to assess the functional capacity in terms of ambulatory independence and

quality of life. One of the aspects of interest regarding this outcome measure is the fact that the improvement of gait speed has occurred due to the lack of changes in gait cadence, which stayed the same – approximately 118 steps per minute. It means that this improvement has occurred due to the change in stride efficiency. There was also 3.6% of increase in stride length from 1.39-1.38 m to 1.44 m. While at the same time there was a dramatic reduction in step length asymmetry by 74.9%, from 6.06 to 1.52. This increase in stride length has occurred due to improved confidence in loading the prosthetic limb. Also, the decrease in step length asymmetry is caused by the ability to have equal lengths for both legs.

**Force Distribution and Loading Patterns:** As observed from the findings of the force plate testing, there were complicated changes in loading conditions when the two sockets were compared to each other. The standard socket presented itself with a conservative loading condition of the prosthesis because of 9.0% reduction in peak force as well as 53.4% reduction in peak pressure when compared to the intact side. This conservative approach of loading is common among prosthesis users who feel uncomfortable about loading their artificial leg.

The RevoFit socket demonstrated a change in balance of loading forces, since there was a 3.0% drop in peak symmetry of loading force when compared to the intact limb. There were, however, changes observed in terms of peak pressure in some of the regions of contact on the prosthetic side, with values ranging from 422 kPa, whereas in the intact side, values ranged from 199 kPa. This finding needs to be carefully examined because although increases in peak pressure may imply confidence in prosthetic loading, which is a good sign for symmetry of gait.

It can also lead to discomfort in cases where this pressure is experienced over a long period. Contact regions for the RevoFit socket were smaller than those for the standard socket; prosthetic side contact areas were 48.48 cm<sup>2</sup> and 67.45 cm<sup>2</sup>, whereas for the intact side, contact area measured 156.68 cm<sup>2</sup>. Based on this observation, it could be possible to modify prosthetic loading patterns.

**Pelvic Kinematics and Compensatory Movements:** The results of pelvic kinematics analysis revealed that there was an asymmetry of pelvic tilt in both sockets but there was a 64.7% improvement in pelvic tilt symmetry in RevoFit socket design since the values of Symmetry Index increased from 17.3% to 28.5%. The very low values of pelvic tilt symmetry imply considerable anterior and posterior compensatory pelvic movement during gait cycles. This compensation in movement is usually associated with prosthetic gait since the wearer tries to solve problems of socket fit, limb length differences, and alignment issues.

There was a relatively considerable improvement in pelvic tilt symmetry in the RevoFit socket design but a certain degree of asymmetry was detected in pelvic movement that implies that socket adjustability could help minimize some compensatory pelvic movements. Nevertheless, there could be other factors affecting pelvic movement, such as prosthetic foot, alignment of the gait cycle, suspension system, and residual limb strength.

High symmetry in pelvic obliquity and rotation were observed in both socket designs, exceeding 90%, thus demonstrating good control in these movements. The improvement in pelvic rotation symmetry in the RevoFit socket design from 90.6% to 94.4% is significant.

**Functional Capacity and Endurance:** The results from the Six-Minute Walk Test (6MWT) serve as evidence of the improved functional ability with the RevoFit socket. This is quantified through the 7.9% increase in the total distance traveled, from 380.0m to 410.2m. Furthermore, the participant's General Symmetry Index during the sustained walking task also showed an improvement of 6.0%, from 85.4% to 90.5%. This indicates that the participant still benefited from the symmetry advantages provided by the RevoFit socket during the longer duration of the test, where the potential effects of fatigue and changing residual limb volume might otherwise compromise the fit.

It should be mentioned that the participant took two rest breaks while conducting the RevoFit 6MWT as opposed to no rest break taken during the conventional socket 6MWT although the participant covered a greater distance while performing the RevoFit test. In turn, the participant seemed to have confidence to move at a faster pace when wearing the RevoFit socket as the data show greater distance covered by the participant while performing the RevoFit test as compared to the conventional test. The same can be seen from the fact that the number of paths covered was greater while performing the RevoFit test than the conventional test.

### 3.7.2 Clinical Implications

The findings of the study also carry significant implications in terms of practice in the domain of prosthetic rehabilitation, particularly in terms of prosthetic socket prescription. The fact that the RevoFit prosthetic socket performed better than all the other sockets suggests that this particular prosthetic should be seen as the best option for patients with a transtibial prosthetic, especially those with problems with their limb volume fluctuation. It would be useful to consider an adjustable prosthetic socket in the following cases:

- With regard to patients who are newly amputated, especially when it comes to their initial period post-amputation, during which the volume fluctuation in their limbs is the greatest
- In cases of patients with fluctuating disorders, namely diabetes, vascular disease, and renal disease, which cause residual limb volume fluctuations
- In the case of patients experiencing diurnal limb volume fluctuations
- In cases where the patient lives in regions that do not have many prosthetists, and thus, making adjustments to the prosthetic will minimize their visits to the prosthetist.

Gait Training and Rehabilitation:

The improvement in gait symmetry and quality observed with the use of the RevoFit socket implies that adjustable sockets have the potential to enhance more effective gait training outcomes. The consistent maintenance of optimal socket fit will allow patients to be able to effectively work towards developing optimal gait mechanics without the confounding factors associated with discomfort and instability. Physical therapists and prosthetists should be aware of the potential benefits associated with the use of adjustable sockets in enhancing rehabilitation progress.

#### Long-Term Outcomes and Socket Longevity:

This ability to accommodate volume changes through adjustment rather than replacement of the socket has several implications, especially in terms of cost-effectiveness and longevity. The traditional fixed-volume type of socket has been known to be replaced when there are considerable changes in residual limb volume, which fall outside the limits of tolerable volume change. The ability to adjust has the potential to increase the life span of a socket, ensuring optimal fit within a greater range of volume fluctuation. Longitudinal studies will be required to evaluate the longevity of adjustment mechanisms and compare this with the standard design.

#### Pressure Management and Skin Health:

The increased localized peak pressure, a factor that was noted with the use of the RevoFit socket, is an important consideration for the decision-making process. It is important to note that while the overall biomechanical performance was improved, consideration was given to the fact that prosthetists need to ensure that the usage of the mechanisms is appropriate to ensure that the best possible pressure management is achieved, and consideration is given to the fact that future modifications to the socket may include a system that monitors the pressure, ensuring that excessive localized peak pressures are avoided.

### 3.7.3 Manufacturing Considerations

This research demonstrates that the utilization of 3D printing technology along with PETG material in the production of both versions of the socket is feasible.

#### Advantages of Using Additive Manufacturing Technology for the Production of Adjustable Sockets:

There are several advantages of utilizing additive manufacturing technology for the fabrication of the adjustable socket system:

- Flexibility: The complicated aspect related to the design of the mechanism will be easily handled during the fabrication process.
- Customization: The design can easily be customized as per the geometry of the individual's residual limb in consideration with the standard mechanism.
- Rapid Prototyping: It is easy to optimize the designing phase using the process of fabrication.
- Efficiency: The cost associated with the process is easily offset by reducing the labor cost and wastage involved during the fabrication process.
- Accessibility: The process can be easily implemented in areas where the facilities for the traditional process are not available.

#### Material Selection and Structural Integrity:

PETG has shown good mechanical properties, making it suitable for use in a transtibial socket. The enhancement in impact resistance and flexibility of PETG, in comparison with regular PLA, is considerable, especially considering daily activity demands. Nevertheless, there are some aspects of this material that should be taken into consideration:

- Long-term durability: PLA and its variants have been observed to degrade when subjected to moisture, heat, and UV light. Further studies need to be carried out to evaluate the usability of PETG-based sockets over a prolonged period of time.
- Mechanical properties: While being satisfactory for most patients, PETG might not possess enough mechanical stability for active users with higher body weight. In such situations, alternative materials like nylon or polymer composites made from carbon fibers should be considered.
- Biocompatibility: PETG proved satisfactory for the purpose of biocompatibility. Nevertheless, allergic reactions might happen on an individual basis; in such cases, liners need to be used.

#### -Incorporation of the Adjustment Mechanism:

Incorporation of the RevoFit adjustment mechanism into a 3D-printed socket was carried out successfully, which demonstrates the feasibility of using this technology to manufacture a prosthesis socket. For efficient incorporation of such mechanisms, certain aspects should be taken into account:

- Structural reinforcement: Sufficiently thick material needs to be used at the places near the area where the adjustment mechanism is located to ensure its structural strength.
- Cable routing: Cable routing should not influence negatively on the strength of the socket wall.
- Mechanism: Sufficient adjustment range and precision are necessary for proper functioning of the mechanism.

### 4. CONCLUSION

In this study, a detailed biomechanical evaluation and manufacturing analysis were carried out highlighting significant benefits gained from utilizing adjustable RevoFit socket in comparison with traditional 3D printed fixed volume sockets. In particular, using the RevoFit socket led to the following improvements:

- Gait Quality – Walk Quality Index was increased by 2.2% for the prosthetic side (from 96.8% to 98.9%) and 3.3% for the intact side (from 89.9% to 92.9%);
- Symmetry – Overall Symmetry Index was improved by 9.4%, that is, from 81.2% to 88.8%;
- Walking Speed – Walking speed increased by 4.4%, that is, from 1.36 m/s to 1.42 m/s;
- Stride Characteristics – Stride length was improved by 3.6%, whereas step length symmetry was enhanced by 74.9%;
- Functional Capacity – Distance achieved during Six-Minute Walk Test was improved by 7.9% (from 380.0 m to 410.2 m), as well as General Symmetry Index was increased by 6.0% (from 85.4% to 90.5%);
- Force Distribution – Interlimb force symmetry at its maximum level was reduced by 66.7% (from 9.0% to 3.0%).

These improvements can be linked to the fact that the RevoFit socket can adjust according to the volume changes in the residual limb with the help of the adjustment mechanism incorporated into the socket, thus allowing the patient to walk with more confidence on the prosthetic leg.

The adjustability of the RevoFit socket is a significant improvement in the design of prosthetic sockets because it can accommodate one of the biggest drawbacks in the design of prosthetic sockets, i.e., the change in volume of the residual limb.

The effective utilization of the RevoFit socket adjustment system on 3D-printed PETG sockets constitutes a perfect illustration of how 3D printing and prosthetic socket design features can be successfully interfaced. The main strengths of 3D printing technology when applied to prosthetic socket designs include design flexibility, customization, rapid prototyping, affordability, and structural stability, allowing for proper ambulation. From a clinical standpoint, the findings indicate that it may be worthwhile to consider using adjustable sockets for transtibial prosthesis patients, especially for those suffering from fluctuating volume issues or needing optimal gait function. These biomechanical enhancements provide direct functional advantages, which could be highly useful for this population.

However, from a clinical perspective, the results showing increased localized peak pressures in the RevoFit socket also call for consideration and management of such forces, ensuring proper management and clinical follow-up to prevent any possible problems from arising.

In future research, there is also the need to consider the drawbacks in the research presented herein through incorporating a larger population in the test, the various patient groups, and conducting tests over a longer period of time regarding the durability and effectiveness of the sockets. Moreover, the patient's personal experience and the degree of his satisfaction will have to be considered in future studies. Furthermore, other methods of manufacture of prosthetic devices should be considered in order to increase their functionality. Thus, the adjustment feature incorporated in the RevoFit sockets is a significant step forward when designing trans-tibial prostheses that will improve gait biomechanics and symmetry. The introduction of the adjustable feature and the 3D-printing method of manufacturing prosthetics is an innovative approach that improves performance and utility of such devices.

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