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Article

Design and development of universal leg prostheses with size adjustment using polylactic acid (PLA)

Diseño y desarrollo de prótesis de pierna universal con ajuste en tamaños utilizando ácido poliláctico (PLA)

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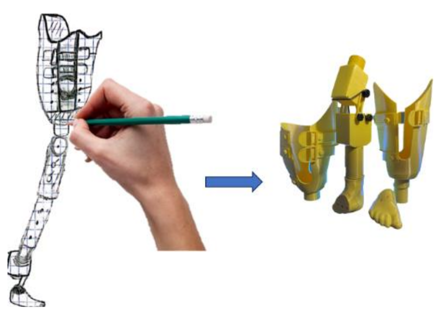
Abstract

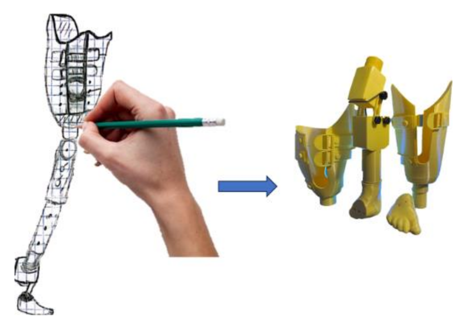
The history of leg prosthetics is a journey of continuous innovation and progress. In Mexico, according to INEGI (2015), there are 780,000 people with amputations; of the 75,000 amputees, only 10% have a prosthesis, and 7% do not know how to use it. The leading cause is Type 2 diabetes. Current prosthetics vary in cost and technology, ranging from hundreds to hundreds of thousands of dollars. Losing a limb affects mobility and psychological, social, and physical well-being. Unlike the rudimentary ones of the past, modern prosthetics are more advanced and functional. This study, with 50 participants, analyzes various anthropometric measurements to design an adjustable universal prosthesis, improving the quality of life for amputees through an interdisciplinary approach combining biomechanical analysis, material evaluation, and types of prosthetics. The results highlight the importance of considering gender for an optimal fit.



Analysis, Biomechanical, Functional, Participants

Resumen

La historia de las prótesis de pierna es un recorrido de innovación y progreso continuo. En México, según INEGI (2015), hay 780,000 personas con amputaciones; de 75,000 amputados, solo el 10% tiene una prótesis y el 7% no sabe usarla. La causa principal es la diabetes tipo 2. Las prótesis actuales varían en costo y tecnología, desde cientos hasta cientos de miles de dólares. La pérdida de una extremidad afecta la movilidad y el bienestar psicológico, social y físico. Las prótesis modernas, a diferencia de las rudimentarias del pasado, son más avanzadas y funcionales. Este estudio, con 50 participantes, analiza diversas medidas antropométricas para diseñar una prótesis universal ajustable, mejorando la calidad de vida de los amputados mediante un enfoque interdisciplinario que combina análisis biomecánico, evaluación de materiales y tipos de prótesis. Los resultados destacan la importancia de considerar el género para un ajuste óptimo.



Análisis, Biomecánico, Funcional, Participantes

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Introduction

Leg prosthetics have come a long way since the earliest recorded attempts to create a functional replacement for a missing limb (Grimmer & Seyfarth, 2014). The hi story of leg prosthetics is a story of innovation, creativity, and continuous progress (Raschke, 2022).

The evolution of this technology has been driven by the constant pursuit of improving the quality of life for amputees (Sinha et al., 2011). Technological advancements have converged centuries to address significant leg prosthetics challenges (Nizamis et al., 2021).

In Mexico, there are 780,000 people with amputations, according to INEGI in 2015, and out of 75,000 amputees, only 7,500 have a prosthesis (10%), of which 5,250 (7%) do not know how to use it. The leading cause of amputation is Type 2 Diabetes Mellitus. Today, a wide range of prosthetics is available on the market, with costs ranging from a few hundred dollars to several hundred thousand, depending on the type of prosthesis, the materials used, and the incorporated technology (Instituto Nacional de Desarrollo Social, 2017).

Losing a lower limb is a life-changing event that can have profound physical and emotional effects on a person (Rees et al., 2019). It can affect their mobility and psychological, social, and physical well-being. The loss of a limb can be caused by a variety of factors, including genetic conditions, congenital malformations, automobile, sports, or work accidents, and diseases such as diabetes, gangrene, or cancer, among others (Pasquina et al., 2014).

In the past, the only option for amputees was to use rudimentary prosthetics, which were often uncomfortable and cumbersome and did not provide adequate support or functionality (Murray, 2009). However, prosthetics have become more advanced, comfortable, and functional with advancements in science and technology. Modern prosthetics are designed to provide amputees with a better quality of life by enabling them to perform daily activities and participate in sports and other physical activities (Keszler et al., 2019).

The development of prosthetics technology has been driven by a desire to create more advanced, more sophisticated devices that mimic a natural limb's movements. The earliest prosthetics were made from wood, metal, and leather and were designed to provide essential support and stability (Finch, 2011).

Over time, prosthetics have become more advanced, incorporating carbon fiber, titanium, and silicone to provide a more natural feel and better functionality (Cruz et al., 2020).

Today, several types of prosthetics are available on the market, from the most basic to the most advanced (Barrios-Muriel et al., 2020). The type of prosthesis a person chooses depends on their individual needs, the level of amputation, and their budget. (Laferrier & Gailey, 2010).

The cost of a prosthetic can vary widely depending on the type of prosthesis, the materials used, and the incorporated technology (Andrysek, 2010). A leg prosthesis can range from a few hundred dollars to several hundred thousand. This cost is often a barrier to many amputees who cannot afford the high prices of modern prosthetics. Therefore, solutions are being sought to reduce costs while maintaining the quality of materials, resistance, adaptability to any stump, and intuitive maintenance ("do it yourself").

The history of leg prosthetics is a fascinating narrative of innovation and continuous progress. Today, technological advancements are converging to address significant challenges in the field of leg prosthetics.

This research encompasses various topics related to the causes, materials, and solutions for implementing a universal leg prosthesis with size adjustments. The aim is to improve the quality of life of amputees through a universal leg prosthesis with size adjustments for individuals aged 15 to 60. The documentary research focuses on an interdisciplinary analysis combining biomechanical analysis, materials evaluation, and types of prostheses, injuries, and therapies.

This study aims to advance the design, creation, and implementation of a new leg prosthesis that surpasses the limitations of conventional designs, which often do not meet the needs or expectations of the user.

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Methodology

This study was conducted on a sample of 50 individuals, evenly divided between males (M) and females (W) (25 M and 25 W), to collect detailed data on various anthropometric measurements of the lower limbs. These data included age, weight, height, measurement from the stump to the knee, measurement from the knee to the foot, measurement of the stump above the knee (circumference near the groin), measurement of the stump above the knee (circumference near the knee joint), measurement of the stump below the knee (Calf circumference close to the knee), measurement of the stump below the knee (Ankle circumference close to the foot), Heel width measurement, and measurement along the foot.

Graph 1a shows the age distribution of the participants, with a minimum age of 15 years for both M and W and a maximum age of 60 years for W to 69 years for M. The average age in our sample was 31 years in W and 32 years in M. Regarding weight, there was wide variability in both groups, as shown in graph 1b. The minimum weights were 40 kg in W and 42 kg in M, while the maximum weights were 100 kg in W and 120 kg in M.

The average weight in the sample was 68.4 kg in W and 80.16 kg in M. It is important to note that the standard deviation of the population's weight was 15.81 kg in W and 19.69 kg in M. Graph 1c presents the height data, with minimum heights of 1.5 m in W and 1.6 m in M, and maximum heights of 1.74 m to 1.9 m in W and M, respectively. The average height was 1.6 m in W and 1.72 m in M.

The standard deviation of the population's height was 0.05 m in W, and 0.08 m in M. Graph 1d shows the measurement from the knee to the stump, with minimum measurements of 26 cm in W and 22 cm in M and maximum measurements of 49 cm in W and 40 cm in M.

The averages of these measurements were 35.88 cm in W and 27.76 cm in M, with standard deviations of 5.68 cm in W and 3.89 cm in M.

Box 1

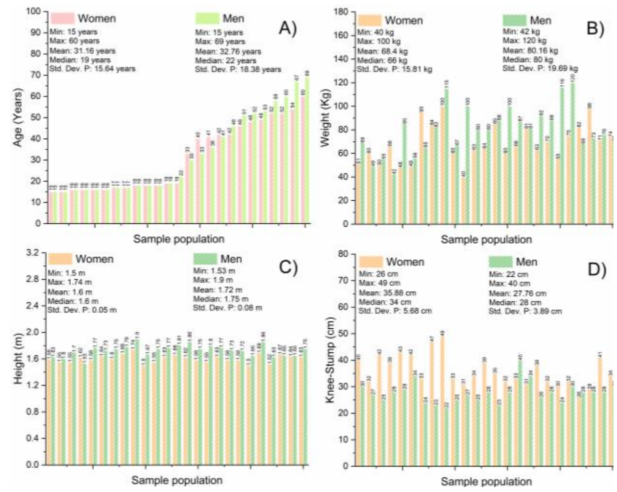

Figure 1

Population data on A) Age, B) Weight, C) Height, and D) Measurement along the stump to the knee

In figure 2a, we have the measurement along the knee to the foot, with minimum measurements of 46 cm in W and 43 cm in M and maximum measurements of 53 cm in W and 59 cm in M.

The averages of these measurements were 49.16 cm in W and 53.32 cm in M, with standard deviations of 2.2 cm in W and 4.03 cm in M. In figure 2b, we can observe the measurement of the circumference near the groin, with minimum measurements of 47 cm in W and 38 cm in M and maximum measurements of 75 cm in W and 83 cm in M.

The averages of these measurements were 59.68 cm in W and 53.12 cm in M, with standard deviations of cm in W and 10.67 cm in M. In figure 2c, we can observe the measurement of the circumference near the knee joint, with minimum measurements of 35 cm in W and 34 cm in M, and maximum measurements of 58 cm in W and 61 cm in M.

The averages of these measurements were 46.48 cm in W and 44.44 cm in M, with standard deviations of 6.67 cm in W and 7.19 cm in M. Now, in figure 2d, we can observe the measurement of the calf circumference close to the knee, with minimum measurements of 31 cm in W and M, and maximum measurements of 47 cm in W and 49 cm in M. The averages of these measurements were 36.84 cm in W and 39.56 cm in M, with standard deviations of 3.82 cm in W and 7.19 cm in M.

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Box 2

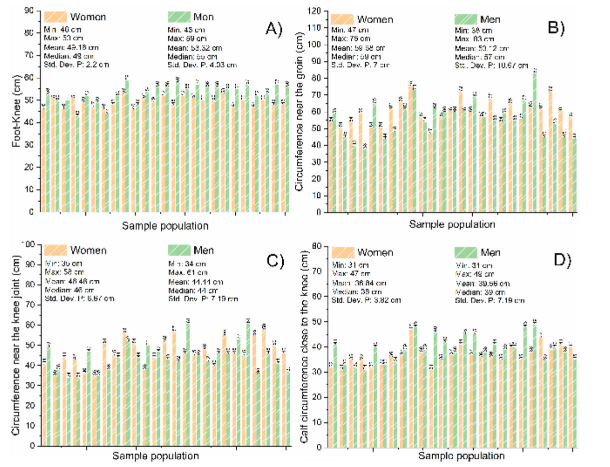

Figure 2

Population measurement data of A) foot to knee, B) stump above the knee circumference touching the groin, C) stump above knee circumference at knee level, and D) stump below the knee (calf) circumference hugging knee

In figure 3a, we can observe the measurement of the ankle circumference close to the foot, with minimum measurements of 20 cm in W and M, and maximum measurements of 27 cm in W and 30 cm in M. The averages of these measurements were 23.76 cm in W and 25.24 cm in M, with standard deviations of 2 cm in W and 2.81 cm in M. In figure 3b, we can observe the measurement of the heel width, with minimum measurements of 5 cm in W and M and maximum measurements of 9 cm in W and M.

The averages of these measurements were 6.96 cm in W and 7 cm in M, with standard deviations of 1.03 cm in W and 0.89 cm in M. In figure 3c, the measurement along the foot, with minimum measurements of 23 cm in W and 24.5 cm in M, and maximum measurements of 27.5 cm in W and 30 cm in M.

The averages of these measurements were 25.02 cm in W and 27.54 cm in M, with standard deviations of 1.04 cm in W and 1.17 cm in M. These data are essential for the design and development of universal leg prostheses with adjustable sizes that adapt correctly to the lower extremities of men and women in an individualized manner.

The results highlight the importance of considering gender when designing leg prostheses to ensure optimal fit and improve users' quality of life.

Box 3

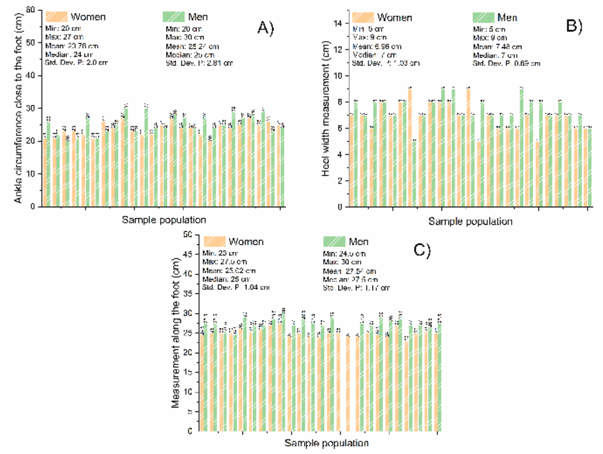

Figure 3

Population measurement data of A) the Stump below the knee (calf) circumference hugging the foot, B) the width of the heel, and C) the length of the heel

The software used was UltiMaker Cura 5.7.1, and the filament was Kardenal brand, with a diameter of 1.75 mm, extruded at a temperature of 190°C to 220°C, using a 0.4 mm nozzle for both printers.

The 3D printer used for printing the entire knee and foot part was the Creality Ender-3 V2, with dimensions of 475 x 470 x 620 mm, a bed size of 220 x 220 x 250 mm, and a weight of 8 kg. The total printing time was 67 hours and 32 minutes, with an infill speed of 40 mm/s and a wall speed of 20 mm/s, with a bed temperature of 60°C and a nozzle temperature of 220°C. The infill percentage for all parts was 20% in zigzag, with a retraction of 2 mm.

To print the sockets, the Creality Ender-3 V3 SE was also used. Its dimensions were 420 x 366 x 640 mm, the bed size was 220 x 220 x 250 mm, and it weighed 7.32 kg. The printing time was 47 hours and 34 minutes, with an infill speed of 180 mm/s and a wall speed of 90 mm/s, a bed temperature of 60°C, a nozzle temperature of 220°C, an infill percentage of 20% in zigzag, and a retraction of 2 mm.

Results

The construction of a universal prosthesis presents a series of obstacles. With the data presented in figures 1, 2, and 3, the necessary parameters are obtained to establish a range of measurements.

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For the ⇳ length measurement (stump - knee), an average of 35.88 cm for W and 27.76 cm for M is obtained; this indicates that the screw providing these measurements should be 8.12 cm, although to allow space for fasteners, a length of 9.5 cm is suggested. As for the length measurement ⇳ (knee-foot), the average for W was 49.16 cm and for M 53.32 cm.

Therefore, the screw for these measurements should be 4.16 cm, although a length of 5.5 cm is recommended to allow space for fastening.

For the ⇔ stump above knee (circumference near to groin), the average was 59.68 cm for W and 53.12 cm for M. Therefore, this part should be printed with a circumference of 56.4 cm, with a stretching and compression capacity of ± 2.66 cm.

For the ⇔ Stump above knee (Circumference near the knee joint), the average was 46.48 cm for W and 44.44 cm for M. Therefore, the piece should have a circumference of 45.46 cm, with a stretching and compression capacity of ± 1.02 cm. For the circumference of the ⇔ Stump below knee (Calf circumference close to knee), the average was 36.84 cm for W and 39.56 cm for M.

Therefore, this part should be printed with a circumference of 38.2 cm and a stretching and compression capacity of ± 2.72 cm. For the ⇔ Stump below knee (Ankle circumference close to the foot), the average was 23.76 cm for W and 25.24 cm for M. Therefore, the piece should have a circumference of 24.5 cm, with a stretching and compression capacity of ± 0.74 cm.

Regarding the ⇦⇨ heel width measurement, an average of 6.96 cm for W and 7.48 cm for M was obtained so that the size will be 7.22 cm. For the ⬉⬊ measurement along the foot, the average was 25.02 cm for W and 27.5 cm for M.

However, it was decided to use a minimum of 23 cm for women and a maximum of 30 cm for men because the variation in height in most measurements is not proportional. Therefore, the foot screws will have a length of 10 cm in order to allow anyone to adjust the foot size from 23 cm to 30 cm.

All this information is represented through the symbols in Figure 4.

Box 4

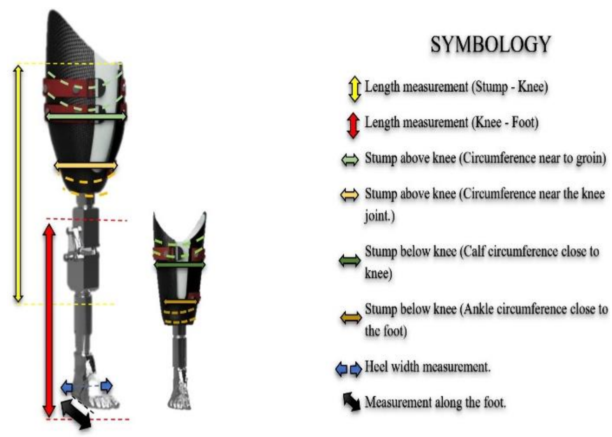

Figure 4
Symbology to measure the leg parts and design the universal prosthesis

With the provided information, the design of the leg prosthesis was initiated, taking into account all measurements.

The printing times were as follows: transfemoral socket (Figure 5A): 23 hours and 7 minutes, transtibial socket (Figure 5B): 24 hours and 27 minutes, two units of the first coupling (Figure 5C): 3 hours and 2 minutes, second coupling (Figure 5D): 1 hour and 17 minutes, first part of the knee (head) (Figure 5E): 6 hours and 17 minutes, second part of the knee (base) (Figure 5F): 7 hours and 53 minutes, two large anchors (Figure 5G): 51 minutes, small anchor (Figure 5H): 22 minutes, swivel nut with hat (Figure 5I): 23 minutes, third coupling (Figure 5J): 1 hour and 44 minutes, two units of the fourth coupling (Figure 5K): 8 hours and 26 minutes, two units of the fifth coupling (Figure 5L): 1 hour and 46 minutes, two units of the sixth coupling (Figure 5M): 2 hours and 52 minutes, seventh coupling (extension for the transtibial) (Figure 5N): 3 hours and 3 minutes, two forefeet (toes) (Figure 5O): 9 hours and 22 minutes, two hindfeet (heel) (Figure 5P): 14 hours and 40 minutes, six buckles (Figure 5Q): 2 hours and 12 minutes, six extension nuts for foot (Figure 5R): 3 hours and 18 minutes.

The total printing time to complete the prosthesis was 89 hours and 28 minutes.

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Box 5

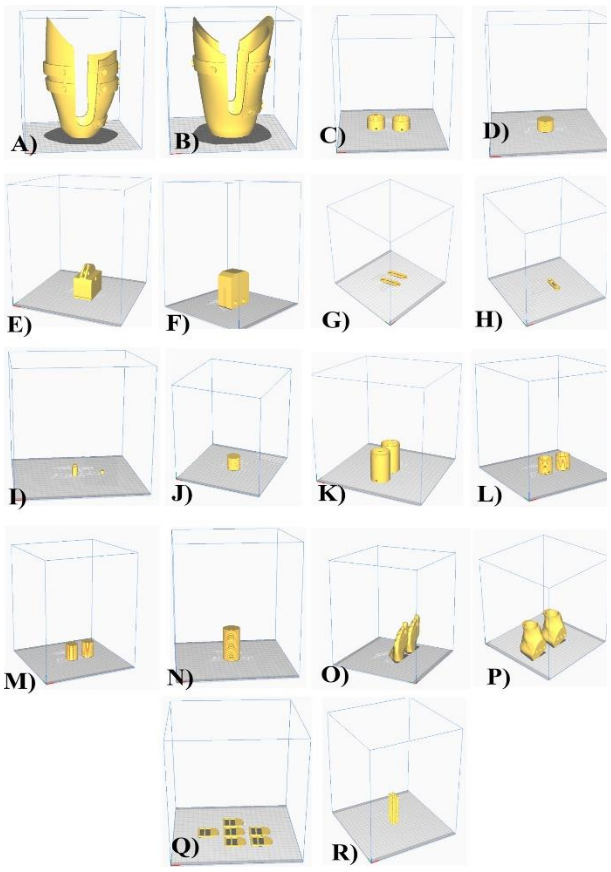

Figure 5

Printing time: A) Socket transfemoral, B) Socket transtibial, C) First coupling, D) Second coupling, E) First part of knee, F) Second part of knee, G) Large anchors, H) Small anchor, I) Swivel nut with hat, J) Third coupling, K) Fourth coupling, L) Fifth coupling, M) Sixth coupling, N) Seventh coupling, O) Forefoot (toes), P) Hindfoot (heel), Q) Buckles and R) Extension nuts

The total grams used for the prostheses, transfemoral and transtibial, were 586 g and 518 g respectively (see figure 6). The quantity of each printed part is shown in Table 1. With this documented information, it was determined that each gram of filament costs 0.29 pesos, calculated using the formula 298.99 pesos (filament price) divided by 1000 g, resulting in 0.29 pesos per gram.

Once the cost per gram was calculated and considering the total grams used in each prosthesis, the total filament cost for each was determined. The production cost of the transfemoral prosthesis was 169.94 pesos and that of the transtibial prosthesis was 150.22 pesos. These calculations were performed as follows:

For the transfemoral prosthesis:

$$(586gr)\left(0.29\frac{pesos}{gr}\right) = 169.94\,pesos$$

For the transtibial prosthesis:

$$(518gr)\left(0.29\frac{pesos}{gr}\right) = 150.22\,pesos$$

Box 6

Table 1

Quantity in grams of each piece of the leg prosthesis with adjustment in sizes

Quantities	Pieces	Grams
1	Socket transfemoral	263 gr
1	Socket transtibial	333 gr
2	First coupling	18 gr
1	Second coupling	11 gr
1	First part of knee	55 gr
1	Second part of knee	70 gr
2	Large anchors	5 gr
1	Small anchor	2gr
1	Swivel nut with hat	2 gr
1	Third coupling	15 gr
2	Fourth coupling	48 gr
2	Fifth coupling	12 gr
2	Sixth coupling	24 gr
1	Seventh coupling	26 gr
2	Forefoot (toes)	78 gr
2	Hindfoot (heel)	118 gr
6	Buckles	12 gr
6	Extension nuts	12 gr

The results shall be by section of the article.

Box 7

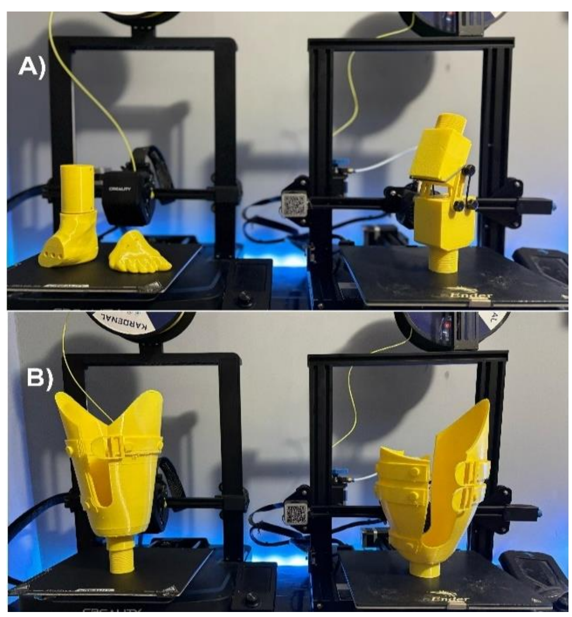

Figure 6

Leg prosthesis with adjustment in sizes A) Knee and foot, B) transfemoral and transtibial

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Several authors have conducted extensive research on the process parameter optimisation of the FDM process. Afrose et. al (2015) studied the fatigue behavior of polylactic acid (PLA) parts processed by fused deposition modelling (FDM) additive manufacturing process. The authors reported the effect of part build orientations on the tensile fatigue properties of PLA material.

A Cube 3D printer was used to print dog-bone test specimens in three (X, Y and 45°) different build orientations. Results show that the 45° build orientation components exhibit a longer fatigue life for the same proportion of applied static stresses than the parts in the X and Y construction orientations. Eryildiz (2021) studied the FDM 3D-printed PLA parts fabricated at different build orientations to examine the effects of build orientation on the tensile properties and build time of material.

The author reported that the tensile strength reaches a maximum for 0° orientation. Also, for upright (vertical) build orientation, 36% less tensile strength was obtained compared to flat orientation.

Syrlybayev et al. (2021) considered includes the influence of pre-processing of the printed part to improve the part strength and new research trends such as, vacuum-assisted FDM that has shown to improve the quality of the printing due to improved bonding between the layers. The authors reported that the layer thickness is the most critical factor among the studied ones. Furthermore, tensile strength decreases with increased layer thickness for both ABS and PLA filaments.

Algarni & Ghazali (2021) studied four FDM materials: polylactic acid (PLA), acrylonitrile butadiene styrene (ABS), polyether ether ketone (PEEK), and polyethylene terephthalate glycol (PETG). The authors reported a comparative study was conducted on four materials depicting that strength decreases for all materials with increased printing speed.

Conclusions

This study, conducted on a sample of 50 individuals evenly divided between males (25) and females (25), aimed to collect detailed anthropometric measurements of the lower limbs.

Data included age, weight, height, measurements from knee to stump and foot to knee, stump circumferences, heel width, and length. Graphs depict the distribution of these measurements by gender.

Key findings include:

- Age: The average age was 31 for W and 32 for M.
- Weight: Average weight was 68.4 kg for W and 80.16 kg for M.
- Height: Average height was 1.6 m for W and 1.72 m for M.
- Stump to Knee Measurement: Averages were 35.88 cm for W and 27.76 cm for M.
- Foot to Knee Measurement: Averages were 49.16 cm for W and 53.32 cm for M.
- Stump Circumferences: Averages for the stump above the knee were 59.68 cm (W) and 53.12 cm (M), and below the knee were 36.84 cm (W) and 39.56 cm (M).
- Heel Width: Average width was 6.96 cm for W and 7 cm for M.
- Heel Length: Average length was 25.02 cm for W and 27.54 cm for M.

These data are crucial for designing universal leg prostheses with adjustable sizes, ensuring a correct fit, and enhancing users' quality of life. Gender-specific considerations are vital in prosthesis design to achieve optimal fitting.

Declarations

Conflict of interest

The authors declare no interest conflict. They have no known competing financial interests or personal relationships that could have appeared to influence the article reported in this article.

Authors´ contribution

Murillo-Rendón, Pablo-Antonio, and *Cuate-Gomez, Diego-Hernan:* Will conduct the development, experimentation, different measurements of people's legs, and article writing.

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Garzón-Román, Abel and *Lugo-Quintal, Jesús Manuel*: Helped with the correction of the manuscript.

Availability of data and materials

The data that support the findings of this study are available from the corresponding author, Murillo-Rendon, upon reasonable request.

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Abbreviations

ABS	Acrylonitrile butadiene styrene
FDM	Fused deposition modelling
INEGI	National Institute of Statistic and Geography
M	Male
PEEK	Polyether ether ketone
PETG	Polyethylene terephthalate glycol
PLA	Polylactic acid
W	Female

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