Utilizing Additive Manufacturing for Economical Prosthetic Limb Prototyping: A Guide from Regression Modelling

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Abstract

This study investigated the development of a low-cost prosthetic limb using additive manufacturing techniques, guided by anthropometric data and regression modeling. Anthropometric measurements were collected from 250 healthy young adults to characterize limb dimensions. Statistical analysis revealed the mean, standard deviation, and range for right and left leg and elbow lengths. A regression model was formulated to estimate limb lengths based on these measurements. A robust regression model demonstrated a significant correlation ($r = 0.993$, $r^2 = 0.986$) between right limb measurements and corresponding left limb measurements, indicating that right leg and elbow lengths could accurately predict left side measurements. The derived regression equation (RLL = 2.253 + 0.959 LLL + 0.054 LEL) provides a practical tool for designing customized prosthetics. Utilizing 3D printing technology, these findings can enhance the production of tailored prosthetic limbs, improving comfort and functionality for users. The study recommends further validation across diverse populations, integration into clinical practices, and continued research and development supported by policy and funding initiatives. These steps will advance the accessibility and effectiveness of personalized prosthetic solutions.

Keywords: anthropometric, ergonomic, disability design: prosthetic limb, amputee

Introduction

In recent years, the field of prosthetics has undergone a significant transformation, with a shift towards utilizing advanced manufacturing techniques to develop cost-effective solutions (Bhatt et al., 2023). Additive manufacturing, in particular, has emerged as a promising method for crafting prosthetic limbs that offer improved affordability and customization. Efforts to design suitable prosthetic limbs often face significant challenges due to the absence of individualized anthropometric data. This study utilized a regression model, guided by the anthropometric dimensions of the recipients, to design customized prosthetic limbs. This study investigates the convergence of additive manufacturing and prosthetics, emphasizing the potential of this technology to revolutionize the accessibility of prosthetic limb design. Through the utilization of additive manufacturing capabilities, researchers and engineers can provide innovative novel designs, optimize functionality, and ultimately provide access for individuals with limb differences to high-quality prosthetic solutions at a fraction of traditional costs.

The application of advanced additive manufacturing techniques for prosthesis fabrication enables a user-centric development process that addresses all user demands, resulting in better fit, comfort, and enhanced stability for gait rehabilitation (Bhatt et al., 2023). A prosthetic implant serves as an artificial device utilized in medicine to replace a missing body part resulting from trauma, illness, or congenital conditions. These prostheses are tailored to restore the lost functionality of the missing body part. For instance, a transtibial amputee, who has undergone leg amputation below the knee, may opt for a below-the-knee prosthetic to regain some degree of movement (Safari, 2020). The loss of a limb necessitates significant adjustments to an individual's mental and financial well-being, limiting abilities such as reaching, grasping, tactile sensation, and gestural communication, thereby profoundly affecting the quality of life (Safari 2020; Stelt et al., 2021; Shamsuddin et al., 2023).

The global demand for prosthetic limbs is on the rise, propelled by factors such as heightened awareness, advancements in healthcare, and a growing population with limb differences. However, many individuals, particularly in underserved communities, still face significant challenges in accessing affordable and customizable prosthetic solutions (Gorski et al., 2022).

The design and evaluation of prostheses can be conducted manually or with the assistance of computer-aided design (CAD), a software platform that offers tools for analysis, optimization, and the creation of computer-generated 2D and 3D representations (Maat et al., 2017; Ognen and Kocov, 2020; Gorski et al., 2022). Prostheses are artificial limbs designed to replicate the functionality and/or appearance of missing body parts. Lower limb prostheses are intended to imitate the movement of the body's lower extremities, including the hip, thigh, knee, ankle, and foot (Fig.1). The key components of lower limb prostheses typically include the socket, knee joint, pylon, and foot (Pitkin, 2010).

Figure 1 Lower limb amputees

Gorski et al. (2022) conducted a study on automated design and rapid manufacturing, employing 3D printing based on the 3D scanning of a patient's upper limb. Additive manufacturing, commonly referred to as 3D printing, offers distinct advantages in terms of cost-effectiveness, rapid prototyping, and customization. By layering materials to construct intricate structures based on digital designs, additive manufacturing facilitates the creation of prosthetic limbs tailored to the specific needs and preferences of users. Furthermore, its scalability and versatility make it well-suited for producing prosthetic limbs at a fraction of the cost of traditional manufacturing methods (Stenvall et al., 2020).

The convergence of additive manufacturing and prosthetics, particularly in the modeling of low-cost prosthetic limbs, holds the potential to democratize access to prosthetic solutions, empowering individuals with limb differences to regain mobility and independence. The process of blending materials in additive manufacturing reduces the reliance on molds or templates while enhancing the efficiency of materials. Medical device design often benefits from 3D imaging to further personalize items manufactured through additive manufacturing. Molds and templates are replaced by 3D models of scanned body parts, facilitating the development of medical devices that fit and function optimally. Additive manufacturing allows for the production of implants and prosthetics with complex structural shapes composed of various materials. Similarly, it enables the cost-effective production of medical devices in regions that may lack access to conventional manufacturing techniques. The reduced costs are attributed to lower expenses associated with packaging, storage, and delivery of the desired products (Liaw et al., 2017).

An artificial limb, commonly known as an upper limb prosthesis or lower limb prosthesis, serves as a prosthetic that replaces a missing extremity (Shahar et al., 2020). The absence of a hand significantly impacts various aspects of human life, including the development of one's identity and image, interpersonal interactions, sexual identity, abilities, self-expression, and psychological response to adversity (Daniel et al., 2018; Radu et al., 2021; Gorski et al., 2021). The objective of this study was to develop a regression model equation to facilitate the anthropometric measurement in designing customised low-cost prosthetic limbs utilizing additive manufacturing technology in addressing individual needs and ergonomics.

Materials and Methods

The research involved collecting anthropometric measurements from healthy young adults to develop a regression model for customized prosthetic limb design. To estimate the length of a lost limb, measurements from alternative limbs were used in conjunction with the model.

A total of 250 healthy young adults (both male and female) without any physical disabilities were selected through the snowball sampling technique. This method was chosen due to concerns about human kidnapping and insecurity in Nigeria. Participants were randomly recruited from the Ifo and Ibogun areas in South Western Nigeria, with ages ranging from 22 to 35 years. Data collection occurred between June 2023 and October 2023.

Anthropometric dimensions, specifically Right Leg Length (RLL), Left Leg Length (LLL), Right Elbow Length (REL), and Left Elbow Length (LEL) were measured using a measuring tape. All the recordings of the lengths were in centimeters.

Procedure for Leg length and Elbow length measurement

Fig. 2 and 3 show the procedure for the measurement of leg length (LL) and elbow-length (EL) which is essential for fitting prosthetic limbs and other medical purposes. Below is the description of the exercise.

Figure 2 Leg length measurement

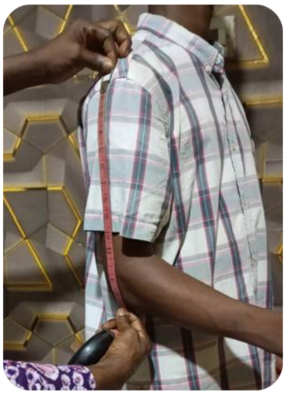

Figure 3 Elbow length measurement

Leg length: Leg length can be measured using either the total leg length (from the hip to the ankle) or segmental leg length (thigh length and lower leg length). For this research, the total leg length from hip to ankle was used. The individual stood straight with weight evenly distributed on both feet, and a flexible measuring tape was used for accuracy. First, the anterior superior iliac spine (ASIS), the bony prominence on the front of the hip, was identified. Similarly, the medial malleolus, the bony prominence on the inside of the ankle, was identified.

The measuring tape was positioned at the ASIS and extended down to the medial malleolus, ensuring it was straight and followed the natural contour of the leg without slack. The individual was kept in a relaxed position to avoid muscle contraction that could affect the measurement and wore light clothing to prevent any interference with the tape.

Elbow length: The individual was positioned standing straight with their arms relaxed at their sides. For accuracy, a flexible measuring tape was used. The acromion process, the bony prominence on the shoulder where the arm meets the shoulder, was identified. Similarly, the olecranon process, the bony point of the elbow, was also identified.

The measuring tape was placed at the acromion process and extended down the length of the upper arm to the olecranon process. It was carefully positioned to be straight and follow the natural contour of the arm without any slack. The arm was slightly bent to accurately locate the olecranon process, and the individual was kept in a relaxed position to avoid muscle contraction that could affect the measurement. The measurement was repeated several times to ensure consistency and accuracy.

The anthropometric measurement data were analyzed using SPSS software version 21 and Microsoft Excel 2010 with its data analysis tools. The analysis included calculating the mean, standard deviation, and range (minimum and maximum) for RLL, LLL, REL, and LEL. Additionally, statistical parameters such as the correlation coefficient (r), coefficient of determination (r^2), Standard Error of Estimates (S.E.E), and 95% confidence intervals were examined. Multivariate regression analyses were performed to create model equations for estimating limb length (LL) based on other anthropometric measurements.

To utilize the advantages of cost-effective and accessible additive manufacturing techniques for creating 3D models of prosthetic limbs, a low-cost prosthetic limb was developed using additive manufacturing based on the generated model results. CAD software (Solidworks) was used to design the 3D model of the prosthetic limb. Fig. 4. shows the prototype of the prosthetic lower limb.

Figure 4 Prototype of lower limb prosthesis

Results and Discussion

The study conducted a thorough descriptive analysis of anthropometric data collected from 250 healthy young adult participants. This analysis provided valuable insights into the mean, standard deviation, and range of limb measurements, which are essential for understanding the baseline characteristics of the study population. The descriptive analytical evaluation of the anthropometric data collected in the study is presented in Table 1, along with the regression model equation utilized to determine limb length.

Table 1 displays the statistical analysis of the variables, showcasing the mean, standard deviation, and range of limb measurements from the two hundred and fifty participants.

Table 1 The statistical analysis of the variables

Variable	N	Mean (cm)	Standard Dev (±)	Minimum (cm)	Maximum (cm)
Right Leg Length	250	100.62	6.63	82.6	112.0
Left Leg Length	250	100.59	6.71	82.0	112.0
Right Elbow Length	250	35.34	3.49	26.8	42.6
Left Elbow Length	250	35.35	3.49	26.0	42.2

Additionally, Table 2 shows the regression model summary of the variables. The regression model investigates the associations between left leg length and left elbow length with corresponding measurements on the right side.

Table 2 Regression model summary

					Change Statistics				
Model	**r**	**r^2**	**Adjusted (r^2)**	**SEE**	**r^2 Change**	**F Change**	**df 1**	**df 2**	**Sig. F Change**
1	0.993	0.986	0.986	0.7915	0.986	3425.488	2	97	0.000

The result reveals that the correlation coefficient (r) is 0.993 and the coefficient of determination (r^2) is 0.986 with a Standard Error of Estimation (S.E.E) of 0.7915. The results indicate a favorable and statistically significant association ($p < 0.0001$) between RLL and additional anthropometric measurements, including LLL, REL, and LEL. Higher values of the correlation coefficients and adjusted coefficient of determination (above 0.75) indicate improved predictive performance and model fit (Nafees, et al., 2021; Ohana-Levi, et al., 2022). The regression model employed in the study was used to investigate the associations between various anthropometric measurements on both sides of the body. The results revealed a highly significant correlation between left leg length and additional anthropometric measurements, indicating the inter-relatedness of these variables.

A very accurate model fit is often indicated by an r-squared score of 0.986. The r-squared is a metric that shows how much of the variance in the dependent variable can be accounted for by the model's independent variables (Musa et al., 2023). The value is a number between 0 and 1, where 1 denotes an ideal match. It was discovered that there exist relationships between right leg length (RLL) and left leg length (LLL), as well as right elbow length (REL) and left elbow length (LEL). The model's significance was assessed to determine if variations in the right-side measurements contribute significantly to the left-side measurements.

The regression analysis demonstrated a remarkably high coefficient of determination (r^2) of 0.986, indicating that the independent variables (right leg length and right elbow length) accounted for approximately 98.6% of the variability in left leg length and left elbow length. This suggests a strong and statistically significant association between the variables, highlighting the predictive power of the model.

Variations in right leg length and right elbow length account for nearly all of the variability in left leg length and left elbow length, with an R-squared of 0.986. The observed data and the model fit each other incredibly well. The almost flawless r-squared value indicates an excellent model fit. It is imperative to consider the particular environment and anticipated outcomes when elucidating the dependent variables. Given that the model can account for almost all of the variation in the left elbow and leg length, it can be concluded that the independent variables chosen have a major impact on our comprehension of these measures taken from the left side.

The regression analysis in Table 3 further elucidates the significant positive correlation between the dependent variable (right leg length) and the other independent variables (left leg length and left elbow length). The formulated regression model equation, as derived from the study, facilitates the estimation of right leg length based on the measurements of left leg length and left elbow length.

Table 3 Model regression analysis

Model	Unstandardized Coefficients		Standardized Coefficients	T	Sig	95.0% Confidence Interval for B	
	B	Std. Error	B			Lower Bound	Upper Bound
Constant	2.253	1.212		1.858	0.066	-0.153	4.659
LLL	0.959	0.018	0.971	51.937	0.000	0.923	0.996
LEL	0.054	0.036	0.029	1.529	0.129	-0.016	0.125

Dependent variable: RLL (right leg length),

Independent variables: LLL (left leg length), LEL (left elbow length).

Referencing Table 3, the result shows that there is a significant positive correlation between the dependent variable (right leg length) and the other independent variables (left leg length and left elbow length), indicating that changes in the left leg length are linked to significant changes in the right leg length. Maintaining other factors constant, an increase of one unit in the left leg length is correlated with a 0.971 rise in the dependent variable, right leg length. That is to say, practically speaking, the right leg length should rise by 0.971 units for every unit increase in the left leg. Since the left elbow length has a significantly smaller coefficient than the right, changes in the left elbow length will likely have a less significant impact on changes in the right elbow length. This relationship is assuming that the right elbow length is variable. When all other factors are held constant, a one-unit increase in the left elbow's length is correlated with a 0.029 rise in the dependent variable (in this case, the right elbow's length). That is to say, practically speaking, the right elbow length should rise by 0.029 units for every unit that the left elbow length raises.

Table 3 further shows the model regression analysis generated from the study. A generalized regression equation is written below. Due to the number of the independent variables which is three, a multivariate regression equation was used to determine the dependent variable.

Regression model equation,

$Y = C + b_1x_1 + b_2x_2 + b_3x_3 + \ldots b_nx_n$ (multiple regression equation)

where, Y = dependent variable (right leg length)

C = constant

b = Independent variable

From Table 3, the model equation was formulated as

Right Leg Length (RLL) = 2.253 + 0.959 LLL + 0.054 LEL - 1

where RLL – Right Leg Length,

LLL - Left Leg Length,

LEL - Left Elbow Length

The formulated regression model equation allows for the estimation of right leg length based on measurements of left leg length and left elbow length. This equation provides a practical tool for predicting limb lengths, which is crucial for designing customized prosthetic limbs tailored to individual anatomical variations. Given the generated model, the result obtained can be transmitted into the 3D printer for the production of the prototype of the prosthetic limb (Fig.5).

Validation of the Regression Model

The regression model was validated using the measured anthropometric values presented in Table 1. Specifically, the observed Right Leg Length (RLL) of 100.62 ± 6.63 cm was compared with the values predicted by the model.

From Table 1,

LLL = 100.59 ± 6.71cm

LEL = 35.35 ± 3.49cm

Assuming upper limit (+),

LLL = 107.30cm

LEL = 38.84cm

From equation 1, the Model Equation was formulated as

Right Leg Length (RLL) = 2.253 + 0.959 LLL + 0.054 LEL

RLL = 2.253 + 0.959 (107.30)cm + 0.054 (38.84)cm (2)

Therefore,

RLL = 107.250cm (from equation 2)

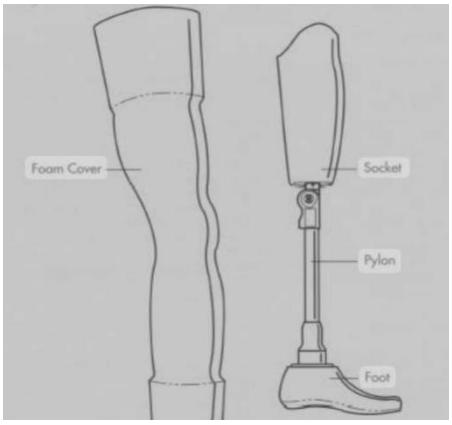

Figure 5 Developed Lower Prosthetic limb

The results obtained from the study's model can be utilized to produce a prototype of the prosthetic limb using a 3D printer, as depicted in Fig. 4. Bhatt et al. (2023) and Stenvall et al. (2021) have previously explored various additive manufacturing methods for fabricating lower limb prostheses, including the utilization of bio-composites derived from forestry-based materials. These studies highlight the potential for developing flexible and systematic prosthetic solutions using additive manufacturing technology.

The study's findings have significant implications for prosthetic design and manufacturing. By leveraging the regression model equation and additive manufacturing technology, researchers can develop low-cost, customized prosthetic limbs that accurately replicate the length and proportions of natural limbs. This approach enhances accessibility to prosthetic solutions and promotes a comfortable fit for users, ultimately improving their quality of life.

Conclusion and Suggestions

This study was a comprehensive descriptive analysis of anthropometric data from 250 healthy young adult participants, providing valuable insights into the baseline characteristics of limb measurements. The statistical analysis, presented in Table 1, highlights the mean, standard deviation, and range of measurements for right and left leg and elbow lengths, establishing a foundational understanding of the study population.

The regression model summary, detailed in Table 2, demonstrates a strong and statistically significant association between right limb measurements and corresponding left limb measurements. With a high correlation coefficient ($r = 0.993$) and coefficient of determination ($r^2 = 0.986$), the model shows that approximately 98.6% of the variability in the left leg and elbow lengths can be explained by the right leg and elbow lengths. This suggests a robust predictive performance and model fit, highlighting the inter-relatedness of these anthropometric variables.

Further regression analysis, as shown in Table 3, reveals that right leg length (RLL) can be accurately estimated using left leg length (LLL) and left elbow length (LEL). The formulated regression model equation ($RLL = 2.253 + 0.959\ LLL + 0.054\ LEL$) offers a practical tool for predicting limb lengths, which is crucial for designing customized prosthetic limbs.

Validation of the regression model using the measured anthropometric values confirmed the model's accuracy in predicting right leg length. This validation underscores the model's practical applicability in real-world scenarios, particularly in the field of prosthetics.

The study's findings have significant implications for prosthetic design and manufacturing. By leveraging the regression model equation and additive manufacturing technology, researchers can develop low-cost, customized prosthetic limbs that accurately replicate the length and proportions of natural limbs. This approach enhances accessibility to prosthetic solutions, promotes a comfortable fit for users, and ultimately improves their quality of life. The potential for developing flexible and systematic prosthetic solutions using additive manufacturing, as explored in previous studies by Bhatt et al. (2023) and Stenvall et al. (2021), further supports the feasibility and benefits of this innovative approach.

Based on the findings, we recommend using the regression model equation to design customized prosthetic limbs, leveraging 3D printing for cost- effective and rapid production. Further research should involve diverse populations to validate and refine the model. Healthcare providers should integrate predictive models into clinical practices. Exploring additional anthropometric variables and focusing on patient- centered approaches will enhance prosthetic development. Finally, policy and funding support are crucial for advancing research and innovation in customized prosthetics.

Author Contributions

Author 1: Conceptualization, Development or design of methodology, Manuscript writing, Manuscript review and editing,

Author 2: Provided materials subjects or patients, Investigation, Collection of data, Data analysis and interpretation.

Author 3: Provided materials subjects or patients, Investigation, Collection of data, Data analysis and interpretation.

Ethical Approval

All procedures involving human subjects in this study were conducted following relevant laws and institutional guidelines. Informed consent was obtained from all participants, and their privacy rights were strictly observed and protected throughout the study.

Conflict of Interests

All authors declare that they have no conflicts of interest.

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