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# Anthropometric Evaluation of Two Low-Cost 3D Digitizers for Lower Limb Prosthetics: A Preliminary Study

Alina S. L. Rodrigues[1,2], Marina C. Oliveira[2] and Alana E. F. Da Gama[2]

[1]Department of Mechanical Engineering, Universidade Federal de Pernambuco, alinaslrodrigues@gmail.com
[2]Rehabilitation Engineering Research Group, Department of Biomedical Engineering, Universidade Federal de Pernambuco, oliveiramarina23@gmail.com, alana.elza@ufpe.br

Corresponding author: Alana E. F. Da Gama, alana.elza@ufpe.br

**Abstract.** The use of 3D scanners to aid prosthetics design, contributing towards more adequate fittings, has been widely explored. However, before these technologies can replace traditional anthropometry, objective analyses must be conducted to assess their level of accuracy in representing the affected limb. This study intends to perform a preliminary evaluation of how closely two low-cost digitizers can replicate stump measurements in comparison with the conventionally adopted clinical approach. Twenty-four measurements related to residuum length and cross-sectional perimeters were in total observed from four participants with lower limb amputation. The stumps of the subjects were scanned using Sense 3D and Microsoft Kinect v2, and the same dimensions were extracted from the digital models. Bland-Altman analysis was performed to evaluate the agreement between methods. The results demonstrated that mean deviations between methods lied below differences found in previous studies. The digitizers evaluated in this work have shown to be useful low-cost tools in replicating residual limb measurements. Even though proper targeting of future efforts is required for clinical implementation, the results are promising and suggest the potential of the studied scanners in aiding prosthetics design.

**Keywords:** 3D scanning, anthropometric measurements, methods agreement, prosthetics.
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## 1 INTRODUCTION

A successful prosthetic device is one that not only fulfills its function but also contributes towards independence and quality of life enhancement [1]. The design and manufacturing processes of high-quality sockets must lead to products that reflect the geometric and mechanical properties of the residual limb, allow good load response, and provide safety while not interfering with blood flow [2]. However, the perception of discomfort and pain in the affected limb is still highly experienced by people with motor impairments, mainly due to poorly fitted sockets [3]. When it comes to lower limb amputations, the occurrence of complex load transfer mechanisms and limb fluctuations in shape, volume, and tissue composition makes the rehabilitation process even more challenging [4]. Studies have estimated that between 32% and 90% of prosthetics and orthotics users experience skin problems, such as dermatitis, blisters, cysts, and ulcers [5], leading to high rates of abandonment of devices [6].

Despite being patient-specific, the traditional manufacturing process of a prosthetic fitting, especially in developing countries, still relies mostly on the use of plaster casts, foam impressions, and manual measurements [7]. However, the short- and long-term changes that can occur on the affected limb might require frequent adjustments or replacements on the socket, often generating an incompatibility with the subjective, iterative, and laborious nature of the classic techniques. In this context, the search for alternative methods to aid socket design and fabrication performs an essential role in creating successful fittings [8]. Over the past years, efforts have been directed towards developing technologies that provide better outcomes with analogous time and cost requirements while being less dependent on the prosthetists' experience [9].

With the emergence of new CAD/CAM (Computer-Aided Design/Computer-Aided Manufacturing) technologies, the use of 3D scanners for capturing the limb's shape has been increasingly explored [10]. This approach allows greater repeatability over the traditional anthropometry methods, which are more observer-dependent and error-prone [11]. Besides, scan-derived images can be re-evaluated without the subject's presence, which facilitates the measurement process for people with mobility impairments [12]. Even though reproducibility and reliability might vary among digitizers, scanning the region of interest for prosthetics design decreases manufacturing time in comparison with traditional anthropometry [13]. It also offers the possibility of obtaining more complex measurements, such as mass and volume, which cannot be directly extracted from manual techniques [14]. Changing from a disposable plaster mold to a digital limb model makes it possible to store patients' data for future consultations, building a database that allows limb change monitoring and predictive modeling work to be performed [4]. Besides serving as a basis for the prosthetic device design, the resulting 3D digital models can be used along with finite element analysis software for functional performance evaluation and optimization even before the prosthesis is manufactured [3].

A wide variety of 3D scanners is available on the market and can be classified according to features like resolution, accuracy, portability, and cost [15]. Industrial 3D scanning solutions, for instance, offer a precise recognition of details that is usually accompanied by a cost increase, which makes this technology unaffordable for most practitioners, especially from developing countries [16]. Low-cost alternatives have been explored, aiming to enhance accessibility. While some of these tools have generated satisfying representations for the adopted purposes [17], others have demonstrated poor reliability in residual limb volume measurement [18], making its use currently unfeasible for clinical practice.

For 3D scanning technologies to replace traditional anthropometry techniques, it is essential that the adopted scanners accurately replicate the desired shape. The validity and repeatability of 3D scanning systems in comparison with manual measurements have been evaluated by several studies for multiple body parts dimensions [11,19–22]. For prosthetics- and orthotics-directed applications, efforts have been made in replicating foot shape [23], knee geometries [16], and rigid residual limb plaster models [14],[24]. When it comes to evaluating scanners' performance for residual limbs of people with amputation, inter-rate reliability has been assessed [10]. To the best of the authors' knowledge, there is no literature consensus on which variations would be clinically acceptable since thresholds between 1% [16] and 5% [25] have been discussed.

This work aims to perform a preliminary evaluation of the validity of two low-cost handheld scanning systems in replicating dimensions of residual lower limbs. Because manual measurement is still the most commonly used method for obtaining human body dimensions for prosthetics design, it was used as the trueness criterion.

## 2 METHODS

In this study, the stumps of people with lower limb amputation were scanned by the same observer, using two different low-cost digitizers: Sense 3D scanner (3D Systems, USA) and Kinect v2 sensor (Microsoft, USA). The generated 3D meshes were processed on a CAD software, without altering the original shape of the limb. Statistical analyses were performed to assess the agreement between lengths and circumferential measurements extracted from scanners-generated models and those directly read from a tape measure. Operational features, like the ease of equipment usage, visual quality of the models, and time for scanning and post-processing were qualitatively evaluated for each of the studied digitizers. An overview of the adopted protocol is shown in the diagram of Figure 1 and will be detailed in the following sections.

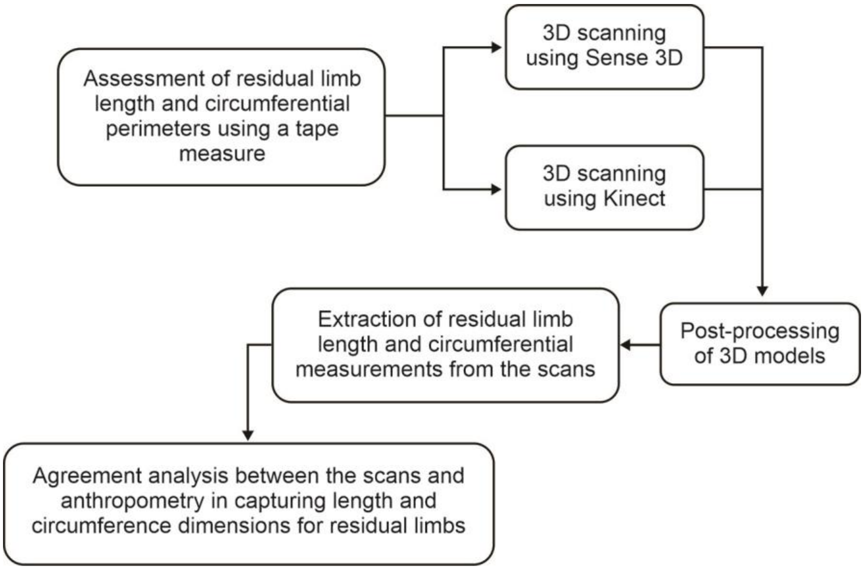


**Figure 1**: Descriptive flowchart summarizing the steps involved in this work.

### 2.1 Participants

Four unilateral participants with lower limb amputation, being two males and two females, were enrolled in this study. The volunteers were recruited from a local prosthetics clinic and from the university's Para-athlete Project. All subjects had at least two years of prosthesis usage experience and therefore presented stable residual limb volume. Any physical, orthopedic, or neurological conditions that could interfere with candidate positioning during data collection were taken as exclusion criteria. The adopted research protocol was approved by the Federal University of Pernambuco Research Ethics Committee (CAAE98711818.8.0000.5208), and the participants provided written consent before data collection. Table 1 details the sample information.

| *Participant* | *Gender* | *Level of amputation* |
|---|---|---|
| P1 | Male | Transfemoral |
| P2 | Female | Transfemoral |
| P3 | Female | Transfemoral |
| P4 | Male | Transtibial |

**Table 1**: Characteristics of the volunteers who participated in the study.

## 2.2 Equipment

The traditional process applied for prosthetics design relies on anthropometry techniques. For this reason, this work has adopted manual measurements as the criterion for evaluating two low-cost handheld scanning systems. Sense 3D is a commercial scanner based on the emission of an infrared pattern, providing an accuracy of 1 mm [26] at a cost of $499, which justifies its application for prosthetics design in low-resource realities [27]. On the other hand, Microsoft Kinect v2 is a motion sensor that can be purchased for around $199 and that has been used for the most diverse purposes, from 3D environment reconstruction to motion tracking [28]. Table 2 shows the main differences between the studied devices [26],[29].

| *Properties and features* | *Sense 3D* | *Kinect v2* |
|---|---|---|
| Field of view (H × V) | 45° × 57.5° | 70° × 60° |
| Depth resolution (pixels) | 240 × 320 | 512 × 424 |
| Operating range | 0.35 m – 3 m | 0.5 m – 4.5 m |

**Table 2**: Comparison between Sense 3D and Kinect v2 main characteristics.

## 2.3 Experimental Protocol

In a sitting position, each participant was requested to doff the prosthesis. Rubber markers were placed along the residual limbs to ensure that digital and manual measurements were extracted from the same locations. By palpation, two observers identified the appropriate anatomical landmark for each case and placed a marker in the detected location, being greater trochanter for participants with transfemoral amputation and tibial tuberosity for those with transtibial amputation. Three additional rubber markers were placed in each of the residual limbs to bound their distal ends, delimiting a cross-section parallel to the anatomical transverse plane. The exact location of these markers along the longitudinal axis is not determinant to the conduction of the adopted methodology, since its purpose is only to assure that manual and scan-derived measurements were obtained from the same regions.

Volumetric fluctuations that occur after removing the prosthesis can significantly influence socket design and bias the measurements of interest for the present work. To reduce this effect, a minimum interval of eight minutes was established before data collection, based on the previously reported averaged time required for residual limb volume stabilization after doffing [30].

Manual measurements were performed by a single observer using a standard flexible tape measure (sensitivity of 1 mm). The tape tension was qualitatively controlled, such that measurements were obtained adjacent to the limb and that the soft tissues did not experience any shape alteration. Stump length was reported, considered as the distance between the previously identified anatomical landmark and the distal end. Multiple stump circumferences were evaluated, equally spaced by 50 mm, starting from the previously markers-delimited distal end. These cross-sections were established such that each one of them composed a plane normal to the corresponding body segment. Therefore, for transfemoral residual limbs, all circumferences were parallel to each other. On the other hand, for the participant with transtibial amputation, static knee flexion was allowed throughout the protocol for being a more comfortable position, which resulted in a change in orientation between thigh and shank cross-sections. In this case, the 50 mm offset along the transition region was measured from the anterior side of the knee.

The scanning sessions occurred in a clean and spacious room to allow the observer to freely rotate around the region of interest. The participants were instructed to stand in an upright position without their prostheses, such that the residual limb was fully visible, and remain in this posture during the data collection process, with the aid of crutches for support, if necessary (Figure 2). The environment lighting was not modified from the already ceiling-installed LED lamps and the scanning position was chosen to minimize the occurrence of shadow in the participants' residual limbs. The software packages Kinect Fusion (Microsoft, USA) and Sense (3D Systems, USA) were used for capturing the desired shapes with the respective tools. Scans were taken by a single observer, that completed a full steady rotation of each studied device around the region of interest. Captures that resulted in software crashing or in models with missing parts (holes at specific regions or rotation not fully completed) were disregarded, causing the process to be repeated. At the end of the sessions, one successful scan per subject and per equipment was obtained, resulting in eight three-dimensional models to be analyzed.

**Figure 2**: Experimental set-up adopted for the scanning protocols. In this case, the subject was a transfemoral (above-knee) amputee and used crutches for support. It is also possible to observe the positioning of markers in the residual limb.

### 2.4 Data Processing

The virtual 3D geometries generated after the scanning sessions were exported in the "STL" file format. Meshmixer (Autodesk, Inc., USA) was used during the first post-processing step, directed towards the smoothing of visually rough areas and eventual imperfections. Extra care was taken during the modification of surfaces, not to alter the original shape and bias the variables of interest. In the software set-up, the adopted brush size was varied according to the extension of the region that required treatment but was always maintained below 10 to avoid the selection of larger areas. The smoothing type was configured as shape-preserving, for the process not to generate local swellings nor sags.

Once refined, models were exported to SpaceClaim 18.1 (SpaceClaim Corporation, USA), for removal of undesired external regions and evaluation of the measures of interest. For each case, a plane was delineated perpendicular to the thigh segment to serve as a reference for cutting off the residual limb 3D models from other captured body parts. The only requirement for positioning this plane was that it should be located more proximally than the greater trochanter marker for participants with transfemoral amputation and more proximally than the liner opening for the transtibial residual limb.

From the upper surfaces of the markers placed along the residual limbs' distal ends, a reference plane was traced for each model. This plane determined the most distal circumference to be measured and was considered the starting point for delimitation of the other cross-sections. Replicating the protocol adopted for manual measurements, each section was offset by 50 mm from the previous one and was traced perpendicularly to the corresponding body segment, as shown in Figure 3.

Completeness of the model, scanning time, ease of equipment usage, and measurements agreement were the variables selected to assess how well each studied method replicates the actual residual limb dimensions.

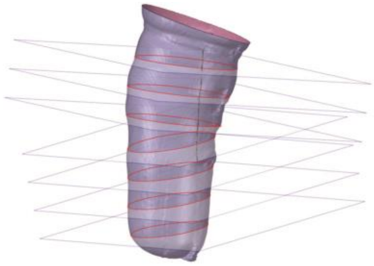

**Figure 3**: Example of a 3D model generated after residual limb scanning. The cross-sections of interest are highlighted. This case is related to a transtibial (below-knee) amputee and was obtained by the Sense 3D scanner.

### 2.5 Statistical Analysis

Obtaining anthropometric information for the design of new products requires the target population characteristics to be properly represented. Therefore, for the three-dimensional digitization techniques to replace the traditional methods without compromising data validity, it is fundamental that the variables of interest present trustworthy and reproducible values.

Statistical studies on the behavior presented by the differences between two data sets are useful when it is desired to evaluate the level of agreement among such groups [31]. In this work, the validities of Sense 3D scanner and Microsoft Kinect v2 were assessed through the conduction of a Bland-Altman analysis [32], considering the manual measurements as the criterion. The absolute and relative biases and the 95% limits of agreement were computed. A Shapiro-Wilk test with a significance level equal to 0.05 demonstrated that the dimensions obtained from the tape measure and from each of the studied digitizers were normally distributed, which provided means for the conduction of parametric analysis. The Pearson (product-moment) correlation coefficient was reported, and a paired-sample t-test was conducted, with the significance level set at 0.05. The statistical analysis was performed using Matlab R2018a (MathWorks, USA).

### 2.6 Volume Estimations

Variations in residual limb volume exert a direct influence in the decision-making process during the design of a prosthetic socket, affecting timing of fit, need for new prescriptions, and accommodation strategies [33]. Several methods have been assessed for estimating residuum volume [14], and the indirect determination of this parameter through the use of circumferential measurements is a consolidated approach [34]. In this work, an analysis of error propagation was conducted, to evaluate the impacts of girth measurement errors on the total residual limb volume. After the computation of measurements differences, the frustum formula was adopted [35], aiming assessment of the stump volume for each of the studied methods (manual, Sense 3D, and Kinect). Two consecutive cross-sections were considered to delimit the frustum of a cone, and the total residual limb volume was obtained by combining the volumes of all frustums. This approach was adopted for being applicable to the three methods of interest, thus providing a baseline for comparison. Relative differences between the stump volumes calculated from scans and from manual anthropometry were also observed.

## 3 RESULTS

Measuring stump circumferences with intervals of 50 mm resulted in different amounts of cross-sectional perimeters to be evaluated for each subject since shorter residual limbs contained fewer sections. In this context, dimensions extracted from the four participants resulted in data sets that contained twenty-four samples for each studied method (Sense 3D, Kinect, and manual). Metrics related to the agreement of each scanning method with manual measurements are summarized in

Table 3. The t-test results indicate that no significant differences were observed for the analyzed body dimensions since the p-values were greater than the established threshold ($p > 0.05$). Overall biases calculated through Bland-Altman analysis showed a tendency for scanners to slightly overestimate measurements. Strongly linear positive correlations were verified for the performed comparisons (Sense 3D × manual and Kinect × manual), as demonstrated by the Pearson correlation coefficient values (Table 3). Linear regressions for Sense 3D and Kinect are shown in Figure 4a and Figure 4b, respectively.

| *Equipment* | *p-value* | *Overall bias (%)* | *Limits of agreement* | *Pearson CC* |
|---|---|---|---|---|
| Sense 3D | 0.2605 | 0.23 | -4.79 to 5.24 | 0.9981 |
| Kinect | 0.4575 | 0.25 | -9.88 to 10.38 | 0.9861 |

**Table 3**: Methods agreement.

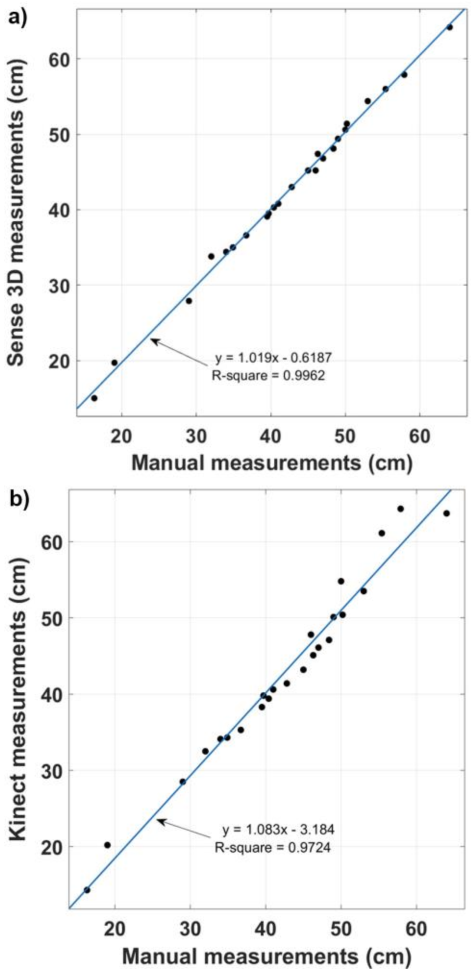


**Figure 4**: Linear regressions between scan-extracted measurements and anthropometry. From top to bottom, it is possible to observe data related to (a) Sense 3D and (b) Kinect.

Volume estimations of Sense 3D- and Kinect-generated models are compared in Table 4 against those calculated from manual measurements. The presented means and standard deviations are related to the four participants of this study. Differences in Kinect models were considerably higher than those obtained from Sense 3D scans.

| *Participant* | *Calculated volumes (mL)* | | | *Relative differences (%)* | |
|---|---|---|---|---|---|
| | *Manual* | *Sense 3D* | *Kinect* | *Sense 3D* | *Kinect* |
| P1 | 4101.02 | 4254.36 | 4063.39 | 3.74 | -0.92 |
| P2 | 2028.16 | 2020.35 | 1919.31 | -0.39 | -5.37 |
| P3 | 3300.39 | 3335.79 | 3950.79 | 1.07 | 19.71 |
| P4 | 4274.26 | 4267.56 | 4134.31 | -0.16 | -3.27 |
| *Overall volume differences (mean ± standard deviation)* | | | | 1.07 ± 1.89 | 2.54 ± 11.59 |

**Table 4**: Differences between volumes calculated from scans and from manual measurements.

The obtained Bland-Altman plots can be seen in Figure 5 (Sense 3D × manual) and Figure 6 (Kinect × manual). It is possible to infer that the measurements taken from the analyzed scanning-generated models presented a good agreement with traditional anthropometry techniques, slightly overestimating the residual limb dimensions in general. From visual inspection, no apparent relationship between measurements magnitude and differences values was observed, so constant biases were adopted for all cases. The majority of the differences between methods were within the calculated limits of agreement. Kinect-based geometrical reconstructions have shown higher deviations from the reference manual measurements and therefore have presented wider limits of agreement.

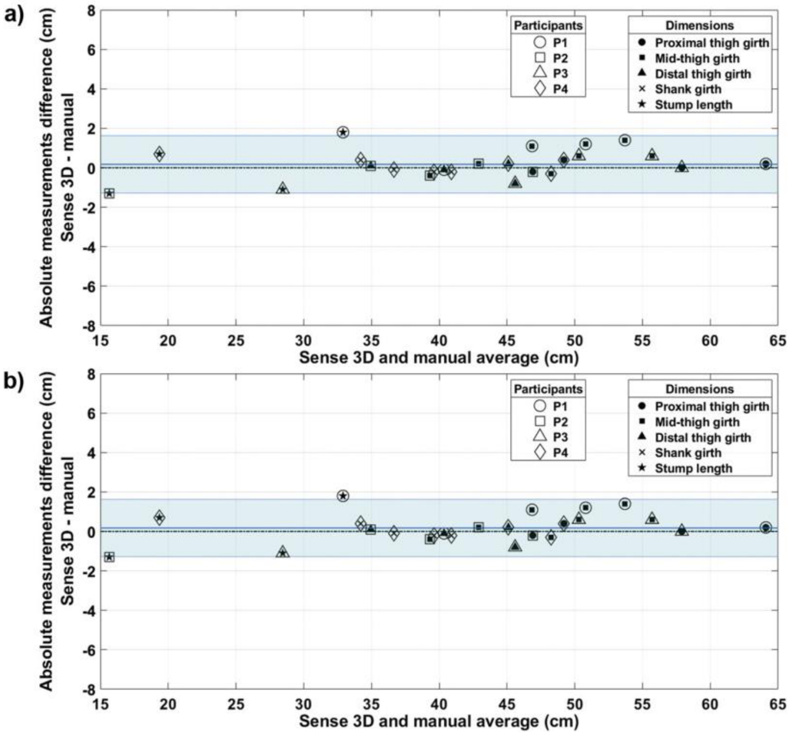


**Figure 5**: Agreement between Sense 3D scanner and manual measurements. These Bland-Altman plots illustrate the absolute (a) and relative (b) differences between the analyzed dimensions for the studied methods, as function of the values average. The limits of agreement were calculated as mean ± (1.96 × standard deviation).

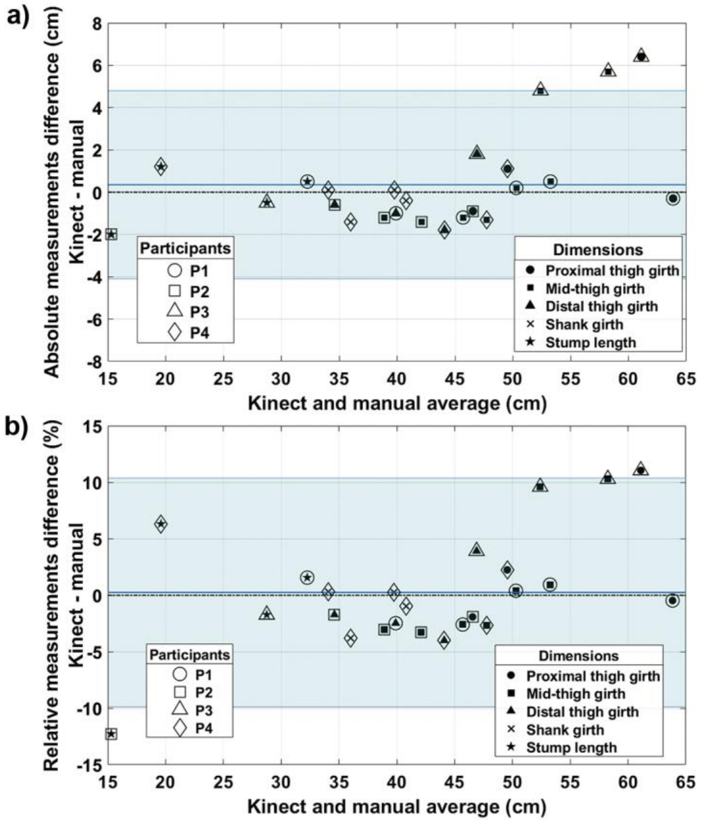


**Figure 6**: Agreement between Kinect sensor and manual measurements. The Bland-Altman analyses for absolute (a) and relative (b) differences were performed similarly to what has been described for the previous figure. Wider limits of agreement can be observed for this case.

A qualitative comparison between the visual aspects of the generated 3D models showed that the field of view for both digitizers is similar, with regions other than the residual limb also being captured, which required extra post-processing efforts in minimizing external influences. Overall, the Sense 3D scanner created meshes with a higher number of triangles, which is translated to smoother three-dimensional models in comparison to the Kinect-generated ones. As a consequence of greater instabilities observed during Kinect usage, it was not possible to increase the resolution for these models. Besides, Kinect demonstrated greater difficulties in correctly bounding the used markers, often merging them with the lower limb representations or creating holes nearby. Both scanners failed in separating residual and sound limbs at their proximal ends for transfemoral geometries.

## 4 DISCUSSION

Adequate fitting is one of the most decisive factors in the rehabilitation process of prosthetics and orthotics users, directly affecting the subject's quality of life and how functional independence is restored [3],[36],[37]. However, the traditional workflow for developing artificial limbs is iterative, laborious, and time-consuming, relying on anthropometric manual measurements that, despite their low cost and simplicity, might offer poor reliability and restricted information on leg shape [16],[21]. Besides, residual limbs are often subject to daily volumetric fluctuations [38], which might affect the prosthesis timing of fit, loading distribution, and accommodation strategies [4]. In this context, appropriate 3D scanning techniques have the potential to collaborate towards a faster, less invasive, and more reliable method of assessing limb's shape and volume, with data storage capabilities.

This work has investigated the Sense 3D scanner and the Kinect v2 sensor as possible alternatives to traditional anthropometry in replicating residual limb length and cross-sectional perimeters. Compared against manual measurements, the studied digitizers overestimated the residuum contour by mean biases of 1.75 mm (0.23%) and 3.5 mm (0.25%) for Sense 3D- and Kinect-generated models respectively. These values represent the differences between dimensions obtained from the scans and from the tape, averaged along the residual limbs and among subjects. To provide clinical context regarding what would be an acceptable deviation, it is interesting to analyze previous investigations in terms of lower limb socket manufacturing. Mehmood et al. [39] reported a mean difference of 1.2% in circumference measurements between a conventionally-made cast (prior to any modifications) and the corresponding residuum, for a person with transtibial amputation. Similarly, an averaged overestimation of 1.26% in girth dimensions of positive casts relative to stumps can be inferred from the discoveries of Hajiaghaei et al. [40]. The mean biases observed in the present work for the low-cost 3D scanners lied below these previous recordings related to the traditionally used method for residual limb shape capture. Besides, the results also presented excellent correlation with tape-measured values, indicated by High Pearson coefficients, and remained smaller than the relative differences between scan-generated and manual measurements found by previous studies for thigh, knee, and calf circumferences [11],[41]. These findings could constitute possible indicators of clinical acceptance for the studied digitizers. However, when the data dispersion was analyzed through Bland-Altman plots, broad intervals were observed. Even though the presented discrepancies, greater for Kinect-generated models, were not statistically significant, it is important to highlight that strict limits must be defined when it comes to designing a perfectly fitted prosthetic or orthotic device. Future studies must consider adequation to the maximum error allowed by international standards [42],[43]. Despite being costly, another interesting evaluation to be further conducted would be to design and manufacture socket prototypes from the obtained scans and ask the same participants to don such devices for assessing comfort and quality of fitting. This approach would provide complementing means for verifying if the scan-derived measurements are acceptable for clinical practice in prosthetics design.

By analyzing the position of each measurement in the residual limb, the stump length was the most divergent dimension between Sense 3D scanner and manual anthropometry. Two of the four samples related to this variable were outside the 95% limits of agreement range. For measurements obtained from Kinect-generated scans, no tendency was detected in terms of location, but the samples corresponding to participant P3 presented the highest deviations. This observation suggests that the accuracy of Kinect scans in replicating circumferential measurements of residual lower limbs is subject-dependent. It is not conclusive, however, which factors determine whether a specific person is easier to scan than another, but some interesting aspects to be analyzed in further research are the residuum shape (if it is highly uniform or contains abrupt variations) and the subject ability to maintain the stump still during the acquisition protocol. If the data points related to Kinect scans of participant P3 were considered as outliers ad removed from the statistical analysis, the stump length would be the most deviated dimension, relative to the corresponding manual measurement. This pattern was observed for both digitizers and might have been caused by possible orientation differences between the tape measure and the line used as reference for obtaining the lengths in the virtual models. The extraction of a higher number of circumferential measurements, obtained from more closely-spaced cross-sections, might provide a more accurate representation of the residual limb without the need of capturing length.

For volume estimations, the propagation of errors in circumferential measurements generated mean deviations of 1.07% and 2.54% for Sense 3D and Kinect, respectively. These differences are larger than those previously reported in a study that analyzed the validity of girth measurement for residual limb volume calculation [34], but are comparable to preceding works that evaluated the accuracy of CAD/CAM technologies for assessing stump volume [4],[39],[44]. Limits for clinical acceptance in terms of volume change have also been suggested. Lilja et al. [25] discussed that volumetric fluctuations above 5% influence prosthetic fitting, requiring compensation and possible new prescriptions. In the present work, relative differences in limb volume between estimations from Sense 3D scans and from manual measurements remained below the 5% threshold for all the participants. For Kinect models, half of the analyzed stumps exceeded the maximum desired volume variation.

The reported deviations observed for some dimensions do not invalidate the studied equipment for the proposed application. A source of error might arise from the test protocol itself, which required the participants to remain in a one-legged support position for a few minutes. Even though the use of crutches improved postural balance, muscle fatigue still occurred in some cases, causing the resulting models to be displaced from their original positions. On the other hand, a sitting test position could not have been implemented, since it would complicate the posture maintenance and require greater muscle contractions. Besides, an operational problem would arise in this case. Sense 3D scanner requires a minimum distance of 38 cm from the region of interest for an appropriate functioning [26]. If the participants were seated, the device would need to be close to the ground while scanning the posterior side of the residual limb. This would cause the distance between the digitizer and the stump to be shorter than the suggested minimum.

A handheld approach in which the observer rotates the scanner around the region of interest has made the protocol susceptible to operational inaccuracies. This factor was especially observed during Kinect usage, when a higher level of instability was present: moving the sensor slightly faster caused the Kinect Fusion software to crash and the protocol to be repeated. In some cases, the adopted resolution needed to be decreased for the model to be smoothly completed. Future efforts can be directed towards the development of custom-made holding platforms, in which the scanners can be assembled and automatically rotated around the desired region at a predefined speed, with minimal interference from the observer.

When it comes to model visual quality, the main problem observed was that the medial sides of the lower limbs (residual and sound) were merged at their proximal ends for transfemoral geometries. Such limitation, as well as eventual missing parts, needed to be fixed during post-processing, which introduces girth measurement errors and might justify the higher deviations observed for greater magnitude cross-sectional perimeters. There were no significant differences in skin tone among the four participants, and therefore no performance discrepancies were identified in this aspect for the analyzed digitizers. The residual limb shape and scars positioning also did not generate detectable divergences in terms of ease of geometry acquisition. Further studies with a greater number of participants might provide more enlightenment regarding the influence of these and other optical factors on the scanning process. A post-processing circumstance that must be highlighted is that the authors were not blinded to the tape measure data when geometry repairs were performed nor when cross-sections were delimited. Even though care was taken not to bias measurements obtained from the scans, having access to the target values is a limitation and might have influenced the results. A stricter post-processing protocol, with parametrized and automatized steps, would make the process more reliable and less susceptible to human errors.

Overall, both systems and software are user-friendly, requiring nothing but a computer with at least 2GB of RAM to establish the connection through a USB port. However, some limiting factors might impair clinical implementation. Sense's cable is short, narrowing the allowed range of motion and demanding the computer to be rotated along with the scanner around the region of interest. This setup might be time-consuming and troublesome if executed without assistance. For Kinect usage, a power supply is necessary, which generates an entanglement of wires that eventually caused the protocol to collapse. In a clinical context, this side effect would require a protocol of effective safety measures to extinguish tripping hazards. The observed scanning times were similar for both digitizers and slightly higher than the time required for taking manual measurements.

The emergence of CAD/CAM technologies has enriched the traditional process of fabricating prosthetics and orthotics, equipping practitioners with tools that aid decision-making [4]. However, accurate, consolidated, high-level 3D scanners are expensive and non-affordable, especially for the realities of developing countries. The preliminary results shown in this work suggest that the two evaluated low-cost digitizers presented a good agreement with manual measurements for replication of residual limb dimensions. The high deviations from the mean reinforce the need for stricter data collection protocols that overcome the observed limitations related to handholding the studied devices and to standing test positions. Besides, greater sample sizes and scanning repetitions might improve statistical reliability.

The results are promising but are not enough to support the immediate implementation of Sense 3D and Kinect scanners for replicating residual limbs dimensions. This study was concerned with the validity of the studied low-cost digitizers against manual measurements, but future research is required towards more robust analysis. The limited sample size was an obstacle to drawing conclusions whether the scanning easiness is subject-dependent. The extraction of manual measurements without proper tape tension control might have influenced readings as a consequence of undesired soft tissue deformation for less stiff stumps. When it comes to scans post-processing, the adopted procedure was highly based on visual observations and on the observer's judgments. This subjective approach might be impractical for clinical practice, requiring practitioners to be highly trained on the used software. Further efforts directed towards implementing more parametrized modifications in the 3D models might make the process less susceptible to human errors. Even though inter-rater and intra-rater reliability were not assessed in this work, they must be evaluated before any recommendations of use are made, since consistency in measurements is essential for designing proper lower limb prosthetics fittings.

## 5 CONCLUSION

The Sense 3D scanner and the Microsoft Kinect v2 sensor presented a good agreement with traditional anthropometry techniques in replicating residual limb measurements. The studied digitizers overestimated the analyzed dimensions by mean biases of 0.23% and 0.25%, respectively, lying within the established threshold for clinical acceptance. The performed paired t-tests indicated no significant differences between measurements provided by the compared methods, and the calculated Pearson coefficients demonstrated strong correlations between data sets. Therefore, the evaluated digitizers are useful low-cost tools in replicating the residual limb dimensions, potentially contributing to the prosthetics and orthotics design process. However, the presented results are preliminary and do not constitute a strong enough basis to support immediate clinical implementation. Further studies can provide protocol improvements, especially in terms of sample size, scanning repetitions, test position, and movement of the device, possibly enlightening the observed data dispersion issues.

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*Alina S. L. Rodrigues*, https://orcid.org/0000-0003-0908-1962
*Marina C. Oliveira*, https://orcid.org/0000-0003-4143-3745
*Alana E. F. Da Gama*, https://orcid.org/0000-0002-2092-8688

## REFERENCES

[1] Sinha, R.; van den Heuvel, W. J. A.; Arokiasamy, P.: Factors affecting quality of life in lower limb amputees, Prosthetics and Orthotics International, 35(1), 2011, 90–6.

https://doi.org/10.1177/0309364610397087.
[2] Colombo, G.; Filippi, S.; Rizzi, C.; Rotini, F.: A new design paradigm for the development of custom-fit soft sockets for lower limb prostheses, Computers in Industry, 61(6), 2010, 513–23. https://doi.org/10.1016/j.compind.2010.03.008.
[3] Dickinson, A. S.; Steer, J. W.; Worsley, P. R.: Finite element analysis of the amputated lower limb: a systematic review and recommendations, Medical Engineering and Physics, 43, 2017, 1–18. https://doi.org/10.1016/j.medengphy.2017.02.008.
[4] Seminati, E.; Talamas, D. C.; Young, M.; Twiste, M.; Dhokia, V.; Bilzon, J. L. J.: Validity and reliability of a novel 3D scanner for assessment of the shape and volume of amputees' residual limb models, PloS One, 12(9), 2017, e0184498. https://doi.org/10.1371/journal.pone.0184498.
[5] Quintero-Quiroz, C.; Pérez, V. Z.: Materials for lower limb prosthetic and orthotic interfaces and sockets: Evolution and associated skin problems, Revista de La Facultad de Medicina, 67(1), 2019, 117–25. https://doi.org/10.15446/revfacmed.v67n1.64470.
[6] Paternò, L.; Ibrahimi, M.; Gruppioni, E.; Menciassi, A.; Ricotti, L.: Sockets for limb prostheses: a review of existing technologies and open challenges, IEEE Transactions on Biomedical Engineering, 65(9), 2018, 1996–2010. https://doi.org/10.1109/TBME.2017.2775100.
[7] Chen, R. K.; Jin, Y.; Wensman, J.; Shih, A.: Additive manufacturing of custom orthoses and prostheses—a review, Additive Manufacturing, 12, 2016, 77–89. https://doi.org/10.1016/j.addma.2016.04.002.
[8] Aherwar, A.; Singh, A.; Patnaik, A.: A review paper on rapid prototyping and rapid tooling techniques for fabrication of prosthetic socket, High Value Manufacturing: Advanced Research in Virtual and Rapid Prototyping, CRC Press, Boca Raton, FL, 2013, 345–53. https://doi.org/10.1201/b15961-64.
[9] Barrios-Muriel, J.; Romero-Sánchez, F.; Alonso-Sánchez, F. J.; Rodriguez Salgado, D.: Advances in orthotic and prosthetic manufacturing: a technology review, Materials, 13(2), 2020, 295. https://doi.org/10.3390/ma13020295.
[10] Dickinson, A. S.; Donovan-Hall, M. K.; Kheng, S.; Bou, K.; Tech, A.; Steer, J. W.; et al.: Selecting Appropriate 3D Scanning Technologies for Prosthetic Socket Design and Transtibial Residual Limb Shape Characterization, JPO: Journal of Prosthetics and Orthotics, 2021, https://doi.org/10.31224/osf.io/s4kbn.
[11] Bragança, S.; Arezes, P.; Carvalho, M.; Ashdown, S. P.; Castellucci, I.; Leão, C.: A comparison of manual anthropometric measurements with Kinect-based scanned measurements in terms of precision and reliability, Work, 59(3), 2018, 325–39. https://doi.org/10.3233/WOR-182684.
[12] Lindell, E.; Tingsvik, H.; Guo, L.; Peterson, J.: 3D body scan as anthropometric tool for individualized prosthetic socks, Autex Research Journal, 2021, https://doi.org/10.2478/aut-2021-0007.
[13] Geil, M.: Consistency, precision, and accuracy of optical and electromagnetic shape-capturing systems for digital measurement of residual-limb anthropometrics of persons with transtibial amputation, Journal of Rehabilitation Research & Development, 44(4), 2007, 515–24. https://doi.org/10.1682/jrrd.2006.08.0088.
[14] Armitage, L.; Kark, L.; Czerniec, S.; Kwah, L. K.: Reliability and validity of measurement tools for residual limb volume in people with limb amputations: a systematic review, Physical Therapy, 99(5), 2019, 612–26. https://doi.org/10.1093/ptj/pzz010.
[15] Bragança, S.; Arezes, P. M.; Carvalho, M.: An overview of the current three-dimensional body scanners for anthropometric data collection, Occupational Safety and Hygiene III, 2015, 149–54. https://doi.org/10.1201/b18042-32.
[16] Dessery, Y.; Pallari, J.: Measurements agreement between low-cost and high-level handheld 3D scanners to scan the knee for designing a 3D printed knee brace, PloS One, 13(1), 2018, 1–14. https://doi.org/10.1371/journal.pone.0190585.
[17] Colombo, G.; Rizzi, C.; Regazzoni, D.; Vitali, A.: 3D interactive environment for the design of

medical devices, International Journal on Interactive Design and Manufacturing (IJIDeM), 12(2), 2018, 699–715. https://doi.org/10.1007/s12008-018-0458-8.
[18] Armitage, L.; Kwah, L. K.; Kark, L.: Reliability and validity of the iSense optical scanner for measuring volume of transtibial residual limb models, Prosthetics and Orthotics International, 43(2), 2019, 213–20. https://doi.org/10.1177/0309364618806038.
[19] Bragança, S.; Carvalho, M.; Xu, B.; Arezes, P.; Ashdown, S.: A validation study of a kinect based body imaging (KBI) device system based on ISO 20685:2010. Fifth Int. Conf. Exhib. 3D Body Scanning Technol., 2014, p. 372–7.
[20] Jaeschke, L.; Steinbrecher, A.; Pischon, T.: Measurement of waist and hip circumference with a body surface scanner: feasibility, validity, reliability, and correlations with markers of the metabolic syndrome, PloS One, 10(3), 2015, e0119430. https://doi.org/10.1371/journal.pone.0119430.
[21] Koepke, N.; Zwahlen, M.; Wells, J. C.; Bender, N.; Henneberg, M.; Rühli, F. J.; et al.: Comparison of 3D laser-based photonic scans and manual anthropometric measurements of body size and shape in a validation study of 123 young Swiss men, PeerJ, 5, 2017, e2980. https://doi.org/10.7717/peerj.2980.
[22] Lu, J.-M.; Wang, M.-J. J.: The evaluation of scan-derived anthropometric measurements, IEEE Transactions on Instrumentation and Measurement, 59(8), 2010, 2048–54. https://doi.org/10.1109/TIM.2009.2031847.
[23] Telfer, S.; Gibson, K. S.; Hennessy, K.; Steultjens, M. P.; Woodburn, J.: Computer-aided design of customized foot orthoses: reproducibility and effect of method used to obtain foot shape, Archives of Physical Medicine and Rehabilitation, 93(5), 2012, 863–70. https://doi.org/10.1016/j.apmr.2011.12.019.
[24] Dickinson, A. S.; Steer, J. W.; Woods, C. J.; Worsley, P. R.: Registering a methodology for imaging and analysis of residual-limb shape after transtibial amputation, Journal of Rehabilitation Research and Development, 53(2), 2016, 207–18. https://doi.org/10.1682/JRRD.2014.10.0272.
[25] Lilja, M.; Johansson, S.; Öberg, T.: Relaxed versus activated stump muscles during casting for trans-tibial prostheses, Prosthetics and Orthotics International, 23(1), 1999, 13–20. https://doi.org/10.3109/03093649909071606.
[26] 3D Systems.: Sense 3D scanner user guide. 2014.
[27] Moretti, F.: One Hand for Syria: 3d printed prosthetic limbs for Damascus University, 2017, https://www.3dwasp.com/en/one-hand-for-syria-3d-printed-prosthetic-limbs-for-damascus-university/. https://www.3dwasp.com/en/one-hand-for-syria-3d-printed-prosthetic-limbs-for-damascus-university/ (accessed July 4, 2019).
[28] Paolis, D.; Hofmann.: Augmented Reality, Virtual Reality, and Computer Graphics. Springer International Publishing; 2018.
[29] Gonzalez-Jorge, H.; Rodríguez-Gonzálvez, P.; Martínez-Sánchez, J.; González-Aguilera, D.; Arias, P.; Gesto, M.; et al.: Metrological comparison between Kinect I and Kinect II sensors, Measurement, 70, 2015, 21–6.
[30] Sanders, J. E.; Harrison, D. S.; Cagle, J. C.; Myers, T. R.; Ciol, M. A.; Allyn, K. J.: Post-doffing residual limb fluid volume change in people with trans-tibial amputation, Prosthetics and Orthotics International, 36(4), 2012, 443–9. https://doi.org/10.1177/0309364612444752.
[31] Giavarina, D.: Understanding Bland-Altman analysis, Biochemia Medica: Biochemia Medica, 25(2), 2015, 141–51. https://doi.org/10.11613/BM.2015.015.
[32] Bland, J. M.; Altman, D. G.: Measuring agreement in method comparison studies, Statistical Methods in Medical Research, 8(2), 1999, 135–60. https://doi.org/10.1177/096228029900800204.
[33] Sanders, J. E.; Fatone, S.: Residual limb volume change: systematic review of measurement and management, Journal of Rehabilitation Research and Development, 48(8), 2011, 949–86. https://doi.org/10.1682/jrrd.2010.09.0189.
[34] Boonhong, J.: Validity and reliability of girth measurement (circumference measurement) for

calculating residual limb volume in below knee amputees, 2004,.
[35] Sukul, D. K.; Den Hoed, P. T.; Johannes, E. J.; Van Dolder, R.; Benda, E.: Direct and indirect methods for the quantification of leg volume: comparison between water displacement volumetry, the disk model method and the frustum sign model method, using the correlation coefficient and the limits of agreement, Journal of Biomedical Engineering, 15(6), 1993, 477–80. https://doi.org/10.1016/0141-5425(93)90062-4.
[36] Geil, M.: Consistency and accuracy of measurement of lower extremity amputee anthropometrics, Journal of Rehabilitation Research & Development, 42(2), 2005, 131–40. https://doi.org/10.1682/jrrd.2004.05.0054.
[37] Lee, W. C. C.; Zhang, M.: Using computational simulation to aid in the prediction of socket fit: a preliminary study, Medical Engineering and Physics, 29, 2007, 923–9. https://doi.org/10.1016/j.medengphy.2006.09.008.
[38] Sanders, J. E.; Harrison, D. S.; Allyn, K. J.; Myers, T. R.: Clinical utility of in-socket residual limb volume change measurement: Case study results, Prosthetics and Orthotics International, 33(4), 2009, 378–90. https://doi.org/10.3109/03093640903214067.
[39] Mehmood, W.; Abd Razak, N. A.; Lau, M. S.; Chung, T. Y.; Gholizadeh, H.; Abu Osman, N. A.: Comparative study of the circumferential and volumetric analysis between conventional casting and three-dimensional scanning methods for transtibial socket: A preliminary study, Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine, 233(2), 2019, 181–92. https://doi.org/10.1177/0954411918816124.
[40] Hajiaghaei, B.; Ebrahimi, I.; Kamyab, M.; Saeedi, H.; Jalali, M.: A comparison between the dimensions of positive transtibial residual limb molds prepared by air pressure casting and weight-bearing casting methods, Medical Journal of the Islamic Republic of Iran, 30, 2016, 341.
[41] Simenko, J.; Cuk, I.: Reliability and Validity of NX-16 3D Body Scanner, International Journal of Morphology, 34(4), 2016, https://dx.doi.org/10.4067/S0717-95022016000400053.
[42] International Organisation for Standardization.: ISO 20685-1:2018 - 3-D Scanning Methodologies for Internationally Compatible Anthropometric Databases. International Organisation for Standardization; 2018.
[43] Stewart, A. D.; Sutton, L.: Body composition in sport, exercise and health. Routledge; 2012.
[44] Johansson, S.; Oberg, T.: Accuracy and precision of volumetric determinations using two commercial CAD systems for prosthetics: a technical note, Journal of Rehabilitation Research and Development, 35(1), 1998, 27.