



Original Article

The Validity and Reliability of a low-cost handheld 3D Scanner for Use in Orthotics and Prosthetics

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ABSTRACT

Background: 3D scanners are used to obtain three-dimensional (3D) shapes of body parts, offering an alternative to conventional techniques such as casting and a variety of potential advantages. However, 3D scanners are usually very expensive and not affordable and accessible for most orthotists and prosthetists, especially in developing countries. Therefore, this study aimed to evaluate the validity and reliability of a low-cost handheld and affordable 3D scanner (3Dsystems, 'sense') for use in orthotics and prosthetics.

Methods: The validity and reliability of the 3D Sense scanner were assessed through repeated scanning and measurement of the predefined circumferences of the stumps of four transtibial amputees and 8 body cast models. Two assessors performed digital scanning and tape measurement on two different days, each consisting of three trials per condition/day. The reliability of the 3D sense scanner was assessed by investigating between trials, the assessors, and day reliability using Intraclass Correlation Coefficients. The standard error of measurement (SEM) was also calculated to assess measurement error. The validity of the 3D sense scanner was assessed using correlation analysis, mean percentage error (the mean differences between scanner and tape measure), and Bland-Altman statistics.

Results: The 3D Sense scanner provides stumps and body cast model measurements with similar reliability to the tape measure. Reliability coefficients for the 3D scanner are relatively high (ICC). The ICCs all are near 1.0 and SEMs all range from 0.06 to 0.10. The 3D Sense scanner demonstrated excellent validity. There was a significant positive correlation between the 3D scanner and tape measure for both stumps and body cast models measurements ($r > 0.850$; $P < 0.0001$). The measurement error between the 3D scanner and tape measure is very low as indicated by mean differences close to zero.

Conclusions: This study introduces a low-cost handheld and affordable 3D scanner, which has proven to be a valid and reliable clinical tool in orthotics and prosthetics. This 3D scanner would have extensive and powerful clinical applicability resulting in valid and reliable digital information of body segments for computer-aided design (CAD) of orthotics and prosthetics.

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Introduction

The recent standards of orthotics and prosthetics (O&P) services prepared by the world health organization (WHO) emphasized that O&P services must be affordable, accessible, effective, efficient, safe and of the highest possible quality [1]. According to a WHO report in 2005, only about 5% of 40 million amputees in developing countries had access to prosthetic care [2] amongst whom 30 to 50% of them have not been regular users of their prostheses, mainly due to limited functionality, discomfort and cost [3].

Customized orthoses and prostheses are recognized as the gold standard in services offering the advantages of individualized prescriptions compared to prefabricated devices [4]. Conventional techniques such as foam and plaster casting methods are frequently used in clinical practice, however, clinical observations and research findings indicate shortcomings such as technical errors, them being time-consuming and cumbersome, dependency on a high level of proficiency and experience, having poor interrater reliability, and finally increased costs [5].

The introduction of computer-aided technologies, including 3D scanners, are used to obtain three dimensional (3D) shapes of body parts offering an alternative to the conventional techniques and a variety of potential advantages [6]. They are widely recognized as the best practice methods in orthoses and prostheses manufacturing and reported to have high accuracy, consistency, fast performance, value for money, ease of use, improved adaptation, they are clean and finally recognized as a good service model in comparison to fabricated orthoses and prostheses using traditional methods such as casting [4].

According to the WHO, appropriate orthotics and prosthetics technology is defined as 'systems that provide fit and alignment that suit the needs of the individual and can be sustained by the country at the lowest price' [6]. However, 3D scanners introduced in the literature are normally very expensive, some costing tens of thousands of dollars and not affordable and accessible for most orthotists and prosthetists, especially in developing countries [7]. They likewise require specialized mastery in the checking procedure and access to PCs and expound handling programming. A potential option is the Sense 3D scanner (3D Systems, USA) which retails for just US\$350 and utilization is straightforward in handling programming to catch geometric portrayals of an item.

Therefore, the aim of this study was to evaluate the validity and reliability of a low-cost handheld and affordable 3D scanner (3Dsystems, 'sense') for use in orthotics and prosthetics.

Methods

In this observational study, the validity and reliability of the 3D Sense scanner were assessed through repeated scanning and measurement of the stumps of four transtibial amputees (3 males) and 8 body cast models

including 3 transtibial stumps, one forearm stump, 3 arms for Sarmiento brace and one for ankle-foot orthosis (AFO).

Isfahan University of Medical Sciences granted ethical approval and all study participants provided informed consent. Four amputees participated in this study voluntarily. They used silicone liners with a shuttle lock as the prosthesis suspension mechanism.

The digital scanning was performed with a 1st generation Sense (3D Systems, Rock Hill, SC, USA), a 3D portable and Structured light scanner. The device was connected to a laptop by USB type 2 cable and Sense v.3.0.209 software was used to scan with colored texture. The working range of the scanner is 0.2 to 2 meter and the accuracy is 1 millimeter, based on the manufacturer's claims. When the geometry is registered, the client strolls gradually around the object to capture the majority of its highlights. The scanner at this point uses the captured pictures to make a three-dimensional model and then was exported as the (.stl) format.

For the validity assessment of the scanner, a standard tape measure was used in the study.

Two assessors performed digital scanning and tape measure on two different days, each consisting of three trials. Assessors scanned the stumps and body cast models and measured the predefined circumferences with a normal tape measure (1 mm sensitivity). Assessors were orthotics and prosthetics practitioners. To ensure the similar method in obtaining 3D scans, each examiner undertook a single training session, before data collection for learning positioning, movement and also the condition of lighting based on the manufacturer's guideline [8]

In terms of scanning of the stumps of amputees in each session, the participants donned their own silicon liner. Then, they lay on a bed in a supine position with 30 degrees of hip flexion and held their knees in a comfortable position. Long paper tape was stuck on their liner longitudinally and a metal goniometer was used, 5 cm intervals were marked from the tip of the liner by each assessor (Figure 1). Then digital scanning was conducted three times per condition.

As for the body cast models, they were fixed on the corner of a table by a metal clamp and the same marking and scanning process was conducted by each assessor three times per condition (Figure 1).

The parameters of interests were circumferences at the five-centimeter intervals. The parameters were measured by tape three times per session. Then the assessors used Rhinoceros v.5.13 (McNeel Inc., North America) software to measure the circumferences from digital scans (Figure 2).

SPSS v.23 (IBM Corp., Armonk, NY, USA) was used for statistical analysis. Shapiro-Wilk statistic was employed to check the normality of the distribution of selected variables. Parametric tests were employed in cases of normal distribution. Reliability of the Sense scanner and tape measure were assessed by investigating between trials, the assessors, and day reliability using mean differences (stated as the percentage of



Figure 1: Preparation, tape measurement and scanning of stumps and body cast models

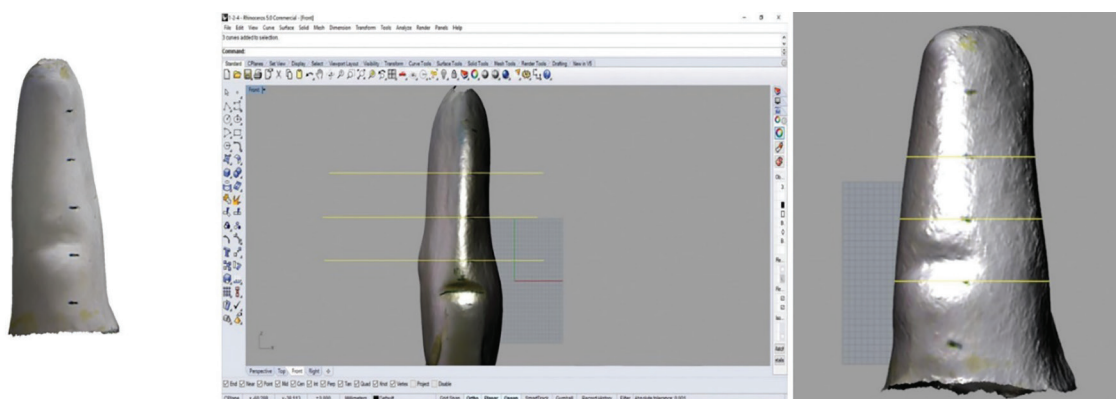


Figure 2: Digital measurements from 3D models of stumps and body cast models

differences relative to the first circumferences measures) and Intraclass Correlation Coefficients (ICC) with 95% confidence intervals (CI). The standard error of measurement (SEM) was also calculated to assess measurement error. The validity of the sense scanner was assessed using bivariate correlation analysis, mean percentage error (the mean differences between scanner and tape measure), and Bland-Altman statistics were adopted to assess the agreement between the sense scanner and tape measure and to examine the validity of the sense scanner.

Results

The overall mean age (SD) of the amputee participants was 39 ± 0.82 years, the mean weight was 90 ± 4.08 Kg and the mean height was 1.65 ± 9.13 m. We had 432 sets of data ((4 stumps and 8 body cast models) X 3 circumferences X 2Assessors X 2Days X 3Trials).

Reliability of the TAPE MEASURE

The results of repeatability analysis and SEM values for the tape measurement of body cast models and stumps are presented in Table 1. This table identifies the mean differences, stated as the percentage of differences relative to the first circumference measurement. ICC and SEM values of circumference measurements of body cast models and stumps were obtained with a tape measure for between trials. (between three trials of assessor 1 day 1 (A1D1), assessor 1 day 2 (A1D2), assessor 2 day 1 (A2D1) and assessor 2 day 2 (A2D2)), between days (A1D1 versus A1D2, A2D1 versus A2D2) and between assessors (A1D1 versus A2D1, A1D2 versus A2D2).

In terms of between trials repeatability analysis of

body cast models measurements, the mean differences range from 0.02 ± 0.14 % to 0.11 ± 0.3 %. The ICC values are all equal 1.0 and SEMs are equal zero %, which means the highest possible degrees of repeatability. The results of between trials repeatability analysis of stump measurements show the mean differences range from 0.14 ± 0.26 % to 0.24 ± 0.35 %. The ICC values are all close to 1.0 and SEMs range from zero % to 0.01 %.

In terms of between days repeatability analysis of body cast models measurements, the mean differences range from 0.07 ± 0.14 % to 0.31 ± 0.70 %. The ICC values are all close to 1.0 and SEMs range from zero % to 0.02 %. The results of between days repeatability analysis of stumps measurements show the mean differences range from 0.28 ± 0.45 % to 8.21 ± 9.74 %. The ICCs vary between 0.579 to 1.0 and SEMs range from zero % to 6.32%.

In terms of between assessors repeatability analysis of body cast models measurements, the mean differences range from 0.10 ± 0.23 % to 1.14 ± 0.33 %. The ICC values are all equal 1.0 and SEMs are all equal zero %. The results of between assessors' repeatability analysis of stump measurements show the mean differences range from 0.28 ± 0.22 % to 0.55 ± 0.62 %. The ICCs are all close to 1.0 and SEMs range from zero % to 0.04 %.

Reliability of the Digital Scanner

The results of reliability analysis and SEM values for the digital scanning measurements of body cast models and stumps are presented in Table 2.

In terms of between trial reliability analysis of body cast models measurements, the mean differences range from 1.31 ± 0.91 % to 1.45 ± 1.20 %. The ICC values are all near 1.0 and SEMs range from 0.03% to 0.04 %. The results of between trials reliability analysis of stumps

Table 1: The mean differences stated as the percentage of differences relative to the first measurement, ICC and SEM of circumferences of body cast models and stumps obtained from the tape measure. A: assessor, D: day

		CAST	STUMP
		Circumferences	Circumferences
Between Trials	A1D1	0.05±0.23	0.18±0.27
		ICC=1	ICC=1
		SEM=0	SEM=0
	A1D2	0.11±0.3	0.21±0.33
		ICC=1	ICC=0.999
		SEM=0	SEM=0.01
	A2D1	0.11±0.49	0.24±0.35
		ICC=1	ICC=1
SEM=0		SEM=0	
A2D2	0.02±0.14	0.14±0.26	
	ICC=1	ICC=0.999	
	SEM=0	SEM=0.01	
Between Days	A1D1 - A1D2	0.18±0.63	8.21±9.74
		ICC=0.999	ICC=0.579
		SEM=0.02	SEM=6.32
	A2D1 - A2D2	0.31±0.72	7.58±9.7
		ICC=0.999	ICC=0.595
		SEM=0.022	SEM=6.17
Between Assessors	A1D1 - A2D1	0.10±0.23	0.28±0.22
		ICC=1	ICC=1
		SEM=0	SEM=0
	A1D2 - A2D2	1.14±0.33	0.55±0.62
		ICC=1	ICC=0.996
		SEM=0	SEM=0.04

Table 2: The mean differences stated as the percentage of differences relative to the first measurement, ICC and SEM of circumference measurements of body cast models and stumps are obtained from the 3D scanner. A: assessor, D:day

		Cast	Stump
		Circumference	Circumference
Between Trials	A1D1	1.45±0.97	1.13±0.89
		ICC=0.999	ICC=0.998
		SEM=0.03	SEM=0.04
	A1D2	1.31±0.91	1.43±1.3
		ICC=0.999	ICC=0.994
		SEM=0.03	SEM=0.1
	A2D1	1.37±1.01	1.56±1.25
		ICC=0.999	ICC=0.996
		SEM=0.03	SEM=0.08
	A2D2	1.45±1.20	1.41±1.35
		ICC=0.999	ICC=0.991
		SEM=0.04	SEM=0.13
Between Days	A1D1 - A1D2	1.15±0.82	1.86±1.55
		ICC=0.999	ICC=0.763
		SEM=0.02	SEM=0.72
	A2D1 - A2D2	2.43±1.46	1.62±1.51
		ICC=0.997	ICC=0.781
		SEM=0.08	SEM=0.63
Between Assessors	A1D1 - A2D1	1.61±1.33	1.73±1.66
		ICC=0.999	ICC=0.996
		SEM=0.04	SEM=0.10
	A1D2 - A2D2	2.32±1.56	1.61±1.32
		ICC=0.998	ICC=0.995
		SEM=0.07	SEM=0.10

measurements show the mean differences range from 1.13±0.89 % to 1.56±1.25 %. The ICC values are all close to 1.0 and SEMs range from 0.04 % to 0.13 %.

In terms of between days reliability analysis of body cast models measurements, the mean differences range from 1.15±0.14 % to 2.43±0.35 %. The ICC values are all close to 1.0 and SEMs range from 0.02 % to 0.08 %. The results of between days reliability analysis of stumps measurement show the mean differences range from 1.62±1.36 % to 1.86±1.55 %. The ICCs vary between 0.76 to 0.78 and SEMs range from 0.63% to 0.72 %.

In terms of between assessors' reliability analysis of body cast models measurements, the mean differences range from 1.61±1.33 % to 2.32±1.56 %. The ICC values are all close to 1.0 and SEMs range from 0.04 % to 0.07 %. The results of between assessors' reliability analysis of stumps measurement show the mean differences range from 1.61±1.32 % to 1.73±1.66 %. The ICCs are all near 1.0 and SEMs all range from 0.07 to 0.10.

Validity

The results of correlation analysis between

circumference measurements obtained from the 3D scanner and tape measure show a significant positive correlation between the 3D scanner and tape measure for both body cast models ($r>0.956$; $P<0.0001$) and stumps ($r>0.850$; $P<0.0001$).

Table 3 shows the mean, maximum and minimum differences of circumference measurements of body cast models and stumps between 3D Sense scanner and tape measure (stated as the percentage of differences relative to the tape measurement).

In terms of body cast model measurements, the mean differences are less than 1.8% for circumferences parameters. The minimum and the maximum differences between scanner and tape measure are 0.02% and 5.5% for circumference measurements.

In terms of stump measurements, the mean differences are less than 1.6% for circumference measurements. The minimum and the maximum differences between scanner and tape measure are 0 and 0.04 % for circumference measurements.

Figure 3 (A-D) shows Bland-Altman plots with 95% limits of agreement (LOA) for the circumference measurements of body cast models and stumps obtained from the 3D scanner and tape measure.

The central red line represents the mean differences

between the scanner and tape measure with 95% confidence intervals (upper and lower dash lines); the upper and lower Blue lines represent the upper and lower 95% limits of agreement (mean differences \pm 1.96 SD of the differences), respectively. Overall, the measurement error between the 3D scanner and tape measure is very low as indicated by mean differences close to zero. The majority of the values are within the limits of agreement.

Discussion

The recent WHO World Report on Disability concludes that disability disproportionately affects vulnerable populations with a higher prevalence in lower-income countries than in higher-income countries [9].

Advanced 3D technologies such as 3D scanners and additive manufacturing are developing exponentially in the field of orthotics and prosthetics and it is anticipated that orthotics and prosthetists will use 3D handheld surface body scanners daily in the coming years [10]. However, some practitioners are still hesitant to take advantage of these advanced technologies for two fundamental reasons. The first is the expense of 3D scanners and the lack of appropriate technical data about the validity and reliability of low-cost scanners.

Table 3: The mean, maximum and minimum differences of circumferences measurements of body cast models and stumps between the 3D scanner and tape measure (stated as the percentage of differences relative to the tape measurement)

	Differences	Circum 1	Circum 2	Circum 3
Casts	Mean \pm SD	1.8 \pm 1.3	1.7 \pm 1.3	1.6 \pm 1.2
	Maximum	5.5	5.3	5.2
	Minimum	0.02	0.03	0.02
Stumps	Mean \pm SD	1.2 \pm 1.0	1.3 \pm 1.0	1.6 \pm 1.2
	Maximum	3.7	3.8	3.8
	Minimum	0.04	0.03	0

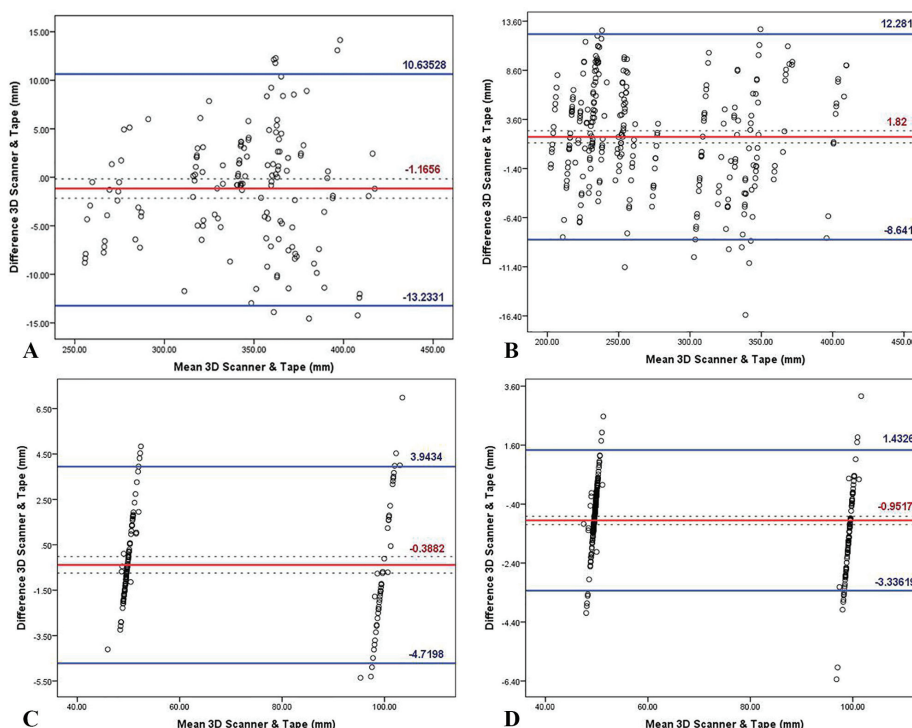


Figure 3: Bland-Altman plots for agreement between the 3D scanner and tape measure for the circumference measures of stumps (A) and body cast models (B) and the length measures of stumps (C) and body cast models (D)

Accordingly, it is important to provide high-quality data to clinicians about the technical aspects of this type of 3D scanner. This study is the first of its kind to demonstrate the utility of a valid and reliable low-cost 3D scanner (3Dsystems, 'sense') in orthotics and prosthetics to determine the quality of data and ensure future clinical application. The findings of the current study have demonstrated the ability of this 3D scanner to precisely record digital information of body segments for CAD.

In the current study, we have stated that tape measures are the reference values for validity analysis because the manual measurement is the technique that is currently being used in clinics to take measurements of body segments for producing orthoses and prostheses and the results of our study showed that this simple and inexpensive method is reliable. For concurrent validity, the 3D Sense scanner has demonstrated good validity compared to the tape measure. Examination of the Bland–Altman plots reveals a small difference in the measured circumference parameters between the two devices. Overall, the 3D Sense scanner demonstrated excellent agreement with the clinical standard of the tape measure.

Our study also showed that the 3D Sense scanner provides stump and body cast models measurements with similar reliability to the tape measure. Reliability coefficients for the 3D Sense scanner appear relatively high. The relatively low values of within and between session SEM during the present study revealed that the random error of measurements was low, showing the high precision of 3D Sense scanner. The relatively higher values of between sessions SEM for stumps in both tape measure and 3D Sense scanner measurements may be due to the stumps positioning or the daily volume fluctuations of stumps as Dickinson mentioned: “the characterization based on scanning of the residual limb itself would be subject to fluctuations in volume that would be strongly influenced by the scanning session protocol” [11].

The validity and reliability of other types of 3D scanners have been investigated in several studies. However, only a few of these studies have reported the same variable (i.e., ICC, mean difference) to allow comparison with the current study. Armitage et al., assessed the reliability and criterion validity of the iSense, a commercial optical scanner for measuring the volume of transtibial residual limb models [12]. The scanner was made by the same manufacturer as the one used in the present study (3Dsystems) but iSense attaches to the camera of an iPad or iPhone and it seems that the ease of use of iSense is more than Sense. They have reported that ICC is more than 0.952 for all intra and inter-rater reliabilities. Their values were excellent as were our reliability analyses ($ICC \geq 0.998$) for the body cast models. The iSense scanner was previously compared with the high-level handheld 3D scanner, EVA (Artec group) in terms of measuring the circumferences of the human knee segment [7]. The bias in EVA vs. manual measurements were less than 2.3% for iSense vs. EVA; while in the current study, the mean differences of circumferences

between the tape measure and 3D Sense scanner is less than 1.8% and 1.6% for casts and stumps, respectively.

Seminati et al. set the Romer scanner (CMS108) as a reference and assessed the validity of EVA Artec scanner for measuring the volume, width, depth and length dimensions of residual limb models and reported the mean difference as less than 0.49 mm (0.36%) [13] but in the current study, these values are less than 1.82 mm (2.1%) for body cast models. They have also reported the reliability results in which all ICC values were more than 0.99 and also absolute bias was less than 0.14% and 0.19% for intra and inter-rater, respectively. In comparison to the current study, we have the same excellent ICC values for body cast models (0.991) but the mean differences are not the same (2.32 % for inter-rater and 2.43% for intra-rater reliability). The Kinect for Xbox 360 (Microsoft corp.) is another low-cost scanner that was compared to the manual measurement method by Taha et al. for measuring the human foot length, width, and circumferences, with a maximum difference of 4.26% [14]. This value is more than our maximum mean-difference 1.6 % in human stumps and 1.8 % in body cast models. They also concluded that the low-cost scanner was accurate in measuring human foot anthropometry. Although both of the scanners (Sense 1st gen. and Kinect 360) have used the PrimeSense depth sensor in their structure [15], it might be concluded that the 3D Sense scanner has greater accuracy. This difference could be due to the different limb or even scanning software [7]. Cau et al. compared lower limb circumferences between the manual tape measure and a high-level handheld 3D scanner, Rodin4D. The mean difference in the total limb volume measures of these methods was less than 0.3 dm³ in the Bland-Altman plots [16]. We did not assess the limb volume.

Dickinson et al. tested the intra rater and inter-rater reliability of three laser scanners (VIUScan GoScan and Sense) on 20 transtibial limb body cast models. All three scanners demonstrated excellent intra-rater ($ICC=0.998$) and excellent inter-rater ($ICC = 0.996$) reliability. The 3D Sense scanner compared with the state of art 3D scanners, had the highest error and was the least tolerant of insufficient lighting and object movement, but it was the most affordable of the three systems [11]. The ICC values of body cast models in the current study are as outstanding as those of Dickinson ($ICC \geq 0.997$).

Additional advantages of the 3D Sense scanner include the fact that it is portable, safe, easy to use, accessible, and affordable. Also, the 3D Sense scanner can detect colors, allowing the identification of anatomical reference points on the skin surface of the patient. This technology fulfills the requirement means of appropriate orthotics and prosthetics technology as defined by the WHO; ‘Systems that provide fit and alignment that suit the needs of the individual and can be sustained by the country at the lowest price [5].

Despite these advantages, the low-cost 3D scanners usually require several attempts to be able to provide valid and reliable data. Inappropriate lighting (indoor versus outdoor lighting), motion (involuntary

movements of the patient), and positioning (scanning outside of the optimal distance range of 38.1 to 152.4 cm) are the main challenges of the low-cost 3D scanners [17]. Furthermore, the 3D scanners have to be used by experienced assessors. Future investigations can investigate the use of increasingly experienced assessors or institutionalizing levels of training [8].

There are several limitations to this study. In the current research, concurrent validity was limited to the tape measure which has its limitations. It is recommended that the scanner be validated with a better measuring tool such as the Artec Eva scanner. Another limitation is the lack of a standard protocol for 3D scanning of lower limb amputees. Our evaluation was limited to 4 transtibial amputees. Further studies are recommended on a larger sample of subjects with concurrent 3D scanning with other clinically routine 3D scanners in orthotics and prosthetics.

Conclusion

This study introduces a low-cost handheld and affordable 3D scanner, which has proved to be a valid and reliable clinical tool in orthotics and prosthetics. This 3D scanner would have extensive and powerful clinical applicability resulting in valid and reliable digital information of body segments for CAD.

Conflict of Interest: None declared.

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