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Clinical usability, reliability, and repeatability of noncontact scanners in measuring residual limb volume in persons with transtibial amputation

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Abstract

Background: In previous studies, noncontact 3D scanners were found to be the most reliable in measuring volume of the residual limb after a transtibial amputation (TTA). Meanwhile newly developed noncontact scanners became available to measure residual limb volume after TTA but should be tested for clinical usability and reliability.

Objective: To determine the clinical usability, reliability, and repeatability of noncontact scanners in measuring residual limb volume in persons with a TTA.

Study design: Original research report; repeated measurements.

Methods: Three noncontact scanners (Rodin4D, Omega Tracer, and Biosculptor) were used to measure the residual limb volume on two occasions by two observers in 30 persons with an unilateral or bilateral TTA. Clinical usability was assessed as scores of the Post-Study System Usability Questionnaire, participant satisfaction (0–10 scale), and time to take the measurement.

Results: The usability score of the Omega Scanner 3D (123.4) and Rodin4D (121.3) was significantly better compared with the Biosculptor (117.8). Participant experience was equal for all. The residual variance was 8.4%, where participant and scanning system explained most of the error variance (80.7%). Repeatability coefficients of the systems were 16.5 cc (Omega Scanner 3D), 26.4 cc (Rodin4D), and 32.8 cc (Biosculptor). The time to perform the measurements was significantly longer (+80 seconds) for the Omega Scanner 3D.

Conclusions For measuring residual limb volume in TT amputees, Omega software (state version 12.2) combined with the Rodin4D scanner was more usable and reliable than the Rodin 4D or Biosculptor systems, when operated by staff with limited experience and training.

Keywords

amputation, CAD/CAM system, transtibial, volume measurement

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Background

To improve functional recovery after transtibial amputation, early mobilization is important in patients. Receiving a good fitting prosthesis and obtaining walking ability in an early stage endorses this importance. Should patients receive a prosthesis too early when residual limb still has too much postoperative edema, wounds may occur on the residual limb resulting in health risks and delaying walking ability. One of the predictors of functioning of persons with a transtibial amputation (TTA) is a good prosthesis fit.[1,2] It remains challenging, however, to measure the residual limb volume accurately, due to person and measurement-related factors such as comorbidity influencing tissue volume (e.g. heart and renal failure), distortion of the residual limb, activity level of the person, change of postdoffing volume, accuracy, and resolution of the system.[3-5] The volume and shape of a residual limb changes over time and becomes more stable several weeks after the amputation, but even in a stable phase, daily fluctuations may occur due to temperature fluctuations in environment and daily changes in activity levels of the person and positioning of the residual limb.[3,6] Clinical methods to measure volume are the water immersion method, circumferential measurements, computed tomography scans, magnetic resonance imaging, or ultrasound measurement.[5,7] No gold standard exists to determine the residual limb volume accurately.[7-9] Previous research compared these different methods on residual limb models and residual limbs of persons with a TTA for research purposes.[7-9] The computer added design (CAD) hand-held scanner (Omega Scanner 3D) had the smallest repeatability coefficient compared with the other methods, in residual limb models and persons with an amputation.[7,8] However, a new generation of hand-held scanners have been developed since those publications. Reliability of these new scanners has been tested on models in a recent study.[9] The CAD systems showed a small difference in repeatability coefficient and usability, so they were reliable in measuring residual limb volume in models.[9] Testing these scanners in persons with a TTA has not yet been performed before, and the question is whether these measurement properties are the same in vivo.

The aim of this study was to determine the clinical usability, reliability, and repeatability of these new generation noncontact scanners (Rodin4D, Omega Scanner 3D, and Biosculptor) in

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measuring residual limb volume in persons with a TTA in repeated measurement research.

Methods

Population

Our study population was selected from a list of persons with a TTA of the Rehabilitation Department of the: Isala Hospital, Zwolle and OIM orthopaedics workshop, Zwolle. Persons were included if they had an unilateral or bilateral TTA, had surgery of the residual limb at least 1 year ago, were at least 18 years of age, and had given informed consent. Exclusion criteria were comorbidity that could influence the residual limb volume (heart failure, kidney disease, deep vein thrombosis, lymphedema, recent fracture, rheumatoid arthritis, complex regional pain syndrome, and dermatologic diseases associated with edema), a wound of the residual limb more than 1 cm in diameter, and/or signs of infection (of which it may clinically be assumed that it would influence the residual limb volume), joint deformity, or weakness of the upper leg were present which makes it impossible to scan the residual limb with the hand-held scanners and insufficient comprehension of the Dutch language to answer questions, follow instructions, or understand the informed consent letter. In case of a bilateral amputation, we scanned both residual limbs for analysis. Because the variance becomes stable in a sample size of at least 30 participants, we aimed to recruit at least 30 residual limbs.[8] The Medical Ethical Committees of the Isala Hospital, Zwolle approved this study. All participants were selected by one physician and tested between April 2017 and December 2017.

Observers

Three observers performed the measurements, two physical therapists working in a rehabilitation center and a resident in rehabilitation medicine. Only the resident had experience with CAD systems due to a former research.[9] One physical therapist performed most measurements. Owing to the absence on two occasions, the therapist was replaced by another. One calibration/training session was held to familiarize the observers with the systems.

Study design

On two occasions, two observers performed the measurements with the three different CAD systems. Each participant was measured 12 times in total. The time between the occasions for individual participants was no more than 2 weeks to diminish the risk of changing volume. In this way, the interobserver and intraobserver reliability could be studied. Before the test occasions, black tape was applied around the residual limb just proximal of the tibial tuberosity since this tuberosity cannot be detected by the scanners. The black tape was the landmark for the measurements as it is not detected by the scanner and thus equal for each observer. In this way, the observers measured the same level of the residual limb. Each residual limb was measured while the person was sitting on the edge of a research table with an extended knee on the amputated side and a foam block underneath the upper leg. Items recorded in Research Data Manager anonymously were as follows: (1) The residual limb volume measured from tibial tuberosity to distal end of the residual limb. (2) Time to perform the measurement per system. (3) Participant's experience grade assessed using a Visual Analog Scale (anchors 1 [unpleasant] and 10 [neutral]). (4) Observer satisfaction, assessed using the Post-Study System Usability Questionnaire (PSSUQ) after each scan. The PSSUQ is a 19-item questionnaire for obtaining user satisfaction of computer systems, using subscales such as overall satisfaction, information quality, interface quality (Cronbach's alpha ranging from 0.83 to 0.96), and system usefulness. Each question has a 7-point scale indicating 1: strongly disagree–7: strongly agree. A higher score indicates a better usability, which is contrary to the original PSSUQ. We chose to use an opposite rating scale because it seemed to be more logical.[9,10] Items of the PSSUQ assess, for example, ease, speed, simplicity, and comfort using the system, efficiency to complete tasks, ability to correct errors, satisfaction with information provided and interface, and simplicity and overall satisfaction with the system.

Scanning systems

The Biosculptor Bioscanner (Biosculptor, Hialeah, Florida) uses a dual-camera laser-line scanner. The residual limb is scanned by a hand-held scanning wand, which uses a motion-tracking device embedded in the scanner.[9]

The Rodin4D O&P Scanner (Rodin4D, Pessac, France) is similar to the Biosculptor Bioscanner but consists of one camera instead of two. Data are imported into the Rodin4D Software to create a 3D view of the residual limb.[9]

The Omega Scanner 3D (Ohio Willow Wood, Mt. Sterling, Ohio) is a hand-held 3D structured light scanner. The scanner picks up distortion in the pattern to determine the shape of the model. The captured images are imported in the Omega Scanner 3D Software (version 12.2) to create a 3D view of the residual limb. Owing to delivery problems, it was not possible to use the scanner itself for this research. The scanner of the Rodin4D was used to capture the images of the residual limb, by converting the image to a directory used by the software of Omega Tracer (version 12.2).[9]

Statistical analysis

Data were checked for a normal distribution using histograms and P-P plots. Non-normally distributed data are reported as median values and interquartile ranges. Because multiple scans were performed on the same participant and to account for autocorrelated data and some missing data, PSSUQ scores and time per scan were analyzed using a multilevel analysis (with a autoregressive first order covariance structure) with participant as the highest level. For the same reason described above also multilevel analysis was conducted to explore the effects of the different measurement conditions (scanning system, observer, and session) on scanning outcomes (residual limb volume). Residuals were checked for a normal distribution. Modified Bland Altman plots were made to visualize the differences (y-axis) against the mean per scanning system (x-axis)[11] because of a systematic measurement differences between scanning systems.

To analyze reliability, main effects, of the measurement conditions (participant, systems, observers and sessions) and their two-way interactions effects, were explored in a variance components analysis (type III ANOVA). Variance components that were negative were set to zero. Error variance was calculated as the sum of the variances of systems, observers, and sessions; their two-way interactions; and the

Table 1. Participant characteristics N (%).		
Gender	**Male**	**22 (73.3%)**
No. of amputations	Unilateral	28 (93.3%)
Amputation side included in analysis	Left	16 (53.3%)
Reason for amputation	Trauma	10 (33.3%)
	Vascular	11 (36.7%)
	Infection	7 (23.3%)
	Others	2 (6.7%)
		Median (IQR)
Age (y)		66.0 (51.8; 73.0)
Time since amputation (y)		5.5. (4.0; 8.3)

residual variance. The contribution of these measurement conditions to the error variance was expressed as a percentage.

The repeatability coefficients for each system were based on one-way ANOVA with the residual limb as factor. The calculation for the repeatability coefficient was as follows: $1.96 \times \sqrt{2} \times \sqrt{\text{residual variance}}$. A smaller repeatability coefficient indicates a more reliable system.

$P < 0.05$ was the significance level set for all the previous calculations. The statistical analyses were completed with IBM SPSS Statistics for Windows, 23; SPSS, Chicago III.

Results

In total, 30 participants with 32 residual limbs met the inclusion criteria. Of those, 28 files were complete and four incomplete (missing one or more measurements because of technical problems with the systems). Two participants had a bilateral amputation. Of the 30 participants, the mean (SD) age was 62.8 (13.8) years (Table 1).

Usability

The Biosculptor showed significantly lower PSSUQ scores than the Rodin4D system (−3.5 points) (Table 2). The Omega Scanner 3D has a higher PSSUQ score than the Rodin4D (+2.1 points), but this was not significant. Occasion (day 1 or 2, 2.9 points) or the observer (−0.9 points) did not have a significant influence on the PSSUQ scores.

The time to perform the measurement was lowest in the Rodin4D system. The measurements using the Omega Scanner 3D took significantly longer (+78.1 seconds) (Table 3). The variable observer was not associated with time needed to perform the measurements. In the second occasion, measurement took 47 seconds less than the first occasion.

Participant experience had a median of 10, only 4 times a 9 was given. Reasons for the participants for not giving a 10 (neutral, no burden of the measurement) were "the laser light is annoying in my face." Another participant with weak quadriceps said that the more measurements performed consecutively, the harder it was to keep the knee straight and the leg lifted.

Reliability

Participant explained 58.2% of the total variance, and the error variance explained 41.8% of the total variance (Table 4). The scanning system explained 53.7% of the error variance. The interaction between scanning system and participant and between occasion (day 1 or 2) and participant explained a smaller part. The residual error explained 20.0% of the error variance. Interactions between participant and scanning system and participant and occasion explained 12.1%, respectively, and 10.3% of the error variance.

Repeatability

Repeatability coefficients ranged from 16.5 cubic centimeter (cc) for the Omega Scanner 3D tot 46.0 cc for observer 2, which means that measurements fall in 95% within a range of ±16.5 cc for the Omega Scanner 3D (Table 5).

The mean volume of the measurements of the Rodin4D system was significantly larger than those of the other systems (Figure 1). For the Biosculptor and the Rodin4D system, the differences from the means were related to the mean values and larger differences were found with larger volumes. This trend was not visible for the Omega Scanner 3D (Figure 2).

Discussion

It is remarkable that we used the camera of the Rodin4D in combination with the software of the Omega Tracer. However, the software is the most important and distinctive part of the procedure.

Usability scores measured with the PSSUQ were highest for the Omega Scanner 3D and Rodin4D. The differences were small, and they seem clinically irrelevant. Particularly, the system failures in the Biosculptor caused lower scores. The usability score seems important for the clinical usability, cause if the observers are not satisfied with how the system works, it will not be used in clinical practice.

Table 2. Results of multilevel analysis to analyze factors influencing Post-Study System Usability Questionnaire scores.

	Estimate	Std error	Sig.	Lower bound	Upper bound
Scanning system					
Rodin 4D[a]	121.3	1.7	<0.001	117.9	124.7
Omega Tracer	2.1	1.4	0.129	−0.6	4.8
Biosculptor	−3.5	1.7	0.041	−6.8	−0.1
Occasion 2	2.9	2.3	0.199	−1.5	7.3
Observer 2	−0.9	1.3	0.495	−3.3	1.6

[a]*Reference categories: Rodin4D, Occasion 1, Observer 1.*

Table 3. Results of multilevel analysis to analyze factors influencing time (seconds) to perform measurements.

	Estimate	Std error	Sig.	Lower bound	Upper bound
Scanning system					
Rodin 4D[a]	356.0	12.9	<0.001	330.4	381.6
Omega Tracer	78.1	12.4	<0.001	53.8	102.5
Biosculptor	12.2	14.8	0.410	−16.9	41.4
Occasion 2	−46.9	17.3	0.007	−80.9	−12.8
Observer 2	5.5	11.1	0.621	−16.4	27.4

[a]*Reference categories: Rodin4D, Occasion 1, Observer 1.*

The Omega Scanner 3D measurements took significantly more time, but the camera of the Rodin4D was used with software of the Omega Tracer. It probably took the observers more time to switch to the other system than it would do with its own camera. Besides, the difference was 78 seconds which probably seems irrelevant in clinical practice although statistically significant. In the second occasion, measurement took 47 seconds less time than the first occasion, suggesting a learning effect of the observers. The time between different measurement days can be of influence on the learning effect which makes small differences in measurement time of the noncontact scanners less relevant.

Table 4. Results of variance estimate components analysis (type III sum of squares).

Variance component	Estimate	% Contribution to total variance	% Contribution to error variance
Participant	441.9	58.2	
Observer	0.2	0.0	0.0
Scanning system	170.7	22.5	53.7
Occasion	2.4	0.3	0.8
Participant * observer[a]	0.0	0.0	0.0
Participant * scanning system	38.5	5.1	12.1
Participant * occasion	32.8	4.3	10.3
Observer * scanning system	0.6	0.1	0.2
Observer * occasion[a]	0.0	0.0	0.0
Scanning system * occasion	9.0	1.2	2.8
Residual	60.4	8.4	20.0
Sum	759.8		
Sum error variance	317.9		
% Error variance	41.8		

Residual variance components: variance that could not be explained by participant, observer, scanning system or occasion, or their interaction effects. Sum: sum of the variance components, Sum error variance: sum of the variance components minus participant variance, % error variance: percentage of contribution of the error variance to the total variance.
[a]*Set to zero because of negative variance components.*

The error variance of 41.8% is high compared with previous research.[8,9] The variance component analysis showed that the subject influenced the variance mainly. This seems logic; every participant has a different residual limb volume. The scanning systems are the second largest influencer of the variance, as already was shown in previous studies.[7-9] Perhaps these differences are related to differences in volume calculations algorithms in the different programs. An interesting difference in residual limb volume is between the Omega Scanner 3D and Rodin4D, as the same camera was used for both. This difference must be related to the software calculations of volume, as none of the other factors had a significant effect.

This influence of the scanning system was also shown in the repeatability coefficients. In general, the Omega Scanner 3D measured smaller volumes and the repeatability coefficient was also small. The Biosculptor measures larger volumes, and the repeatability coefficient was larger. However, the higher a residual limb volume, the less difference in measurement is of influence because the extra volume is divided over a bigger surface. The question remains; which system is more reliable? Seen in Figure 2, the Omega Scanner 3D shows a smaller difference with the mean volume of the participants. The Biosculptor and Rodin4D show a larger difference between the mean and separate measurements. This suggests that the Omega Scanner 3D can be considered to be the most reliable system because the differences between mean and separate measurements were smaller. This outcome was shown in a previous study on residual limb models also.[9]

One of the limitations of this study is that it is not sure what the influence of the bilateral amputation can be on the residual limb volume, especially because the influence of the participant on the variance components is quite large. We excluded data of one of the residual limbs of the bilateral patients in a post hoc sensitivity

Table 5. Repeatability coefficient in cc.

Variable	Repeatability coefficient
Day 1	43.2
Day 2	40.3
Observer 1	43.5
Observer 2	46.0
Biosculptor	32.8
Rodin4D	26.4
Omega Tracer	16.5

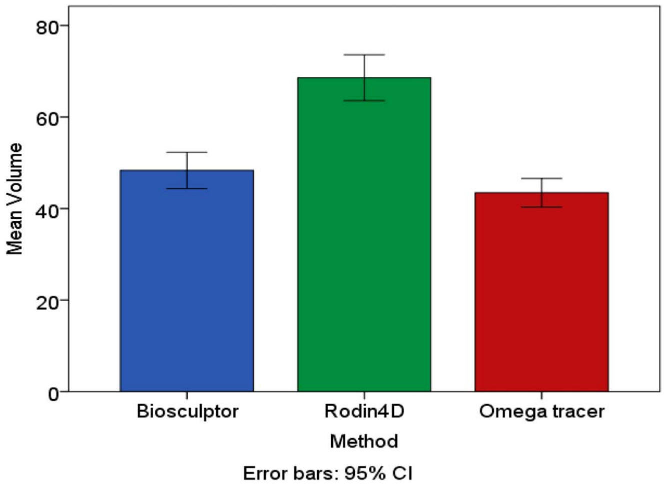

Figure 1. Mean volume per scanning system in cc.

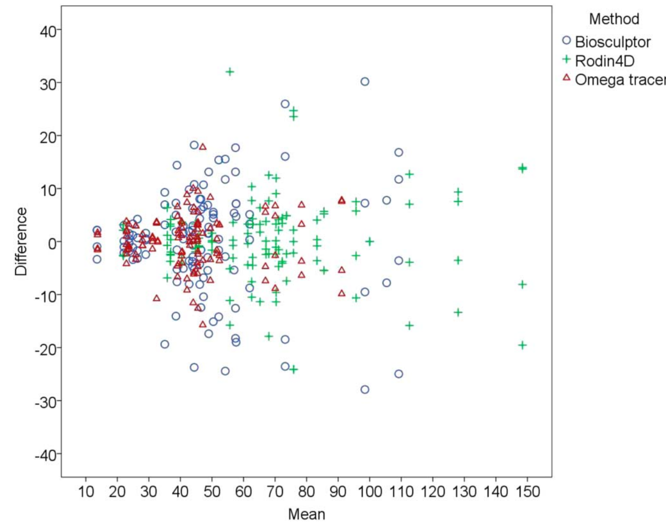

Figure 2. Plot of the difference of the observation (y-axis) against the mean residual limb volume per participant (x-axis) per system.

analysis. The outcomes of that analysis were similar (data not shown).

Also a limitation is the exclusion criteria. In general, the population with an amputation has a lot of the named comorbidities. The population in this study might not be representative for the general amputation patients.

Assuming that there is a learning effect in the observers, the change of the physical therapists could have increased the time to perform the measurements. However, the third observer measured in two occasions instead of the second observer and measured in those two occasions the same patients. So the intraobserver and interobserver repeatability coefficient should not have been influenced. Looking at the results of the multilevel analysis, this influence is small anyway.

Further research should explore effects of measuring residual limb volume of persons postoperatively to see how the residual limb volume changes shortly after the amputation.

Conclusion

Based on this research, the clinical usability, reliability, and repeatability was best tested for the Omega Tracer. For measuring residual limb volume in persons with a TTA, Omega software (state version 12.2) combined with the Rodin4D scanner was more usable and reliable than the Rodin 4D or Biosculptor systems, when operated by staff with limited experience and training.

Author contributions

The authors disclosed the following roles as contributors to this article: study concept and design: R.K., R.E.W., C.H.E., J.H.B.G., and P.U.D. Acquisition of data: R.K. Analysis and interpretation of data: R.K. and P.U.D. Drafting of manuscript: R.K. Critical revision of manuscript for important intellectual content: R.K., R.E.W., C.H.E., J.H.B.G., and P.U.D. Study supervision: R.E.W. and C.H.E. Final approval of manuscript: R.K., R.E.W., C.H.E., J.H.B.G., and P.U.D. Individuals who have provided substantive assistance: A.W. and C.K.

Declaration of conflicting interest

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Blinded information

List of participants selected from the Isala Hospital, Zwolle, and OIM orthopaedics workshop, Zwolle. Medical Ethical Committee: Isala Hospital Zwolle, the Netherlands (ref number: 16.11172).

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Supplemental material

There is no supplemental material in this article.

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