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Accuracy and precision of volumetric determinations using two commercial CAD systems for prosthetics: A technical note

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Abstract—The aim of this study was to evaluate the validity and reliability of volume determinations using the commercially available Seattle ShapeMaker™ CAD/CAM system for production of prosthetic sockets and to compare it with the commercially available CAPOD® system. We used three types of reference objects for volumetric determinations: steel tubes, plaster of Paris casts, and residual limb models. Three different sizes were examined for each type of object. Volume measurements with the two CAD/CAM systems were compared with measurements obtained by water filling, water immersion, or mathematical calculation (tubes only). We found an inconsistent systematic error of less than 3.1% for ShapeMaker and no systematic error for CAPOD. Random errors, represented by the coefficient of variation, were below 1.3% for the ShapeMaker and, in most cases, below 0.4% for the CAPOD. Theoretical changes in volume of 2.6% and 0.8% are possible to detect with these CAD/CAM systems. In our opinion, both systems have sufficient precision for routine clinical use in prosthetics and orthotics. However, in our study, the ShapeMaker committed larger random and systematic errors than CAPOD. This means that, according to our study, CAPOD offers the best possibility to determine and detect small changes in residual limb volume as a function of time.

Key words: *CAD/CAM, prostheses, reliability, transtibial, validity.*

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INTRODUCTION

The fitting of the socket to the residual limb is a critical factor for good function of a prosthesis. Improper fitting gives rise to poor prosthetic function. For the client, this will result in inferior functional status and a lower quality of life. For the society at large, it means that the client must be fitted with a new prosthesis, thus increasing the cost of service, and it may also mean that he or she must be provided with public assistance, with an increase in expenses as a consequence.

In the process of making a prosthesis, errors of different kinds often arise that may jeopardize the fitting of the prosthetic socket. During the last decade, CAD/CAM technique has been introduced for the manufacturing of prosthetic sockets in the hope that such a technique will reduce errors in the production process (1,2). It is a common misbelief that computerized and advanced equipment makes no errors in measurement. The situation may, however, be the opposite. This type of equipment—due to its inherent complexity—may have serious errors, which are not obvious to the user and may be hard to reveal, even for the researcher. If such errors are not known and compensated for, they may jeopardize the measurements, in clinical practice as well as in research.

But new techniques, however sophisticated and computerized, will also introduce new types of errors. To be used with confidence, measurement errors of such new technologies must be detected. Only then can the

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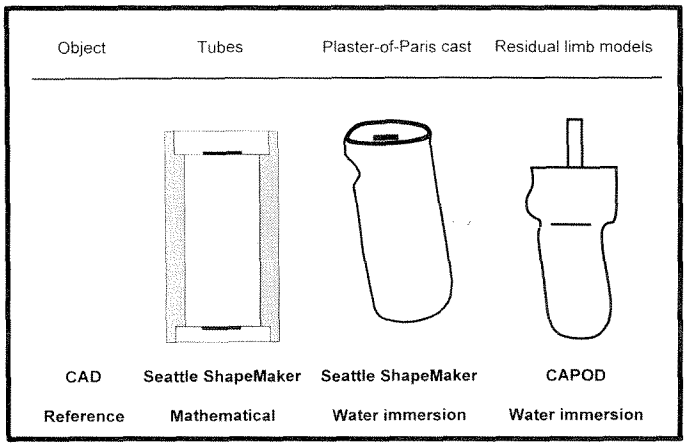

Figure 1.
Test objects and the different measurement techniques.

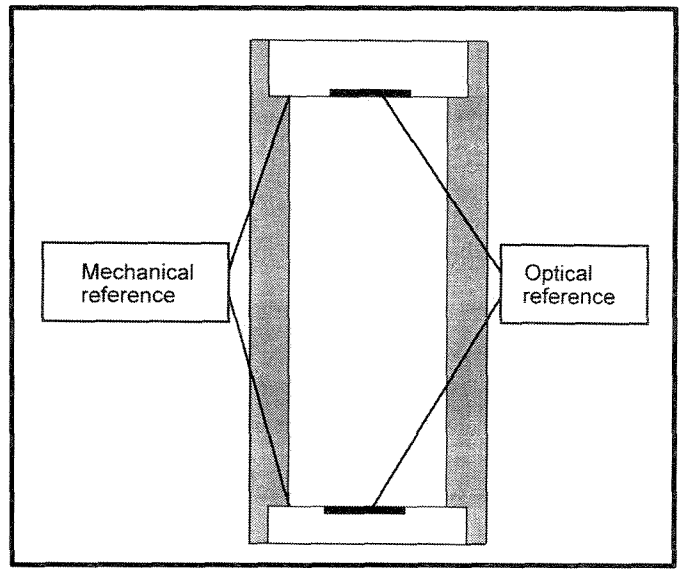

Figure 2.
Principal sketch of the tube with reference marks.

potential of the new technique be fully realized. Today, several commercial CAD/CAM systems are used in daily practice (2). Such systems involve different types of scanning devices, those that utilize skin contact as well as those without any skin contact, to record the shape and volume of the residual limb.

All techniques are certain to have some errors of two types: systematic errors (also referred to as validity, accuracy), and random errors (also referred to as reliability, precision). Systematic errors can often easily be compensated for, but a reduction of random errors often requires an expensive reconstruction of the measurement devices. In the literature, only one CAD/CAM system, the CAPOD® system (CAPOD Systems AB, Karlskoga, Sweden), has been evaluated for errors in measurement (3,4).

The aim of this study was to evaluate validity and reliability of volume determinations using the commercially available Seattle ShapeMaker™ CAD/CAM system for production of prosthetic sockets, and to compare it with the CAPOD system (5).

METHODS

In this study, the volumes of three different test objects (steel tubes, plaster casts, and residual limb models) were evaluated by different methods (water filling or immersion technique, mathematical calculation, and measurement with two commercially available CAD systems) to calculate validity and reliability (**Figure 1**).

Test Objects

Three types of objects were used: a) steel tubes, b) negative plaster of Paris casts of residual limbs, and c) positive plaster cast models of residual limbs in different sizes.

a) *Steel tube models:* Three steel tubes (**Figure 2**), with inner diameters of 80.0, 100.1, and 132.5 mm, respectively, were used. The height of all tubes was 200.2 mm. Both optical and electromechanical reference marks were made inside the tubes for volume determinations.

b) *Plaster of Paris casts:* Plaster of Paris casts, in three different sizes, were made of transtibially amputated limbs. They were lacquered several times to become water-resistant. Optical reference marks were made inside the casts.

c) *Residual limb models:* Three gypsum models of transtibial amputation residual limbs were made. The surface of the models was made water-resistant with Orthocryl-Lack. Black reference marks were used to determine the correct level.

Volume Determination

The volume of the test objects was determined by several different methods: 1) reference measurements made using water filling and immersion technique and mathematical calculation, 2) measurements with the

Seattle ShapeMaker system, and 3) measurements with the CAPOD system.

Reference Measurements Using Water Filling and Immersion Technique and Mathematical Calculation

Negative casts of plaster of Paris were filled with deionized water up to a black reference mark, and the water volume was calculated. The gypsum models were immersed in a tank filled with deionized water. The models were lowered into the water to a black reference mark on the model. At the water surface level was a spout, through which any displaced water was released. The water was collected and weighed on a precision balance (**Figures 3** and **4**). Temperature and atmospheric pressure were recorded to ensure constant measurement conditions. The density of deionized water at 22° C is 0.997770 kg/dm^3. Volume was thus calculated from the weight of the collected water. The measurements were repeated 10 times on each object.

Due to capillary forces, the water surface becomes curved near the test object. This phenomena could introduce a small but negligible error in measurement (3). The volumes inside the tubes were calculated by a standard mathematical formula.

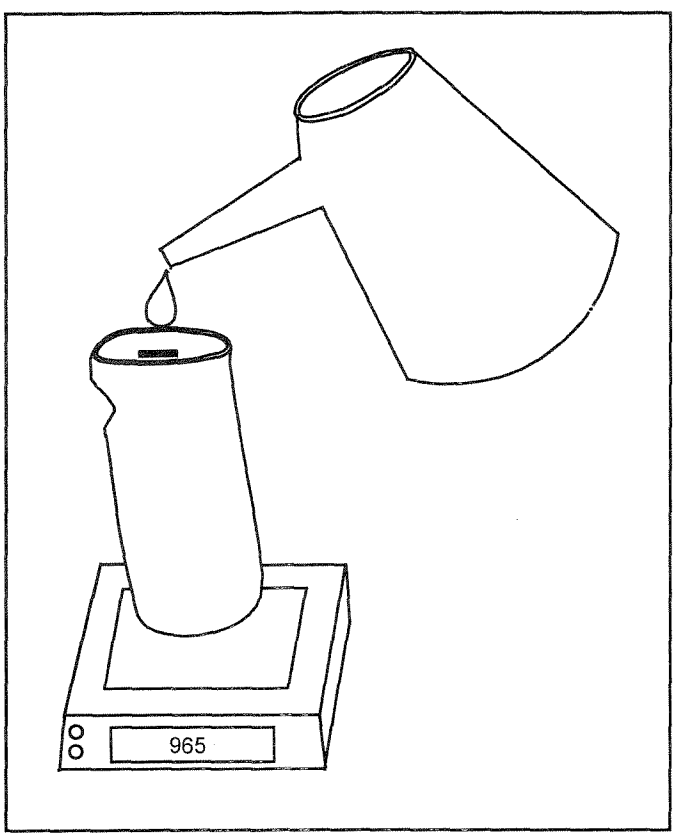

Figure 3.
Equipment for volume determinations of cast models with water filling technique.

Measurements of Volume Using the Seattle Shapemaker System

The Seattle ShapeMaker system consists of an electromechanical scanner (Provel™ d1, USA) with an optical sensor (sensitive to black landmarks on the scanned object), CAD software (M+IND, ShapeMaker version 4.0 for Windows, Seattle Medical Systems Group, Seattle, WA) to rectify socket design, and a milling machine to mill the socket mold. The digitizer was used with default setup mode. The system was calibrated according to the guidelines given by the M+IND documentation (6).

The test objects were scanned and the volumes computed. The volume inside the tubes was calculated to the optical and mechanical reference marks. This was done to validate the measurements of the optical and electromechanical scanning system in the scanner. The measurements were repeated 10 times on each object.

CAPOD Measurements of Volume

The CAPOD system (5) consists of an optical laser scanner for noncontact scanning, CAD software for socket design rectification, and a milling machine. The system was calibrated according to the guidelines set by

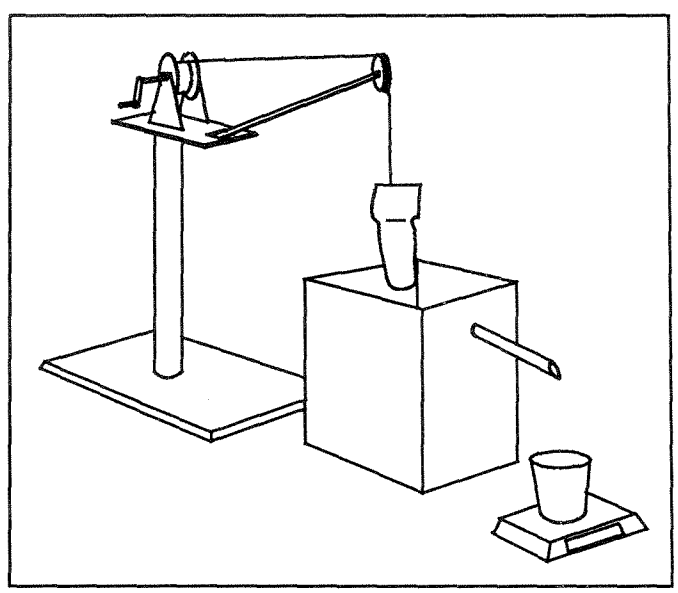

Figure 4.
Equipment for volume determinations of residual limb models with water immersion technique.

the CAPOD Systems Company (7). The scanning of the test objects was repeated 10 times. The volumes up to a black reference mark were calculated.

Statistical Analysis

Means, variances, standard deviations (SD), coefficients of variation (CV: SD as % of mean value) and Students' t-values were calculated according to normal procedures (8).

RESULTS

We found that both systems had systematic and random errors. The size and type of error varied for each system.

Systematic Errors

The absolute volumes of the metal tubes, casts, and residual limbs, yielded by different methods, are shown in **Tables 1–3. Table 4** shows the differences in calculated tube volume between the optical and electromechanical reference systems using the ShapeMaker system, along with the *t*- and *p*-values. **Table 5** shows the differences in measured and calculated volume between the reference measurements (water filling or water immersion) and the volume of the objects obtained by scanning with ShapeMaker or CAPOD, along with the calculated *t*- and *p*-values.

Tube Volumes

The volume inside the steel tubes was measured in two ways: with and without an optical sensor. Both methods determined volumes significantly smaller than those calculated mathematically. However, the volumes obtained from the two types of sensor systems (optical and electromechanical) also differed significantly from each other. For model 1, there were no data from the optical sensor, due to problems with reflections inside the tube.

Cast Volumes

When the volumes inside the negative casts were measured, there was a statistically significant difference between the ShapeMaker results and the reference volumes obtained when the casts were filled with water. For the small and medium models (1 and 2) the volume was underestimated, but for the large model it was overestimated.

Table 1.
Tube volumes (ml). Mean, standard deviations (SD), and coefficients of variation (CV).

Method		Model 1	Model 2	Model 3
Mathematical calculation		773.35	1209.15	2134.07
Seattle ShapeMaker (optical) (n=10)	mean	*	1203.34	2110.64
	SD	*	3.63	19.80
	CV	*	0.30%	0.94%
Seattle ShapeMaker (electromechanical) (n=10)	mean	754.64	1180.62	2067.50
	SD	5.87	5.65	14.47
	CV	0.78%	0.48%	0.70%

*no values due to reflections inside the tube.

Table 2.
Cast volumes (ml). Mean, standard deviations (SD), and coefficients of variation (CV).

Method		Model 1	Model 2	Model 3
Water immersion (n=10)	mean	799.08	905.12	1299.20
	SD	3.04	3.59	3.43
	CV	0.38%	0.40%	0.26%
Seattle ShapeMaker (optical) (n=10)	mean	787.97	889.44	1340.43
	SD	4.29	12.08	17.67
	CV	0.54%	1.36%	1.32%

Table 3.
Residual limb volumes (ml). Mean, standard deviations (SD), and coefficients of variation (CV).

Method		Model 1	Model 2	Model 3
Water immersion (n=10)	mean	799.38	901.56	1304.41
	SD	5.3	4.35	3.40
	CV	0.66%	0.48%	0.26%
CAPOD (n=10)	mean	796.9	899.7	1302.7
	SD	2.96	2.21	2.83
	CV	0.37%	0.25%	0.22%

Residual Limb Volumes

There were no statistically significant differences between the volumes obtained with the CAPOD system and those obtained by the reference water immersion method.

Random Errors

Random errors were estimated by SD and CV (**Tables 1–3**). The CV was below 1.3 percent for the ShapeMaker system and, in most cases, below 0.4 percent for the CAPOD system. This means that 95

Table 4.
Differences in tube volumes (ml and %) compared to mathematical calculation.

Method	Model 1	Model 2	Model 3
Seattle ShapeMaker (optical) (n=10)	*	−5.8(−0.48%)	−23.4(−1.10%)
	*	t=5.0	t=3.7
		p<0.001	p<0.05
Seattle ShapeMaker (electromechanical) (n=10)	−18.7(−2.42%)	−28.5(−2.36%)	−66.6(−3.12%)
	t=10.1	t=15.9	t=14.5
	p<0.001	p<0.001	p<0.001

Table 5.
Differences in cast and residual limb volumes (ml and %) compared to water filling and water immersion.

Method	Model 1	Model 2	Model 3
Seattle ShapeMaker (optical) (n=10)	−11.1(−1.39%)	−15.7(−1.73%)	41.23(3.17%)
	t=8.1	t=3.7	t=7.2
	p<0.01	P<0.01	p<0.01
CAPOD (n=10)	−2.48(−0.31%)	−1.86(−0.21%)	−1.71(−0.13%)
	t=1.29	t=1.21	t=1.22
	N.S.	N.S.	N.S.

percent of the random variations for Seattle ShapeMaker are included within an interval of mean volume ±2.6 percent, and for the CAPOD system within an interval of mean volume ±0.8 percent.

DISCUSSION

Main Results

This study was designed to evaluate validity and reliability of volume determinations performed with the commercially available ShapeMaker CAD/CAM system, and to make comparisons with those of the commercially available CAPOD system. For the ShapeMaker system we found, when compared with the chosen standard measurement, a statistically significant underestimation of the volume inside the steel tubes, and a significant, but inconsistent difference in measurements of volume inside the negative plaster of Paris casts. The measurements obtained with the CAPOD system showed no such systematic errors. Both systems showed little random error, and those that did arise were smaller for the CAPOD system than for the Seattle ShapeMaker system.

To determine whether such errors in measurement are clinically significant, they must be correlated to some pertinent clinical practice. In a recent study, Lilja and Öberg have shown that the volume of one terry cloth sock used to compensate for differences between residual limb and socket volumes is about 5 percent of the typical residual limb volume, and that two terry cloth stump socks are about 10 percent (9). The volume differences observed in this study were 1.4–3.2 percent for the ShapeMaker system, and 0.1–0.3 percent for the CAPOD. For the CAPOD system, the systematic errors can be regarded as negligible. For the ShapeMaker, they are equivalent to less than half the volume of one terry cloth sock.

Water filling and immersion were used as a standard for volume determinations, and are generally considered free from systematic errors. For the metal tubes, we also used mathematical calculation of the inside volume as a standard measurement.

The Seattle ShapeMaker System

As can be seen in **Table 1,** the ShapeMaker systematically underestimates the volume inside the tubes, but the difference was small when the optical sensor was used for detection. We found statistically significant systematic errors of about −0.75 percent with the optical, and of about −2.5 percent with the electromechanical, sensor. This means that use of the optical sensor reduces the systematic error, and we recommend it in all possible cases. For the cast models,

the volume differences were statistically significant, but not consistent. The differences in the results can be due to problems in the procedures recommended by the ShapeMaker for determining the shape of a residual limb, but another cause could be that the calculation algorithm of the software miscalculates the volume of objects, such as casts, with more complex shapes. One way to determine or estimate the error in the calculation algorithm would be to increase both the number of objects and measurements.

ShapeMaker had CVs of less than 1.4 percent. Consequently, 95 percent of the random errors will be included within an interval of ±2.8 percent when using ShapeMaker. This means that 95 percent of the random errors committed by Seattle ShapeMakers will cause volume differences that are half the volume of one terry cloth sock or less.

The CAPOD System

No statistically significant differences in residual limb volumes were found when using the CAPOD system. This indicates that the volume calculation algorithm of the CAPOD system gives a good estimation of the true volume of complex objects like residual limbs.

The CAPOD system's random error will produce a volume difference equal to one tenth the volume of a terry cloth sock. CAPOD's reproducibility was good, with CVs of less than 0.4 percent (i.e., less than for the reference method). Consequently, 95 percent of the random errors will be included within an interval of ±0.8 percent when using CAPOD.

Seattle ShapeMaker Versus CAPOD

When these systems are compared and evaluated in a clinical setting, it is important to remember that the two systems work with different scanning techniques. Seattle ShapeMaker uses electromechanical contact scanning, and CAPOD uses noncontact optical scanning. It is logical to assume that an increased number of steps in a process increase the risk of adding errors to the process. The fact that the plaster wrap cast, which is the starting point for Seattle ShapeMaker, can introduce errors in the shape and volume of the residual limb model (4,10) and that the electromechanical scanning system uses the cast as a starting point, must be remembered when the systems are compared.

In a clinical situation, the plaster casting will probably introduce errors of greater magnitude than those introduced by CAD/CAM systems. This means that the precision of both systems is probably sufficient for normal clinical use. The accuracy of the calculation algorithm for both CAD systems could, if necessary, be further investigated and calculated by increasing the number of measurements and by the use of more test objects (both larger and smaller).

Lilja and Öberg's (2) study is the only one that examines errors of measurement in volumetric determinations using commercially available CAD/CAM systems. Smith et al. (11) and Commean et al. (12) have, in two similar studies, investigated the accuracy and random errors in volumetric determinations of an optical surface scanning system (OSS). They found random errors of less than 0.5 percent and mean systematic errors of 43 and 72 cc. The system they used appears to be a noncommercial one. Comparing their results with those of our model 3 (approximately the same size as the mean of their casts), their system appears to have a random error between the CAPOD (0.22 percent) and the ShapeMaker (1.32 percent), and a systematic error equal to or larger than both the ShapeMaker (41.23 cc) and the CAPOD system (1.71 cc).

Control Charts

One method that is often used to control accuracy and precision in any measuring system is the use of control charts (13). A control chart is only a graphic presentation of the relationship between the true and measured value of a reference object. It does not, in itself, improve the system's accuracy and precision, but it makes the user aware of the size of errors in measurement. It could also alert the user in the event of lost system calibration.

These control charts should be based on regular calibration measurements of well-defined reference objects with different shapes and sizes. The reference objects should be shaped like the scanned objects, not like the cylinders that are used today. The CAD/CAM manufacturer could, in this case, easily integrate a software routine that informs the regular user that the system needs to be calibrated.

CONCLUSIONS

In this study, the accuracy and precision of two commercially available CAD/CAM systems, when used for volumetric determinations, have been examined. We found that both systems probably meet the demands for

low random errors in routine clinical applications for prosthetics and orthotics. There was no systematic error when using CAPOD. For the ShapeMaker, the systematic error was statistically significant but not consistent. The size of the systematic error also varied with the shape of the scanned object. However, we think that the systematic error of the ShapeMaker could be compensated for, if the calculation algorithm is known.

In our study, the ShapeMaker introduced both larger random and systematic errors than CAPOD. This means that, according to our study, CAPOD offers the better possibility to determine and detect small changes in residual limb volumes as a function of time.

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