Validation of spiral CT and optical surface scanning for lower limb stump volumetry

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Abstract
Spiral X-ray Computed Tomography (SXCT), Optical Surface Scanning (OSS), and hydrostatic weighing methods were used to measure stump volume of trans-tibial amputees. The precision and accuracy of these methods were assessed in a validation study. A repeated measures analysis of variance statistical design was employed that required each participant to be measured (scanned) twice at each of two separate measurement sessions. For OSS and SXCT, each scan was segmented twice to determine intra-observer error. Plaster cast replicas of subject stumps were formed by certified prosthetists to serve as a reference standard. Accuracy (bias) of SXCT and OSS was determined by comparison to volumetry by hydrostatic weighing. Ten trans-tibial amputees were recruited for this study and nine completed both sessions. Plaster replica measurement precision error relative to the mean was found to be less than 1% for all modalities. The precision was slightly inferior on subjects, 1.1% and 2.2% error for hydrostatic weighing and OSS respectively, due to patient instability during measurement, but was better with SXCT where the subjects’ stumps were stabilized during scan acquisition. The OSS and SXCT methods offer advantages over hydrostatic weighing and other volumetry methods since the volume data are represented digitally and can be analyzed in multiple ways. SXCT enables study of the stump and its internal tissues with the prosthesis in place. It was found that SXCT is comparable to hydrostatic weighing in both precision and accuracy. While OSS had a high precision and reproducibility, it was found to have an associated bias.

Introduction
The socket/stump interface is known to be the primary factor governing prosthetic fit. To support static weight bearing and ambulation, forces are transmitted from a prosthetic socket through a liner material (silicone sleeve and/or socks), through the soft tissues and patellar tendon, and into the limb skeletal remnant. A well fitted prosthesis has an optimal distribution of pressure, directing forces preferentially through pressure tolerant regions and directing force away from pressure sensitive areas. Pressure tolerance is dependent on individual and prosthesis design differences. It is widely believed that the stump can tolerate very little change in volume due to the prosthesis, therefore, any volume change to accommodate loading must be accounted for elsewhere in the socket. A review of biomechanical principles of prosthetic fitting is given in Murdoch and Donovan (1988).

Lower limb stumps consist of a bony substructure, fibrous and cartilaginous investments, and a soft tissue envelope. The soft tissue envelope is subject to both short and long term changes due to oedema, venous pooling, exercise, weight gain/loss, muscle contraction, and atrophy. In addition, this soft tissue envelope has a heterogeneous composition and is continuously deformable. Lower extremity volumetry methods have been developed to...
quantify and help understand the effects of oedema and atrophy (Lennihan et al., 1973; Fernie et al., 1978; Fernie et al., 1982; Krouskop et al., 1988; Persson et al., 1989; Bednarczyk et al., 1992). Optical surface scanners have been used in CAD CAM prosthetic design (Saunders et al., 1989; Boone et al., 1989; Oberg 1989; Boone et al., 1994), but these reports do not include volumetric analysis of patient stumps. These non-contact methods have limited ability for atrophy and oedema assessment. Surface measurement methods (Lennihan et al., 1973; Persson et al., 1989) where the stump is modelled as a truncated cone, were shown to be unreliable by Fernie et al. (1978) and Bednarczyk et al. (1992). Contact contour tracers (Krouskop et al., 1988; Bednarczyk et al., 1992) suffer from patient motion, skin deformation from contact, and limited resolution. Fernie described and used a water bath on an elevator platform to measure cross-sectional area of the stump (Fernie et al., 1978; Fernie et al., 1982). All measurements were related to the distal end, and were inaccurate due to uncertainty introduced by surface tension between the skin and water as the water bath was lowered. A stated benefit of this method was to enable regional volume change assessment as volumes could be estimated for slices of a given thickness instead of a single volume measurement for the whole stump. Krouskop et al. (1988) attempted to compare the volumes of the socket, unloaded stump, and plaster replica on 5 subjects with contact contour tracer. The volumes determined with this method are basically an extension of the truncated cone method, with a higher number of circumference measurements. All methods described above are limited for prosthetic fit assessment as limb volumetry cannot be performed with the prosthesis in situ. A method for visualization and measurement of the stump, including its internal composition of subcutaneous fat, muscle, and bone with the prosthesis in situ is sought to aid prosthesis fitting. Spiral X-ray Computed Tomography (SXCT) has been developed for this purpose (Fishman et al., 1993).

An Optical Surface Scanner (OSS) (Commean et al., 1994) which employs structured light was developed to accommodate lower limb trans-tibial amputees (Bhatia et al., 1994) and to measure distances between fiducial landmarks (Commean et al., 1994). While OSS does not allow discrimination of sub-surface composition nor in situ evaluation of prosthesis fit, it is a viable volumetry tool when internal information is not required.

SXCT and OSS volumetry methods define the stump in three dimensions at very high resolution. An OSS scan captures approximately 30,000 x,y,z coordinates defining the surface of the stump, over a fixed range of approximately 30cm. For a comparable 30cm Z-axis range (cranial-caudal axis) SXCT captures approximately three million volume elements known as “voxels” that represent the complete morphology of the stump. While the OSS scan range and resolution is fixed, the SXCT range and z resolution can be extended by performing multiple scans, changing the number of gantry rotations per table increment, and/or x-ray collimation. Once captured and processed into three dimensional data, computer stump models can be analyzed repeatedly. Regional volumes can be determined and SXCT volume data analyzed in terms of tissue composition, allowing registration of models by skeletal structure for analysis of regional shape, and determination of local or regional volume differences between scans. Surface and volumetric data from the OSS and SXCT are amenable to solid modelling (Bhatia et al., 1994; Pirolo et al., 1993) enabling finite element analysis (Szabo et al., 1991).

This validation study extends an initial pilot investigation performed on SXCT volumetry using phantoms and a cadaver leg (Smith et al., 1995) and includes comparison with optical surface scanning as a volumetry tool in lower limb prosthetics.

Materials and methods

Ten trans-tibial amputees were recruited to participate in this study. Informed consent was obtained from all subjects. Nine subjects completed the entire protocol. Inclusion criteria required the subjects to have been previously fitted with a permanent prosthesis and to have at least some independent or assisted ambulation. One subject did not complete the study due to personal reasons and another completed the study, but was excluded from the analysis as he had not yet been fitted with a permanent prosthesis. The mean age of the sample was 50
years, with 8 males and 2 females participating (Table 1). Nine of the subjects were left leg amputees and one was a right leg amputee. All subjects were at least 6 months post amputation.

Participants underwent two measurement sessions during the study in which identical protocols were followed at each session. The stump volume was measured using hydrostatic weighing (HW), Optical Surface Scanning (OSS) and Spiral XCT (SXCT) methods. Fiducial marks were used to denote an imaginary “cutting plane” which defined the enclosed volume of interest. Vertical orientation of the stump was desired, but not all patients could attain this position during the hydrostatic weighing procedure. The proximal cutting plane was therefore defined by palpation of the mid-patellar tendon and a fiducial mark made with a permanent black marker. The stump was then immersed in a water bath until the mid-patellar tendon mark intersected the water level. Two additional landmarks were then marked 120° posteriorly (one medial and one lateral) at the water level. During optical surface scanning, 6.25mm round black adhesive markers were placed atop the previously defined landmarks. It is difficult to identify marks smaller than this size with the OSS. Lead BB’s (1.5mm spherical adhesive Beekley X-spots, Briston, CT) were placed over the OSS fiducial marks prior to CT scanning to define the imaginary cutting plane. In addition to the proximal cutting plane which defined the total volume of interest, a set of three additional landmarks were made with one denoting the end of the tibia at the anterior aspect and the other two placed 120° posteriorly in a plane orthogonal to the long axis of the stump. These landmarks were used in a separate investigation of distance measurements.

After the fiducial marks were identified, stump volume was measured with hydrostatic weighing. Hydrostatic weighing is based on Archimedes’ principle of buoyancy (Marks, 1941) which has been shown to be accurate for measuring stump volumes (Smith et al., 1995). The volume of interest was defined as the stump volume including the distal end to an imaginary plane defined by the proximal three landmarks. Repeat volume measures were obtained for determination of measurement precision.

Upon completion of the hydrostatic volume measurement the subjects were transported by wheelchair to the OSS for surface scanning. Elapsed time between HW and OSS was approximately one-half hour. The stump was towel dried and optical reference markers positioned over the previously marked fiducial points (described above). The subject was positioned in the OSS, the camera apertures adjusted for optimal exposure, and two scans recorded. The scan data were then processed to three dimensional data using triangulation and calibration methods previously described (Godhwani et al., 1994). The data were visualized on a graphics workstation (Silicon Graphics 4D/340 VGX, Mountain View, CA) to ensure adequate coverage and data quality.

Upon completion of the surface scan the lead markers described previously were placed directly over the visual fiducial marks. A

<table>
<thead>
<tr>
<th>Patient</th>
<th>Date of Examinations (1994)</th>
<th>Age</th>
<th>Sex</th>
<th>Race</th>
<th>Side of Amp</th>
<th>Type of Amp</th>
<th>Included in Study</th>
<th>Prosth Type*</th>
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<td>49</td>
<td>M</td>
<td>W</td>
<td>L</td>
<td>BK</td>
<td>N</td>
<td>P</td>
</tr>
</tbody>
</table>

* P denotes permanent prosthesis
  T denotes temporary prosthesis

Table 1. Subject information for recruited amputees
prosthetist then took a negative impression of the subject’s stumps by plaster wrap technique. From the negative mould a plaster positive was created. The plaster positive formed with this method had small bumps which denoted the positions of the lead fiducial markers.

The subject was then transported by wheelchair to a spiral CT scanner (Siemens Somatom Plus S, Erlangen, Germany) located in Barnes Hospital (St. Louis, MO). The prosthesis was left off during all procedures to prevent disturbance of the fiducial landmarks. Approximately one to two hours elapsed between plaster wrap and spiral CT scan. The subject was oriented in a supine position on the CT table with stump resting on a foam block covered by a blanket, used to stabilize the stump during examination. A plastic rod of known volume was placed next to the stump as a calibration reference. A 32 second spiral CT scan was obtained with parameters of 120 kVp, 210mAs, 8mm collimation, 8mm table increment per gantry rotation, and a 512 by 512 sensor matrix. The scan started just below the distal end of the stump and ended above the proximal fiducial marks. The CT projection data were reconstructed at 1mm slices on a Siemens Somatom Satellite CT Evaluation Console using half scan linear standard reconstruction algorithm (Paranjpe, 1994). Two scan acquisitions per subject at each of the two measurement sessions were performed to test the precision and response stability. Completion of the spiral CT scans ended the subject’s volume measurement session.

The plaster positive cast representing the patient’s stump was sealed with enamel paint to prevent water absorption during hydrostatic weighing. The bumps denoting the fiducial landmarks were located and clearly denoted with permanent marker. The plaster cast replicas were measured using the same protocol followed for human subjects (described above)

Data analysis

The OSS surface model was represented in a cylindrical coordinate system with the central axis aligned longitudinally and passing through the centroid of the data. The data was resampled to a cylindrical grid consisting of 512 radial surface points and a 1.56mm z-axis spacing. The texture mapped OSS three dimensional surface data was cylindrically unwrapped using programmes developed in the PV-WAVE software environment (Visual Numerics, Inc., Boulder, CO). This software allowed manual digitization of the visual fiducial marks placed on the stump prior to scanning. These coordinates were used to generate a cutting plane to section the volume of interest, defined by the proximal fiducial marks. A discrete wedge may be defined from the OSS surface model using two grid points from the central axis together with four surface points. Each of the two adjacent grid points on the central axis uses two planar adjacent surface points to define the wedge. Summation of all possible wedge volumes enclosed by the stump surface and the cutting plane yields the total volume of interest. The volume in cubic millimeters was determined for the OSS surface data by this method. The process of point digitization, volume generation, and volume determination was performed twice. Figure 1

Fig. 1. Optical Surface Scan (OSS) of a lower limb stump in a frontal three dimensional view. OSS surface data is converted to a solid model by closing the stump surface with a plane through the three proximal fiducial landmarks.
Volume validation of lower limb stump shows an OSS surface data set of a trans-tibial stump with optical fiducial marks.

The SXCT volumetric stump data was imported into Analyze™ software (Robb et al., 1989; Robb et al., 1994; Robb et al., 1988; Robb et al., 1989) running on an imaging workstation (Sun Sparcstation 20, Mountain View, CA) for volume determination. To relax the memory requirements of the workstation and to enhance processing speed, the enormous data sets (125MB) were resampled in Analyze™ to 1mm cubic voxels, resulting in a file size reduction of about 10 to 1. Mid-point thresholding as described in Smith et al. (1995) was used to segment the skin surface envelope of the stump from surrounding air. This threshold also eliminated the foam block/blanket support (used to support the stump during scan acquisition) from the data. The volume of interest defined by the proximal fiducial marks was isolated by passing a cutting plane through the volume data, which intersected the three markers. The volume was then determined using the volume measuring tools available in the Volume Render module of Analyze™. Each volume measurement was done twice. Figure 2 shows a single SXCT stump scan from each of the ten subjects. The volume of interest was segmented from surrounding air and sectioned through the three proximal fiducial landmarks for volume determination. In addition, the calibrated rod volume was measured and compared to the known, to verify scan quality.

Precision relates to the ability of an instrument to consistently measure a variable over repeated trials of the same individual. Precision of the volumetry methods were tested using a precision index known as Method Error (Portney et al., 1993), a measure of variance between two sets of repeated scores. Method Error is defined as:

$$ME = \frac{S_d}{\sqrt{2}}$$

where $S_d$ is the standard deviation of the difference scores.

Unlike other reliability (precision) measures, it is not affected by a low true variance among measurements as it is based on difference scores of repeated measures. To relate the error variance in the difference scores relative to the size of the mean difference the value is converted to a percentage using the coefficient of variation (Portney et al., 1993):

$$CV_{ME} = \frac{2ME}{X_1 + X_2} \times 100$$

This test is applicable both within subjects and across subjects in the sample.

Validity of an instrument pertains to its suitability to measure the desired variable. For the volumetry application, the issue of validity deals with bias or systematic error as well as precision error. The precision or random error could be very small, but if measured volumes are consistently high or low from the true value (truth) then an adjustment in scale or calibration of the instruments would be required before being considered valid. This validity test obviates that the true value or “gold standard” be accurately known. For a test of stump volumes where the volume is dynamic, this test is not as meaningful. For instance, if a bias is found, is it due to systematic error in the instrument or is the change a real effect such as short term change due to swelling? To address this issue, instrument validity testing was conducted using non changing standards. These standards were comparable to the BK stumps of the subject group as they were plaster casts of the subjects’ stumps taken at the time of their measurement sessions.

Results

Of the ten subjects recruited for this study seven successfully completed the entire protocol. One subject with a temporary prosthesis did not meet the inclusion criteria, another dropped out due to personal reasons, and a third subject was omitted due to a corrupted SXCT data set. All three subjects excluded from the analysis were male resulting in a distribution of 5 male and 2 female subjects having a mean age of 52 years, a change of 2 years from the original recruited sample. The three subjects excluded from the analysis are identified in Table 1.

Each of the seven subjects was scanned twice in the OSS and twice in the SXCT to determine the error due to scanning. Each of these scans was segmented twice into the volume of interest (defined by the markers) to determine the error due to segmenting the volume of interest. The patients were brought back for a second visit where the above process was repeated to determine error due to fiducial landmark
placement and to test response stability over time. The hydrostatic weighing method was repeated four times per subject during each visit to assess precision error.

Table 2 details the cumulative precision error (percent) for each step in the volume measurement process for each modality. For example, random error at the segmentation level (OSS and SXCT) relates directly to intra-observer ability to align an imaginary cutting plane through the three proximal fiducial landmarks (which defined the volume of interest) together with any computer errors in volume determination; error at the instrument level includes errors at both the segmentation level and the instrument level (error due to instrument); error at the fiducial landmark placement level includes errors at the
Table 2. Method error (precision) as a percentage of the mean for the three methods

<table>
<thead>
<tr>
<th>LEVEL</th>
<th>n</th>
<th>Subject</th>
<th>Cast</th>
<th>Subject</th>
<th>Cast</th>
<th>Subject</th>
<th>Cast</th>
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</thead>
<tbody>
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<td>N/A</td>
<td>0.5</td>
<td>0.5</td>
<td>0.8</td>
<td>0.8</td>
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<tr>
<td>Instrument</td>
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<td>0.3</td>
<td>2.2</td>
<td>0.5</td>
<td>0.5</td>
<td>0.9</td>
</tr>
<tr>
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<td>10.0</td>
<td>10.8</td>
<td>9.8</td>
<td>10.5</td>
<td>10.9</td>
<td>12.3</td>
</tr>
</tbody>
</table>

A paired T-test showed a significant difference (0.001>p>0.0005) between scan 1 and scan 2 (instrument level) for subjects scanned in the OSS during a given measurement session. This test was necessary as the method error statistic does not detect systematic error between measurements. For other measurements no significant difference between pairs was found.

A paired T-test is inappropriate when comparing more than two group means, therefore, a single factor repeated measures analysis of variance (ANOVA) was performed on the cast data and subject data to test for significant differences in mean volume measurements between modalities. ANOVA was performed at the instrument level with the independent variable being measurement modality with three levels, hydrostatic weighing, OSS, and SXCT. A random number assignment was used to select either the first or second segmentation of a scan to prevent statistical bias due to correlated pairs of data. Tables 3 and 4 show the results of the ANOVA.

Having found a significant difference among methods, it was necessary to perform a multiple comparison test (Tukey’s Honestly Significant Difference (HSD) (Portney, 1993) test for repeated measures) to determine which methods were significantly different. For the cast data a significant difference was found (p<0.05) between the hydrostatic method and OSS, and between the OSS and SXCT methods. No significant difference (p>0.05) was found between the hydrostatic and SXCT methods. For the subject data, a significant difference (p<0.05) was found between both hydrostatic and OSS and hydrostatic and SXCT, but not between OSS and SXCT methods (p>0.05).
These findings are shown in Tables 5 and 6.

**Discussion**

It may be seen from Table 2 that the predominant source of precision error on both casts and subjects for any of the three volumetry methods is attributable to fiducial placement between patient visits. This is explained by the inability of the observer to repeatedly place fiducial marks at identical locations between visits. The mid-patellar tendon was the only anatomic location where a fiducial mark was placed. The placement of the remaining two proximal marks was determined by the angle of the stumps in the water bath together with a subjective placement by the observer at approximately 120° posteriorly from the mid-patellar mark. While the precision of this variance was 10% or more, the mean volume of the repeat visits were nearly identical for all methods indicating no bias between visits. This further suggests the variance in volume was due
to fiducial mark placement rather than a true change in the sample population over time. In fact, the sample group was chosen to contain mature stumps to reduce volumetric change over time.

At the instrument level the three volumetry methods were directly compared. Both hydrostatic weighing and OSS methods had a larger variance for subject volume measurements than for cast volume measurements. In hydrostatic weighing, patient instability presumably caused the larger error variance in volumes. When measuring the cast volume with the hydrostatic weighing method, more time and control was available in taking the measurement, thus reducing the precision error. During scanning in the OSS the cast orientation was fixed in a holding device, however, subject scanning required the patients to hold their stumps motionless in air and to assume a new orientation for each scan. For the SXCT method, surprisingly the casts had a higher precision error than subject stumps. With the SXCT method, neither the subject's stump nor the plaster casts were moved between scans and both were rested on a table during the scan procedure.

To compare between similar scans of a given measurement session a paired T-test was performed for the hydrostatic, OSS, and SXCT methods. A significant difference was found with the OSS segmentation of a single scan for cast data. The most reasonable explanation for this error is intra-observer error (i.e. a systematic error was made in segmenting the data).

Since the true volume of the stump was not accurately known, a repeated measures analysis of variance was performed, followed by a Tukey's HSD multiple comparison test to establish equivalence of methods. The ANOVA on both the cast data and subject data showed a significant difference between methods. Only the cast data was examined for equivalence of methods as that represents a non-changing standard. Lower limb stumps are in a dynamic state and subject to short term swelling that would represent a real effect and not a bias. The multiple comparison test for the cast data showed the hydrostatic weighing and SXCT methods were not significantly different (p>0.05), however, it showed the OSS method to be significantly different from both the hydrostatic weighing and SXCT methods. As hydrostatic weighing is an accepted form of volume measurement, it appears that the OSS has a bias or systematic error associated with it. When measuring lower limb stump volumes, comparisons should be avoided between hydrostatic weighing and OSS and between SXCT and OSS. Intermodality comparisons between hydrostatic weighing and SXCT would be acceptable.

When examining subject data the multiple comparison test showed the OSS and SXCT were both significantly different (p<0.05) from the hydrostatic weighing method. It is believed this is a real effect caused by short term swelling of the subject’s stump over the duration of the measurement session. The hydrostatic weighing was performed immediately upon removal of the prosthesis followed within thirty to forty-five minutes by the OSS session. The SXCT examination was performed with a time lapse of approximately four hours from hydrostatic weighing. Short term swelling is most rapid upon removal of the prosthesis as the fluids pumped from the stump during ambulation return.

The SXCT precision errors may be reduced by implementing metal artifact reduction software during reconstruction or using smaller fiducial markers to reduce the metal artifact component. The precision error of the hydrostatic weighing and OSS methods may be reduced by providing the subject with better support during measurement.

Of the three volumetry methods examined SXCT is the only one capable of measuring stump volume with the prosthesis in situ. The ability to examine quantitatively sub-surface tissues in relation to the external prosthetic socket in a three-dimensional format offers to provide information on prosthetic loading distributions previously unobtainable. The volumetric data obtained with the SXCT can be saved and analyzed in many ways. The data can be sectioned into discrete slices or predefined regions for specific volumetric analysis and/or comparison to the socket volume or volume of the stump with no prosthesis. Figure 3 shows a SXCT digital projection radiograph of a transfibial stump with the prosthesis in place. The area covered by the two-dimensional computed radiograph is digitized and reconstructed into three dimensional data for subsequent analysis.
Hydrostatic weighing provides a low cost approach to limb volumetry. The process, however, is cumbersome and volumetric measurement with prosthesis in place is not possible. In addition, there are concerns regarding water borne infections when subjects have open wounds due to ulceration or other irritation. Optical Surface Scanning (OSS) would be preferred to hydrostatic weighing, but is still limited to volume measurement bounded by the external skin envelope.

Conclusion

SXCT, OSS, and hydrostatic weighing are practical methodologies for volume measurement of trans-tibial stumps. SXCT and OSS require computer processing, but are non-contact methods and are less strenuous for the subject than hydrostatic weighing. SXCT and OSS data can be saved and regional volumes examined at later dates. SXCT offers a means to conduct detailed long term atrophy and short term oedema studies, through data set registration of unchanged bony surfaces. The ability to capture quantitative subsurface information (SXCT) of trans-tibial stumps, with the prosthesis in situ, offers a needed tool for biomechanical assessment of prosthetic fit. OSS provides a low cost tool for short term volume assessment when reference markers can be placed for registration, however, OSS was shown to have a bias when compared to SXCT and hydrostatic weighing volumetry methods and should be considered prior to comparing results. Longitudinal volumetric study of trans-tibial stumps, using fiducial markers on anatomic landmarks for registration, cannot be considered reliable.

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Volume validation of lower limb stump


