

## Influence of prior activity on residual limb volume and shape measured using plaster casting: Results from individuals with transtibial limb loss

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**Abstract**—The purpose of this research was to determine whether prior activity affected the shape of a plaster cast taken of a transtibial residual limb. Plaster casts were taken twice on one day in 24 participants with transtibial limb loss, with 5 s between doffing and casting in one trial (PDI-5s) and 20 min in the other trial (PDI-20m). The ordering of the trials was randomized. The mean  $\pm$  standard deviation radial difference between PDI-20m and PDI-5s was 0.34  $\pm$  0.21 mm when PDI-5s was conducted first and  $-0.02 \pm 0.20$  mm when PDI-20m was conducted first. Ordering of the trials had a statistically significant influence on the mean radial difference between the two shapes ( $p = 0.008$ ). The result shows that prior activity influenced the residual limb cast shape. Practitioners should be mindful of prior activity and doffing history when casting an individual's limb for socket design and prosthetic fitting.

**Key words:** accommodation, activity, alignment, amputee, CAD/CAM, optimization, prosthesis, prosthetics, socket, volume change.

### INTRODUCTION

Advances in computer-aided design/manufacturing (CAD/CAM) may advance prosthetics and allow imaging tools to take a more dominant role in clinical care. For example, quantification of changes in residual limb shape over time, determined by comparing limb shapes, potentially provides insight into a person's needs for socket replacement or volume accommodation [1–2]. In

addition, characterization of shape change may serve as an outcome measurement for testing new technologies and treatment strategies intended to stabilize or compensate for volume fluctuation (e.g., fluid-filled inserts, air-filled inserts, and elevated vacuum systems) [3].

A challenge toward accomplishing these goals is to clinically measure limb shape in a way that other variables, ones outside the clinician's interest, do not confound interpretation. For example, the time between doffing the prosthesis and the initiation of casting is likely to influence cast volume. It has been noted clinically that after a socket is doffed, the residual limb tends to swell over time [2,4]. Ambulation that occurred before the casting might also affect the measurements. It is important to know the influence of prior activity in limb volume and shape assessment. If these factors significantly affect results and a practitioner does not carefully plan the measurements to account for them, then the changes in volume and shape might not be measured

**Abbreviations:** 3-D = three-dimensional, ANOVA = analysis of variance, BMI = body mass index, CAD/CAM = computer-aided design/manufacturing, MRD = mean radial difference, PDI = postdoffing interval, PDI-5s = 5 s postdoffing interval, PDI-20m = 20 min postdoffing interval.

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correctly, leading to a false interpretation of the clinical measurements.

## METHODS

### Participants

Participants were volunteers who had a transtibial amputation more than 15 mo prior to entry in the study and who were considered by their practitioner to have reached a stable residual limb volume. Participants were required to meet a Medicare Functional Classification level of at least K-1 (limited or unlimited household ambulation) [5], and to be capable of ambulating on level surfaces at a fixed cadence. Volunteers were excluded from the study if they had recent injury or existing skin breakdown. Enrollment of participants for whom a socket replacement was imminent was deferred until the new socket fitting was completed.

### Procedures

#### *Casting*

Each participant was seated comfortably with the prosthesis donned until all materials were prepared. A nylon stocking was donned on the residual limb to serve as a barrier between the plaster of Paris bandage and the limb. No liner was worn. Using the thumb to lift the starting end loosely, the practitioner submerged the bandage (Ortho-Care extra-fast setting plaster of Paris bandages 15 cm × 4.6 m; Manchester, New Hampshire) in clean, tepid water (approximately 26°C) for approximately 5 s. The excess water was squeezed out, and the bandage was applied in a left to right fashion, the right hand always holding the bandage. At each bandage turn, the layers were massaged to obtain a smooth surface. A timer was used to document the length of time of the casting procedure. The timer was started when the practitioner began to wrap the bandage around the residual limb and stopped when the completed cast was removed from the residual limb. The casting procedure took less than 4 min to complete on all test subjects. Care was taken to ensure that the times for different castings for each subject were consistent.

After the cast was dry and removed from the subject's residual limb, the practitioner applied a fine layer of talcum powder to the inside surface to serve as a mold release agent. A bucket of tepid water was filled, and dental grade plaster of Paris was added and stirred into

the bucket until a thick consistency was achieved. The cast was filled, and an identifying label placed on the mold. After the mold set, the casting bandages were removed by cutting two strips down the length of the cast using a Dremel and saw blade and prying the bandages off with a flat-head screwdriver and pliers. Care was taken to ensure the mold was not distorted. In this article, we refer to the shape of the mold as the cast shape.

#### *Testing Protocol*

Two trials were performed on each person in a single day, with a short rest and walk interval between the end of the first trial and the beginning of the second. To ensure consistent activity before this procedure was started, at the outset of each study day, participants were submitted to a 40 min protocol of approximately equal durations of sitting with the prosthesis donned, standing, walking on a treadmill at a self-selected walking speed, and sitting with the prosthesis doffed. Then, the participant redonned the prosthesis and walked for up to 1 min until he or she was comfortable, sat down, doffed the prosthesis, and after a prescribed interval, which we termed the postdoffing interval (PDI), we casted the limb. The PDI was 5 s (5 s postdoffing interval [PDI-5s]) in one trial and 20 min (20 min postdoffing interval [PDI-20m]) in the other. The order of the trials was randomized. The basis for using these intervals was previous research showing that residual limb fluid volume was highly sensitive to postdoffing time [2,4]. We expected these intervals to induce different limb volumes. Participants wore their prosthesis but were not active for the 5 to 30 min between castings, other than a walk to a waiting area, a few minutes of rest, and then a walk to return to the laboratory. The interval between castings was typically 15 min, but varied between 5 and 30 min because of differences in the time the subjects required to prepare and don their prosthesis and time to walk the distance between the waiting area and laboratory. Depending on their availability, some participants underwent two more castings on a different day with the ordering of PDI-5s and PDI-20m reversed.

#### *Scanning Instrument*

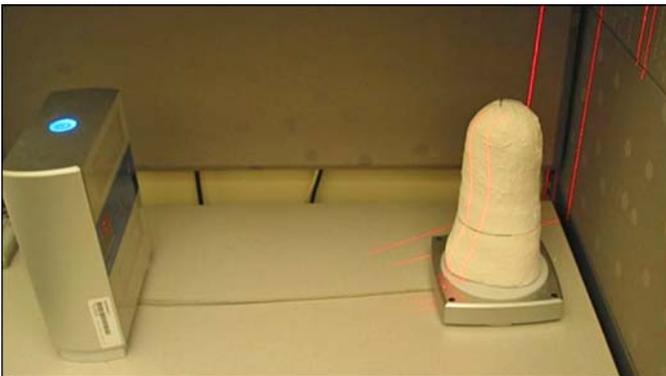
The scanning instrument was a commercial, tabletop, high-performance laser scanner (NextEngine, Inc; Santa Monica, California). The mold was positioned on the scanner turntable with the long axis of the model approximately concentric with the central axis of the turntable

(Figure 1). The scanner projected four separate lasers onto the model and then used a camera to retrieve the data as a three-dimensional (3-D) point cloud. The use of four lasers helped to enhance the quality of the scan over use of just one laser and to ensure no locations on the surface were missed. The 3-D cloud data were then exported to MATLAB (MathWorks; Natick, Massachusetts) where the data were fit with a tensor product B-spline surface. According to manufacturer data, for the image angle setting we used, the instrument had an error of less than 0.38 mm. Based on our experience comparing this instrument with previous technology we developed and characterized [6], we believe the error for residual limb cast measurement to be far less than this maximum.

#### Comparison of Cast Shapes

We compared cast shapes using a technique similar to that described by Zachariah et al. [7], and enhanced by Sanders et al. [8]. The algorithm implemented a combination of minimizing the volume difference and maximizing the shape similarity between the two shapes. Our optimization variable for volume difference was the mean radial difference (MRD). MRD was the average distance between the surface of one shape and the surface of the other shape. Computationally, MRD was (Equation (1))—

$$\text{MRD} = \text{mean}(r_B - r_A), \quad (1)$$



**Figure 1.** Tabletop scanner used for imaging plaster molds. Scanner projected planes of laser light onto mold as mold was rotated, and then processed data to create three-dimensional point cloud of shape.

where  $r_B$  was the radial vector on the PDI-20m surface and  $r_A$  was the radial vector on the PDI-5s surface. Our optimization variable for shape similarity was the local surface tilt similarity between the two shapes. Computationally, it was the mean inverse hyperbolic arctangent of the dot product of the surface normals (Equation (2)):

$$\text{Normal Similarity} = \text{mean}(\tanh^{-1}(n_A \cdot n_B - 10^{-7})), \quad (2)$$

where  $n_A$  was the outward normal vector on the PDI-5s surface and  $n_B$  was the outward normal vector on the PDI-20m surface. The  $10^{-7}$  was subtracted from the dot product of the normals to avoid a Normal Similarity of infinity when the normals were parallel to each other (dot product equals 1).

Thus, we attempted to minimize volume difference and to maximize shape similarity. Computationally, our objective function in the optimization routine was (Equation (3))—

$$f = \text{Radial Weight} \times \text{MRD} - \text{Normal Weight} \times \text{Normal Similarity}, \quad (3)$$

where Radial Weight was the weighting for radial difference and Normal Weight was the weighting for shape similarity.

To stabilize the computational optimization process, we needed to have a good initial first guess at the orientation of the two cast shapes relative to each other in space. To achieve this goal, we first ran the optimization using a Radial Weight of 1.0 and a Normal Weight of 0.0. These settings calculated cast orientations that minimized the volume difference between the two cast shapes. The function *fmincon* in MATLAB was used. This procedure generated a good first guess and appropriate starting point for the subsequent optimization. In the subsequent optimization, a heavily surface-normal-weighted optimization function was used. The Radial Weight was 0.2 and the Normal Weight was 0.8. The basis for selecting these weights was prior clinical experience where we found that a Radial Weight/Normal Weight of 0.2/0.8 performed well for comparing residual limb shapes and 0.8/0.2 worked well for comparing socket shapes [7–9].

#### Analysis

We considered how PDI and ordering of tests affected cast shape. We computed the following metrics for each cast pair (PDI-20m minus PDI-5s).

### Mean Radial Difference

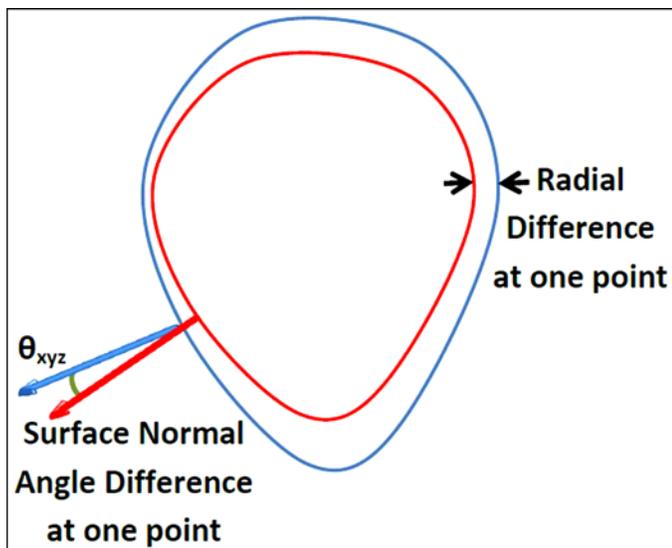
MRD is the average distance between the two cast shapes over the entire surface, expressed in millimeters. It is the average radial difference between each point on the PDI-20m surface compared with its corresponding point (on the same radial vector) on the PDI-5s surface (**Figure 2**). It is approximately proportional to the volume difference between the two shapes after they have been properly oriented to each other.

### Interquartile Range

Interquartile range indicates the degree of regional shape difference between the two cast shapes. The interquartile range is the distance between the 25th and the 75th percentiles of all observed radial differences between the PDI-20m and PDI-5s shape. It is expressed in units of millimeters.

### Mean Surface Normal Angle Difference

The mean surface normal angle difference reflects local curvature differences between the two cast shapes. Mean surface normal angle difference is the average angle difference between a line projecting outward normal from the PDI-20m shape and a line projecting outward normal from the PDI-5s shape, assuming the points



**Figure 2.** Definition of radial difference and surface normal angle difference ( $\theta_{xyz}$ ). For simplification, examples are shown in two rather than three dimensions.

are along the same radial vector directed outward perpendicular to the limb long axis (**Figure 2**).

### Radial Difference Distribution Image

This image is a graphical illustration of the radial differences between the two cast shapes. In the image, regions in which the PDI-20m cast is larger than the PDI-5s cast are shaded blue, while regions in which the PDI-20m cast is smaller than the PDI-5s cast are shaded red.

### Surface Normal Angle Difference Distribution Image

This image is a graphical illustration of the surface normal angle differences between the two cast shapes. In the image, locations in which the surface normal angles do not align well are shown in dark blue. Locations in which they do align well are white.

These metrics were selected because similar metrics were used effectively in previous research assessing manufacturing quality of prosthetic sockets [6] and positive models [9] and the clinical effect of socket shape error [8]. Radial difference data has been used effectively in commercial software packages in the prosthetics industry for socket design to compare socket and limb shapes.

### Repeatability Testing

To test performance of the scanner and to what degree positioning of the mold in the apparatus affected results, we conducted a series of tests on three molds. Relative to others tested, one mold was long, one was average length, and one was short. All molds were subject cases in the present study. Each mold was placed in the scanner and scanned. Then it was removed from the scanner, repositioning on the tabletop, and rescanned. The two scanned images were oriented relative to each other for comparison using the shape-alignment algorithm described previously, and analysis was performed of the MRD, interquartile range, and mean surface normal angle difference.

## RESULTS

### Participants

A total of 24 individuals participated in this research. Seventeen were male, and seven were female. Participants were a mean  $\pm$  standard deviation of  $53.3 \pm 11.9$  years of age,  $92.9 \pm 24.7$  kg in mass, and  $180.1 \pm$

16.3 cm in height. Mean body mass index (BMI) was  $28.7 \pm 6.9 \text{ kg/m}^2$ , mean midlimb circumference was  $33.0 \pm 3.9 \text{ cm}$ , and mean limb length was  $15.8 \pm 3.8 \text{ cm}$ . Time since amputation averaged  $13.5 \pm 15.0 \text{ years}$ . Eighteen subjects experienced limb amputation as a result of trauma; three as a result of peripheral vascular disease; and one each a result of cancer, osteomyelitis, and thrombosis. Fourteen individuals had comorbidities, and ten had no comorbidities. A total of 23 subjects used patellar-tendon-bearing prostheses, while 1 used a suprapatellar design. Twelve subjects used locking pin suspension only; four used only suspension sleeves; one used both a locking pin and a suspension sleeve; five used only vacuum; and two used supracondylar suspension, one with a suspension sleeve and one without a suspension sleeve. On their test day, eight individuals were cast using PDI-5s first and PDI-20m second, while four individuals were cast using PDI-20m first and PDI-5s second. An additional 12 individuals had two pairs of casts made on two different days (one day with PDI-5s first, and one day with PDI-20m first). Thus, we had a total of 36 pairs of casts available for analysis.

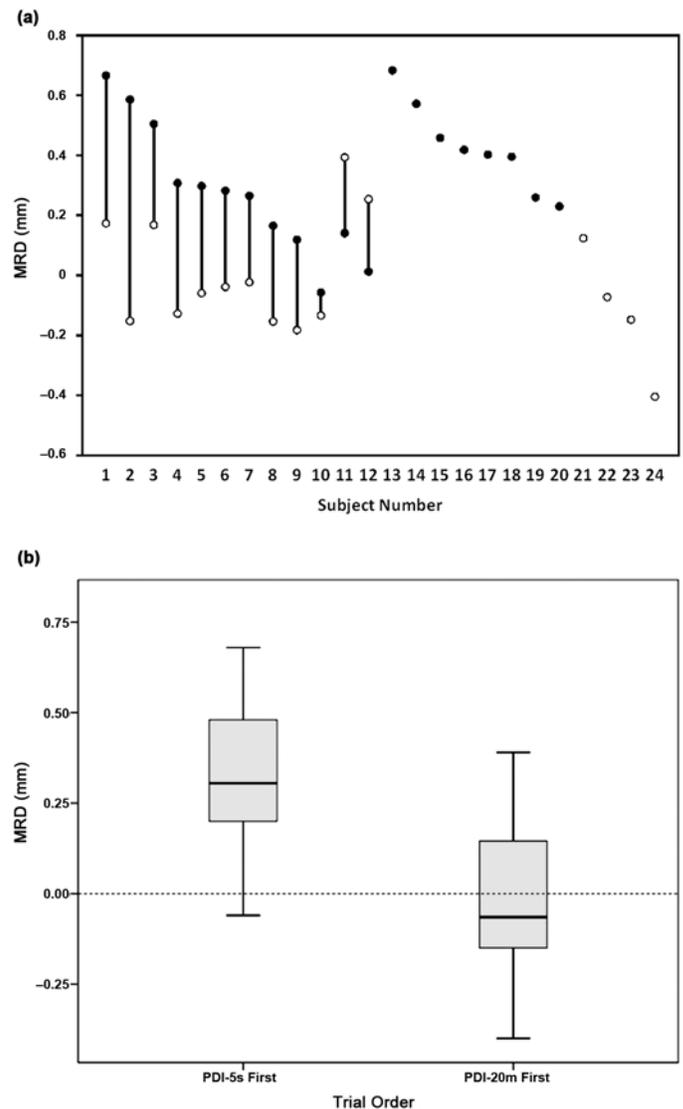
### Instrument Repeatability Assessment

Repeatability testing of the molds all showed absolute errors between scans for the three mold pairs equivalent to or less than 0.01 mm for MRD, 0.04 mm for interquartile range, and  $0.04^\circ$  for mean surface normal angle difference.

### Mean Radial Difference

**Figure 3(a)** shows the MRD for all 36 pairs of casts, with 2 pairs (connected by a line) for the first 12 individuals and 1 pair for the last 12. **Figure 3(b)** presents the percent volume difference for the 20 pairs of casts when PDI-5s was conducted first and the 16 pairs when PDI-20m was conducted first. Values of MRD between PDI-20m and PDI-5s tended to be larger when PDI-5s was conducted first (closed circle markers in **Figure 3(a)**). Using a *t*-test for one mean, we evaluated whether the mean MRD was equal to zero when PDI-5s was conducted first. A total of 20 cases was available. Results showed a mean MRD between PDI-20m and PDI-5s of  $0.34 \pm 0.21 \text{ mm}$ , a median difference of 0.30 mm, and a range of  $-0.06 \text{ mm}$  to 0.68 mm. The difference was statistically different from zero ( $p < 0.001$ ).

Then, we tested whether the mean MRD was equal to zero when PDI-20m was conducted first. A total of 16



**Figure 3.** (a) Mean radial difference (MRD) results for casts taken on same day. Data from all 24 participants are shown. Closed circles indicate MRD for test days in which 5 s postdoffing interval (PDI-5s) was conducted first, and open circles indicate MRD for test days in which 20 min postdoffing interval (PDI-20m) was conducted first. Individuals who had both test orderings are joined by line. (b) Box plots showing MRD results when PDI-5s was conducted first and when PDI-20m was conducted first.

cases was available. Results showed a mean MRD between PDI-20m and PDI-5s of  $-0.02 \pm 0.20 \text{ mm}$ , a median difference of  $-0.07 \text{ mm}$ , and a range of  $-0.40$  to 0.39 mm. The difference was not statistically different from zero ( $p = 0.63$ ).

Finally, using data from the 12 subjects for whom we had two pairs of casts, we performed a repeated measures analysis of variance (ANOVA) to test whether the order of testing (PDI-5s first or PDI-20m first) had an influence on the MRD. Results from the ANOVA showed that order was statistically significant ( $p = 0.008$ ), with larger values obtained when PDI-5s was conducted first.

While the number of individuals in the study does not allow us to statistically assess the influence of other factors, such as BMI, limb length, limb circumference, type of prosthesis, suspension, cause of amputation, and sex, we made plots of MRD by each of those variables (plots not shown) in order to explore possible associations. None of the plots showed any pattern that seemed to indicate potential association between the variable and MRD in this small sample ( $n = 12$ ).

### Images of Shape Difference

Images of shape differences for PDI-20m compared with PDI-5s demonstrated large radial difference distributions and surface normal angle distributions. Results shown in **Figure 4** are typical. The plaster wrap edges were apparent as surface normal angle differences in the surface normal angle difference plots (indicated by arrows in **Figure 4**, right panels). Regions of elevated radial differences (indicated by arrows in **Figure 4**, left panels) tended to be within the boundaries of the edges of the bandage wrap. This result suggests that one turn of the bandage was under different tension and thus applied a different local pressure than an adjacent turn. All but two of the cast pairs showed these results. Those two pairs (images not shown) instead showed relatively uniformly distributed radial difference and surface normal angle difference.

## DISCUSSION

CAD/CAM packages may soon be extended from their current capabilities for socket design to include a capability to compare measurements of residual limb shape. This extension may be important toward understanding how residual limb volume change is relevant to socket fit. In this article, we present insight into how much influence prior activity has on cast shape.

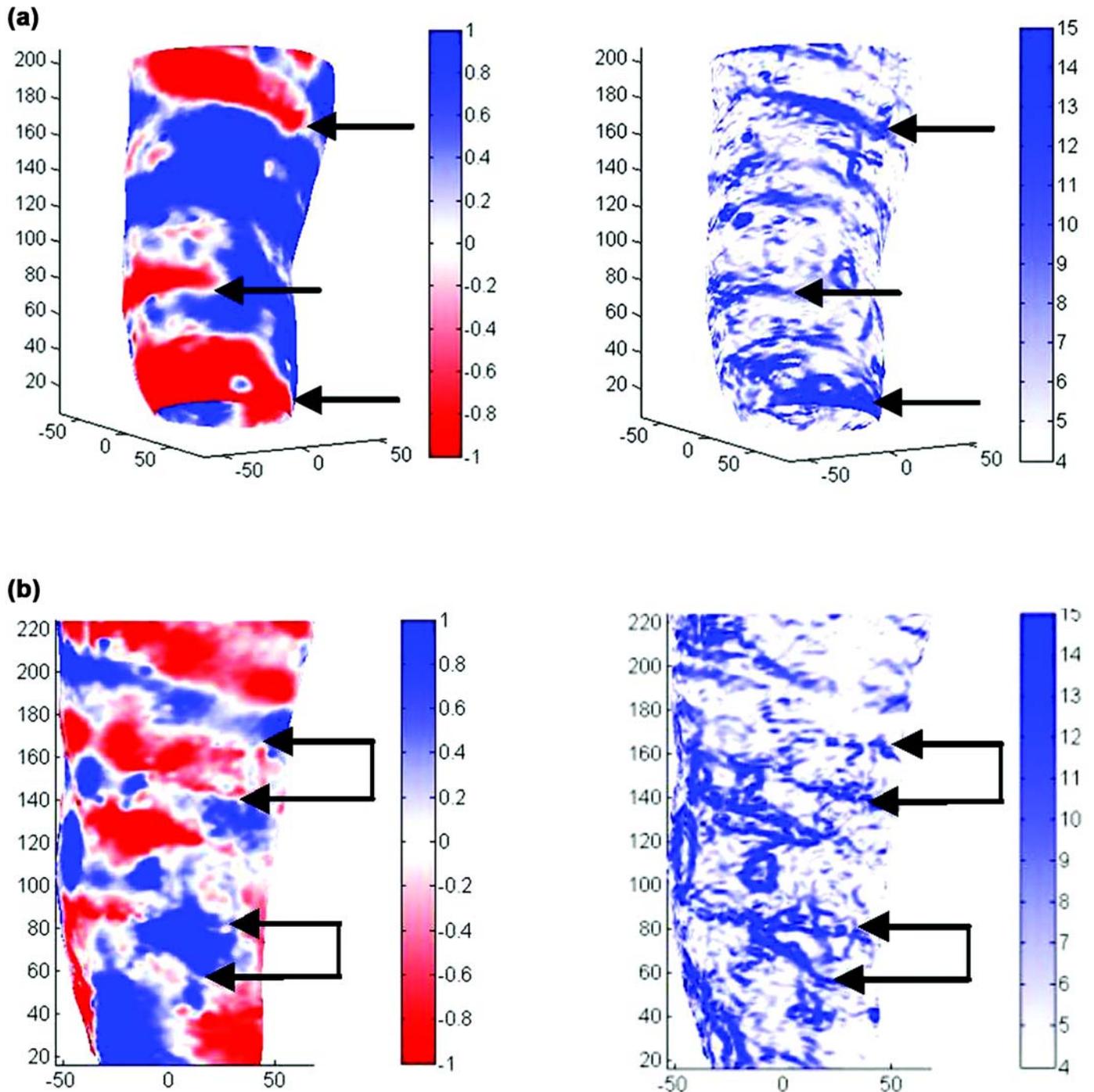
### Sources of Error

The research prosthetist preparing the plaster wraps had over 12 yr of clinical experience as a certified prosthetist. Thus, we believe the casting procedure was conducted in a consistent manner, thereby minimizing the effect of variability in casting time on the results. However, there may be error inherent to the procedure itself that might have affected the data presented here. In other words, inconsistency even by an experienced skilled prosthetist might occur. We recognize that laser scanner products are commercially available and could have been used in the present study to collect the limb shape data, possibly reducing error. However, our intent in this study was to emulate the most common clinical practice and to compare results with investigations reported in the literature that used similar methods of casting as ours.

### Activity Before Casting

We investigated how our results compared with volume changes of clinical studies reported in the literature. Board et al. measured volumes of alginate casts taken before and after 30 min of activity [10]. On 11 individuals with transtibial limb loss who had their amputation as a result of traumatic injury, he reported a 6.5 percent volume gain when subjects used elevated vacuum compared with 3.7 percent volume loss when they used suction. Assuming a standard model for a residual limb [11], these volume differences corresponded to MRDs of 1.4 mm and  $-0.8$  mm, respectively. Goswami et al., using a similar measurement technique to Board et al., reported volume changes over 30 min activity periods using elevated vacuum of 2 percent for undersized sockets, 5 percent for neutral-sized sockets, and 11 percent for oversized sockets [12]. Using Fernie and Holliday's model, these volume differences corresponded to MRDs of 0.4 mm, 1.1 mm, and 2.0 mm, respectively [11]. Graf and Freijah demonstrated a rate of volume reduction of 2.3 percent/day for an experimental group of postoperative subjects who used a polymer gel sock in conjunction with a removable rigid dressing and a rate of volume reduction of 1.2 percent/day for a control group using just a removable rigid dressing [13]. Using Fernie and Holliday's residual limb model [11], these rates of change corresponded to radial changes of  $-0.5$  and  $-0.3$  mm/day, respectively.

In the present study, MRDs between casts taken on the same day for the PDI-20m test compared with the PDI-5s test when the PDI-5s test was conducted first averaged 0.34 mm and ranged from  $-0.06$  to 0.68 mm, values that



**Figure 4.**

Exemplary results illustrating shape differences in casts taken from same subject on same day: 20 min postdoffing interval minus 5 s postdoffing interval. Radial difference images (left panels); surface normal angle difference images (right panels). All x- and y-axes are in millimeters. Color scales for radial difference are in millimeters, and for surface normal angle difference are in degrees. Results in (a) are from one subject (anterior-lateral view), and results in (b) are from different subject (anterior view). Edges of bandage wraps are indicated with arrows.

were comparable to losses over 30 min activity periods reported by Board et al. when subjects used suction sockets and daily losses for postoperative subjects as reported by Graf and Freijah [13]. MRDs when the PDI-20m test was conducted first were smaller (mean of  $-0.02$  mm and range of  $-0.40$  to  $0.39$  mm). This result highlights the importance of doffing history in residual limb shape capture when the practitioner is using casting to collect the limb shape.

Though few subjects ( $n = 12$ ) were evaluated for the order of test procedure (either PDI-5s or PDI-20m first), the finding that order was statistically significant ( $p = 0.008$ ) points to the potential importance of periodic limb doffing and/or prior activity during the day in affecting limb size. Practitioners need to carefully consider the time of the day at which the cast of an individual is collected, as well as what the individual was doing earlier in the day before coming to the clinic for casting. These variables may strongly affect the shape outcome from casting, which will affect the fit of the prosthetic socket on the residual limb.

Though there were consistent trends in MRD for different PDI ordering, the images of shape difference showed nonuniform radial differences over the limb surface (e.g., **Figure 4**, left panels); that is, there was not a uniform radial increase or decrease over the surface for PDI-20m/PDI-5s comparisons. While there were consistent volume differences depending on test ordering, there were not consistent local shape differences depending on test ordering. It may be that while the average tension in the practitioner's bandage was highly consistent and repeatable from cast to cast, there were slight tension differences from one wrap turn to the next within a cast. This hypothesis could be tested by casting and recasting a gel phantom and then assessing reproducibility. In the present study, we propose that local radial differences were induced by slight tension differences, but cast volume was not affected. It has yet to be studied how slight socket shape differences affect quality of fit and patient care, other than our single investigation of 10 subjects [8]. That study indicated that surface normal angle error well identified socket regions deemed by clinical examination (static fitting) to be improperly shaped. Further research investigating effect of shape error is needed. In the present study, it is noteworthy that while cast shape differences were not consistent from subject to subject, trends in the volume differences were reasonably consistent. This result points to the importance of cast volume

being influenced by doffing time and prior activity. Socket volume is an important determinant of quality of fit [8].

The combination of radial difference images and surface normal angle difference images (**Figure 4**) provided insight relevant to interpretation, similarly to a previous investigation [8]. Surface normal angle difference images helped to identify boundaries of regions mismatched in shape, and that insight helped to clarify image data of radial differences. The use of surface normal angle difference in commercial prosthetic design software packages should be considered.

### Future Research

A next step is to extend image analysis and interpretation to evaluate whether information about volume and shape differences over time can be used to clinical advantage. For example, can this information help practitioners decide an optimal socket shape or select accommodation prescription for a patient? Can it be used toward education to facilitate students' understanding of limb shape and volume changes and their affect on prosthetic fit?

While subject factors including BMI, limb length, limb circumference, type of prosthesis, suspension, cause of amputation, and sex did not indicate potential association between the variable and MRD in the present study, the number of individuals in the study was small. These factors should be considered in future studies to test for possible associations.

### CONCLUSIONS

Our results indicate that practitioners should be mindful of prior activity and doffing history when casting an individual's limb for socket design and prosthetic fitting. In the present study, time between doffing and casting and order of testing affected cast volume. When casting 5 s after doffing was performed first and casting 20 min after doffing performed second, then the MRD between the two casts was statistically different from zero (mean  $0.34$  mm). But when casting 20 min after doffing was performed first and casting 5 s after doffing performed second, then the MRD between the two casts was not statistically different from zero (mean  $-0.02$  mm). A repeated measures ANOVA showed that order of testing was statistically significant ( $p = 0.008$ ), with larger values obtained when casting after 5 s was conducted first. Researchers should control for prior activity during

the day and history of doffing in research studies intended to assess residual limb volume.

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*Study concept and design:* J. E. Sanders, M. R. Severance, K. J. Allyn.

*Acquisition of data:* M. R. Severance, D. L. Swartzendruber, K. J. Allyn.

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*Drafting of manuscript:* J. E. Sanders.

*Critical revision of manuscript for important intellectual content:*

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*Obtained funding:* J. E. Sanders.

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**Participant Follow-Up:** The authors do not plan to inform participants of the publication of this study. However, participants have been encouraged to check the study Web site for updated publications.

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