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Medicine and Design Investigate Residual Limb Volume Fluctuations: Three Case Studies

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RESEARCH

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Abstract

Background
Volume fluctuations dramatically affect the daily fit and function of amputees' prosthetic limbs. Prosthetists have experiential knowledge of patient volume fluctuations; however they rarely have access to quantitative evidence. Information regarding volume fluctuations is crucial when determining prosthetic socket design, component selection, and rehabilitation regimens. A collaboration between the Human Dimensioning© Lab (HDL) and Dan Rowe and Associates, a community prosthetic and orthotic provider quantified volume data of individual residuum anatomy.

Method
The project used a 3-dimensional optical body scanner and point cloud digitizing technology, currently used for apparel design, to quantify the daily residuum volume fluctuations in three lower limb amputees. Utilizing the HDL design resources, three amputees were scanned three times at four intervals over a six-hour period. The scans were analyzed using Polyworks® software. Each group of three scans was meshed into an average and each of the four averaged scans was compared to the amputee's remaining three averaged scans.

Results
The results document the changes in volume of the subjects' residuum over the six-hour period. The subjects experienced a range of volume fluctuations from 0.5% to 7.5% of total volume. To validate the method, scanned volume measurements were compared to a simple water displacement measurement. The results from the scanning method and displacement method differed between .71% and 1.16%. The magnitude and period of fluctuation were not consistent between the subjects.

Conclusion
Presently, little is known of the magnitude of short-term volume fluctuations, nor is it known if shape changes accompany short-term volume changes. This design and medicine collaboration provides a platform for compiling accurate and consistent residuum volume data and shape characterization. The method has the potential to affect prosthetic limb design and fit.

Background
Amputees report that socket fit is the most important issue they face when using a prosthesis. One of the most important facets of restoring limb function to the lower limb amputee is precise fitting of the prosthetic socket. Without a proper fitting socket, overall function of the prosthesis is diminished because of improper transfer of forces from the socket to the residual limb. A distribution of forces to non-pressure tolerant areas of the residual limb can result in pain, skin irritation, and tissue breakdown [1]. Considering the intimate fit between residuum and socket, consistent and accurate measurement of the residuum is critically important to create a well fitting socket. A volume increase of just 3% can cause difficulty for an amputee putting on a prosthesis [2]. Residual limb volume change during the course of the day can result in a "mismatch in the volume of the limb and the volume of the" [2] rigid socket. The initial obstacle in quantifying residuum volume is the variability of residuum measurements between prosthetists as reported by Geil [3]. A second obstacle is variability of casting techniques between prosthetists as reported by Houston et al [4]. While volume fluctuation of residuum is a well-known phenomenon to amputees and prosthetists, there is limited data in literature that quantifies volume fluctuation that occurs over the course of the day [2].

One way to obtain volume measurements of residuum is by manual measurement. It is possible to add segmental volumes; however variability between measurements renders accurate and consistent results impossible. Geil conducted a study investigating the accuracy and repeatability of amputee anthropometric devices and found that improper measurement techniques and poor understanding of measurement devices lead to clinically significant errors [3]. Another method for obtaining volume measurements includes digitization of residuum casts. Houston et al showed a 21% difference in cast cross sectional areas, and a 33% difference in cast segmental volumes when different prosthetists were measuring and casting the same subject [4]. Not only did Houston et al find variation between prosthetists, up to 27% variation was reported when one prosthetist cast the same patient three times [4]. In an effort to remedy the variation and inconsistency in measurements Houston et al. used a CAD/CAM system with the potential to reduce the subjectivity of residual limb and limb segment characterization [4]. Houston et al used an instrument called the VA-Cyberware Optical Laser Digitizer to produce accurate and consistent quantitative characterization of limb spatial geometry and surface contours [4]. Houston et al found a maximum of 1.2% volumetric deviation for below-knee amputees and a maximum of 3.0% deviation for above-knee amputees [4]. Houston et al was able to devise a method for consistent and accurate residuum volume measurements and surface topology [4]. However, the equipment and method described by Houston et al was regulated by the VA and unavailable for our use. These two studies highlight the need for a consistent and accurate methodology for measuring residual limbs and quantifying the shape of residuum.

Volume and shape changes occur hourly, daily, and monthly for amputees and as a result, there must be methods to quantify those changes [2]. As more quantitative results become available, prosthetists will be able to better manage socket fit and researchers will develop active shape control technologies to improve socket fit and enhance prosthetic function.

Method

All subjects were lower limb amputees, over age 18, with self described daily volume fluctuations. All participants were amputees as a result of trauma and were at least 7 years post amputation. Participants were required to use crutches for ambulation subsequent to the removal of their prosthesis during the study period. Also, participants were required to demonstrate the ability to ascend and descend two steps with available railings on each side, while wearing a prosthesis. The participants were required to demonstrate the ability to stand for two minutes without a prosthesis but with the aid of crutches or railings. Three subjects participated in the study, two female above knee amputees and one male below knee amputee. All participants were able to complete the study. The study was conducted in compliance with the Helsinki Declaration. The study protocol was approved by the University of Minnesota IRB, #0611M97226.

Subjects were asked to fill out an intial questionnaire after they had consented to participate. Subjects answered questions regarding their perceived volume fluctuations and how those fluctuations affected their prosthetic fit and function throughout the day. Then the subjects were asked to complete a second questionnaire containing questions about daily activities. The second questionnaire was used as a reference to simulate the subjects' daily environments. The simulated daily enviroments were used to obtain volume data that was representative of a subject's normal day.

After the second questionaire was completed subjects were required to participate in crutch and stair training. At the conclusion of the training, each particpant scheduled a day to complete the six hour scan session at the Human Dimensioning© Laboratory. During the six hour scan session, each particpant was scanned at four separate times. Scan sessions were conducted at 9:00am, 11:00am, 1:00pm, and 3:00pm for each subject. Three consecutive scans were taken during each session, resulting in a total of twelve scans for each participant. Each scan lasted for a duration of eleven seconds and the time between scans was approxmately thirty seconds. Each scan was verified by an investigator for completeness prior to initiating the subsequent scans in each session, resulting in the thirty second interval between scans. A meshed average of the three scans was created to reduce intra session variability. For each session the particpant changed into a form-fitting scan suit. The scan suit minimized the fabric interfering with each residuum while still allowing full coverage for each participant. Each subject then approached the scan platform while wearing their prosthesis to maximize residuum containment and to ensure safety. The subjects entered the scanner and removed their prosthesis at the top of the scan platform. Once the prosthesis was removed each subject stood with support aids and was scanned three times. At the conclusion of each scan session, the subjects removed their scan suits, put on their regular clothing, and were asked to resume normal prosthetic wear and typical daily activities.

To obtain meaningful results, each subject was required to simulate their normal daily activities as closely as possible during each two hour break, while maintaining constant prosthetic wear. A room was set up to mimic each subject's daily environment. In addition, walking tours of the campus were available between sessions.

The scanning was done using a VITUS/Smart three-dimensional body scanner from Human Solutions. The body scanner generated realistic three-dimensional images using optical triangulation. Optical trianglulation allowed for precise touchless measurement of each subject's body. The scans allowed for measurements with a standard deviation of 0.1%, as per the VITUS documentation. ScanWorX body measurement software facilitated point cloud manipulation and was used to obtain over one hundred body measurements. Polyworks® v10 by Innovmetric was used to transform and analyze the data. The Polyworks® software allowed for point cloud digitizing, dimensional analysis and comparison, as well as reverse engineering tasks.

Extraneous data collected from the scanner was deleted using ScanWorx. All scan files were transferred from ScanWorx to Polyworks® where the point cloud data was converted into three-dimensional polygonal models. Data loss occurred at the crotch and distal end of the residuum as a result of the orthogonal orientation of the lasers in the scanner. In order to obtain volume measurements critical missing data had to be recreated. In an effort to reduce variability prior to data recreation, averages of each subject's residuum were created from each scan session. The three session scans were imported into the same file space and manually aligned using three-dimensional rotation and translation. After manual alignment, a best-fit alignment task was run. Upon satisfactory alignment of the three scans, Polyworks® created an average polygonal model. The crotch and distal residuum missing data was recreated to fill gaps for each averaged model.

To recreate missing data in the crotch of the residuum models, a prototype was scanned using an alternate orientation in the body scanner. The prototype was then cropped and imported into each scan session average model. Once the prototype was imported, it was merged with the existing polygonal model to close the crotch section.

To address the other model sections with missing data, a reverse engineering tasked called 'hole-filling' was performed. The 'hole-filling' task was an execution of an algorithm the Polyworks® software used to approximate new data in relationship to the existing curves of the polygonal model.

To calculate a volume of the residuum, the polygonal model had to be closed, or 'watertight'. As a result, all missing data was recreated and the proximal edge of the residuum was capped by a plane. The four average polygonal models for each subject were imported into the same file and manually aligned to ensure consistency of the plane orientation. The plane was rotated and/or translated in three dimensions to best fit the inguinal crease of the leg (for the two above knee amputees) or the distal edge of the scan suit, approximately three inches above the knee (for the below knee amputee). After successful alignment, the plane was meshed into the models and the remaining data proximal to the residuum was deleted. The elements of each polygonal mesh were selected and a total volume measurement, comprised of 1000 discrete volumes was obtained.

Water displacement volume measurements were taken from the distal segments of two subject's residual limbs in an effort to provide comparison between a well-known volume measurement standard and the scanning method. The subjects returned to the Human Dimensioning© Lab to undergo the water displacement testing and scanning of the same portion of the limb. The scan data was analyzed and compared to the water displacement volumes.

Results

Case 1

Subject one was a 44 year-old female above knee traumatic amputee with self-described extreme volume fluctuations. She reported loss of prosthetic socket contact during the day if she was more active than usual. She required compression wrapping of her residuum prior to prosthetic wear each morning and she reported daily fit problems for several months leading up to her scan day. Her fit problems significantly limited her ability to ambulate. During subject one's scan day she spent rest periods in the lecture room sitting. Table 1 shows the scan session average volumes for each session.

Table 1 – Subject One Volume Measurements and Changes for Four Scan Sessions

Scan Session (time)	Volume (mm^3)	Volume Change (mm^3)	Percent Change
9:00am	4099754.2	0.0	0%
11:00am	4229398.7	129644.5	3.07% (+)
1:00pm	4353980.7	124582.0	2.96% (+)
3:00pm	4177251.5	176729.2	4.06%(-)

Figure 1 - Subject One Scan Session Residuum Polygonal Model Averages

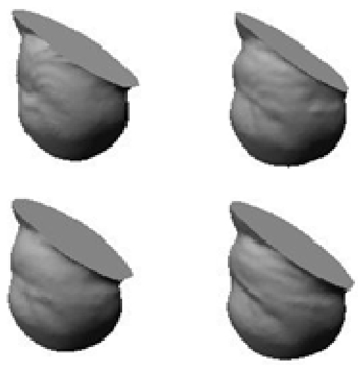

Figure 1
Clockwise from the top left, 9:00am scan session average model, 11:00am scan session average model, 1:00pm scan session average model, and 3:00pm scan session average model.

The percent difference between the largest and smallest recorded volumes was 5.84%. The greatest percent change between two scan sessions occurred between the 1:00pm and the 3:00pm scans with a change of 4.06%.

Subject one was unable to return for water displacement measurements, therefore, no comparative volume data is available.

Case 2

Subject two was a 48 year-old female above knee traumatic amputee with self-described moderate volume fluctuations. She reported no loss of prosthetic socket contact during typical wear. However she reported swelling of her residuum upon waking with a reduction in swelling during activity. She reported a tendency for swelling to occur after a long day ambulating. Subject two reported controlling her volume fluctuations by drinking adequate water, maintaining body weight, and keeping a consistent level of daily activity. No physical interface was used to adjust her socket for volume fluctuations. She was able to put on and take off her prosthesis without difficulty before and after each scan session. During the first break the subject took a 90 minute walking tour of the campus, during the second she ate lunch and took a 60 minute walking tour, and during the third break she sat and read a book. Table 2 shows the scan session average volumes for each session.

Table 2 - Subject Two Volume Measurements and Changes for Four Scan Sessions

Scan Session (time)	Volume (mm^3)	Volume Change (mm^3)	Percent Change
9:00am	4907696.6	0.0	0%
11:00am	5135732.9	228036.3	4.44%(+)
1:00pm	5161473.9	025741.0	0.50%(+)
3:00pm	5205548.1	044074.2	0.85%(+)

Figure 2 - Subject Two Scan Session Residuum Polygonal Model Averages

Figure 2
Clockwise from the top left, 9:00am scan session model average, 11:00am scan session model average, 1:00pm scan session model average, and 3:00pm scan session model average.

The percent change between the largest and smallest recorded volumes was 5.72%. This also equalled total percent change because subject two experienced consistent volume increases over the course of the day. She experienced most of her volume change between the first and second scan sessions, a 4.44% increase.

The volume measurements obtained from the water displacement method and scan method are in Table 3. Due to time constraints subject two was able to have one water displacement measurement and one scan method volume measurement collected. The percent difference between the scan method volume measurement and the water displacement measurement was 1.10%.

Table 3 – Water Displacement Volume Compared to Scan Method Volume

Volume Measurement Type	Volume (mm^3)	Percent Difference
Water Displacement (1)	1308000	
Scan (1)	1293668.6	1.10% (-)

Case 3

Subject three was a 27 year-old below knee traumatic amputee with self-described minimal volume fluctuations. He reported that his limb typically lost volume throughout the day. He reported sixteen hours of prosthetic wear per day including ten hours of standing and walking. He reported larger volume fluctuations with increased activity. During the first break between scans the subject took a 90 minute walking tour of the campus, during the second he ate lunch and took a 60 minute walking tour, and during the third break he sat and took a brief nap. Table 4 shows the scan session average volumes for each session.

Table 4 - Subject Three Scan Session Residuum Polygonal Model Averages

Scan Session (time)	Volume (mm^3)	Volume Change (mm^3)	Percent Change
9:00am	1434252.3	0.0	0%
11:00am	1423110.1	011142.2	0.78%(-)
1:00pm	1537529.2	114419.1	7.44%(+)
3:00pm	1514702.6	022826.6	1.48%(+)

Figure 3 - Subject Three Scan Session Residuum Polygonal Model Averages

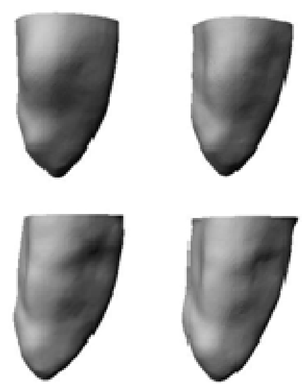

Figure 3
Clockwise from the top left, 9:00am scan session model average, 11:00am scan session model average, 1:00pm scan session model average, and 3:00pm scan session model average.

The percent change between the largest and smallest recorded volumes was 7.44%, which happened to occur between the 11:00am and the 1:00pm scan sessions. The total percent change in volume for the subject over the course of the day was 5.46%.

The volume measurement obtained from the water displacement method and scan method are in Table 5. Subject three was able to have one water displacement measurement and two scan method measurements collected. The percent difference between the water displacement volume and the scan method volume ranged from 0.71% to 1.16%, both scan volume measurements obtained were less than the recorded water displacement measurement.

Table 5 – Water Displacement Volume Compared to Scan Method Volume

Volume Measurement Type	Volume (mm^3)	Percent Difference
Water Displacement	1298000	
Scan (1)	1282941.6	1.16% (-)
Scan (2)	1288792.3	0.71% (-)

The data does not lend itself to many conclusions and it does not indicate fluctuation differences between amputee types. All three subjects experienced a volume fluctuation of at least 4.06% between two scan sessions during the day. The data does not show differences in fluctuation magnitude between gender or amputee activity level. The small sample size of the study limits the data to subject specificity and does not allow for generalizations. However, the data confirms volume fluctuations between scan sessions and throughout the day for all subjects.

The comparison between water displacement volume measurements and scan method measurements provided differences between 0.71% and 1.16%. All scan method volumes were smaller than the water displacement volumes.

Discussion

The aim of this project was to measure volume fluctuations using a 3 dimensional body scanner and point cloud digitizing software. Volume measurements were recorded for all three of the subjects who completed the study. Each subject reported experiencing volume fluctuations during the study day and this project was able to confirm that volume fluctuations were occurring.

The scan suits used in this study may create a confounding variable. Although they are made with a minimally compressive Lycra and nylon blend fabric, they were chosen to provide a fit which just skimmed the body of each subject. The suits do have an ability to minimally smooth some body contours when fitted in this manner.

In the case of the below knee amputee, the scan suit was well above the residuum and the volume of interest. The suit was not observed to constrict the limb in any way. The suit did cover the majority of residuum for each of the above knee amputees. It is unlikely the elastic properties of the scan suit affected the volume readings for these subjects because the leg of the scan suit needed to be pinned to take up excess fabric on the side of the residual limb and the suit did not compress the limb. If anything the looser fit of the scan suit on the residuum may have added volume.

Considering the suit's potential to affect residuum volume in this way, it is recommended that further study be conducted without use of a scan suit, but simply scanning subjects in their own brief-style underwear.

Most limitations of the study stemmed from incomplete data collection by the body scanner. This resulted in significant data loss in the crotch and inner thigh region of each subject scan. The data loss necessitated data recreation using a patching method that merged data from a prototype into each scan. This method used to replace the missing data introduced undesired variability into the volume measurements. However, water displacement measurements indicated only a small percent difference between the two methods. To enhance the accuracy of the scan method, further study involving secondary volume recordings using a method with published accuracy is desirable. A study completed by Starr used "a computerized automated system for the volumetric analysis of the residual limbs of amputees" [5] to determine cross sectional areas and segmental volumes with an accuracy of 98% [5]. This method was not initially incorporated for comparison because it was beyond the scope of the study. However, introducing this volume measurement method would allow for more complete statistical analysis of the scan method.

One of the reasons that there is little meaningful quantification of residuum volume is the challenge of aligning the residual limb shapes. In order for quantification to be useful, residuum must be properly aligned so that 'uniform and localized changes can be accurately determined [6]. Santosh et al created three algorithms to align residual limb shapes [6]. Of the three, they found one method that aligned based on minimizing shape difference and maximizing shape similarity to be useful.[6] Santosh et al's resulting algorithm warrants further investigation for this project. Considering the unknown level of variability introduced by aligning the average polygonal models for plane insertion, it is desirable to find a more consistent and accurate alignment technique.

An additional limitation of the study arises from single investigator data recreation. It was unknown at the conclusion of the study how much variability in volume measurements would be introduced if more than one investigator recreated missing data. Additionally, the investigator charged with data recreation also aligned and averaged all scans and created the necessary closed surface planes for the averaged models. Further study utilizing multiple investigators for model alignment, data recreation, and plane creation is needed to address the robustness of the scan method.

Conclusion

At present little is known of the magnitude of short-term volume fluctuations. Nor is it known if shape changes accompany possible short term volume changes [7]. Considering that socket fit is the amputees' number one concern regarding prosthetic use [2] it is imperative that meaningful data become available regarding the change of limb volume and shape.

This study is a step toward accessing accurate and consistent data regarding residuum volume and shape characterization. However, further research is necessary. Additional analysis of the current data would allow investigation of the reliability of the scan method to reproduce volume measurements over very short periods of time. This project collected scans at intervals of approximately thirty seconds, which were then averaged to create session averages for each subject. Volume calculations on that existing rapid succession scan data would provide a benchmark for the reliability of the method. A subsequent study could explore the method's ability to capture rapid, very small volume shifts, for example, by scanning subjects at intervals of three to five minutes.

Then the accuracy of the data must be analyzed by comparing this method to a method of known accuracy, accuracy and consistency of the hole filling and patching techniques must be assessed, and a consistent method for alignment must be created. Once these tasks are successfully completed, an exceptionally useful study would be to use 3D scanning to identify patterns of residuum change in order to facilitate design of new prosthetic socket options.

Considering the importance of socket fit in relationship to amputee quality of life, further efforts to quantify residuum volume and shape are necessary. The method for this project must be investigated further before validity and clinical usefulness can be assessed.

PEER REVIEW

Not commissioned; externally peer reviewed

CONFLICTS OF INTEREST

The authors declare that they have no competing interests