Validity and Reliability of Three-dimensional Imaging to Measure Limb Volume: A Systematic Review

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Validity and Reliability of Three-dimensional Imaging to Measure Limb Volume: A Systematic Review

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Abstract (230 words)

Introduction: Approximately 30% of women treated for breast cancer will develop lymphedema, yet early identification can prevent this occurrence. It is important to accurately and efficiently measure limb volume to identify pre-clinical lymphedema. Three-dimensional (3D) imaging is emerging as a potential method to meet the need for accuracy and efficiency. The purpose of this review was to evaluate the psychometrics of 3D imaging to measure limb volume.

Methods: A systematic search of 4 databases was conducted for articles using 3D imaging to measure limb volume. Articles were included that compared 3D imaging to water displacement using human subjects from 2000 to present. Data related to relevant psychometrics (validity, reliability, responsiveness) and patient populations were extracted from each article and analyzed. Risk of bias in study design was also assessed for each article.

Results: The initial search of publications included 141 articles, in which 27 articles were selected based on the title and abstract. Only 13 articles were selected after full text review. Evidence from a preponderance of high quality studies demonstrates that 3D imaging is valid and reliable.

Discussion: 3D scanning can provide an accurate and efficient alternative means of measuring limb volume in breast cancer related lymphedema when compared to the reference standard of water displacement. Limitations to immediate clinical adoption include lack of information related to diagnostic accuracy and responsiveness, as well as a uniform definition of lymphedema.

Keywords: lymphedema, breast neoplasms, infrared scanning, psychometrics, measurement

Introduction

Lymphedema is a chronic condition that can affect 30-60% of women treated for breast cancer, impacting up to 2 million women in the United States.[1, 2, 3] Breast cancer-related lymphedema (BCRL) is associated with decreased functional independence, increased treatment costs on average of approximately $1000/year, and decreased overall health-related quality of life when compared to patients with breast cancer without lymphedema.[3, 4] Risk factors for BCRL include a higher body mass index and more extensive cancer treatments such as axillary node dissection and axillary radiation, but no clear pattern of who will develop lymphedema exists.[5] Swelling of the upper extremities is the cardinal sign of lymphedema and frequently is identified by healthcare clinicians through observation.[6] However, by the time swelling is visible, the lymphedema has often progressed to stage 2, and is not reversible. Evidence from a large scale study demonstrates that preclinical lymphedema, that which occurs with a >3% limb volume difference from preoperative values and is not visible clinically, was reversible with the use of compression.[7] It is therefore critical for early identification of increased limb volume before the development of visual swelling, and irreversible lymphedema, occurs.

Limb volume can be measured in multiple ways including water displacement (WD), circumferential measurement (CM), bioelectrical impedance spectroscopy (BIS), and infrared scanning. Current methods of measuring limb volume present challenges in clinical use. Concerns over infection control and efficiency plague the use of water displacement.[8, 9] Limb girth or volumetric calculations using circumferential measures of arm with a flexible tape at set intervals are considered both valid and reliable, however this method of measurement also suffers from time constraints.[9] Additionally, using circumferential measures to calculate volume using a truncated cone formula often overestimates limb volume because the contours of the arm do not match that of a truncated cone or frustum.[10, 11] Bioelectrical impedance does show promise for early diagnosis of limb volume changes, but suffers accuracy in later stage lymphedema because the tissues become more fibrotic and less excess fluid is present.[12] Perometry uses infrared scanning to create a three-dimensional (3D) model and is specifically designed to measure limb volume. It allows for fast, accurate, and hygienic measurements of arm volumes and facilitates routine monitoring of arm volumes.[13, 14] The hefty price tag of a Perometer however, relegates its primary use to research labs or larger academic medical centers. An inexpensive, efficient, valid and reliable method to measure limb volume is needed for early identification of volume increases among women treated for breast cancer.

While measuring limb girth to diagnose lymphedema is relatively common, using the multiple methods, there are nearly as many different diagnostic criteria that confound a consistent definition of what lymphedema is. The International Society of Lymphology consensus document stages lymphedema from Stage 0 – subclinical with no visible swelling through Stage 1 – reversible swelling, Stage 2 – consistent swelling with pitting, to Stage 3 – persistent swelling with skin changes.[15] This guideline does not define a clear objective number associated with the diagnosis of lymphedema at any stage. Other common diagnostic criteria cut points for lymphedema are: a 2 centimeter (cm) increase in limb girth, a 200-mL or more increase in limb volume, or a 5% or greater limb volume change.[5, 6] Pre-clinical lymphedema, defined as a change in limb volume of 3-5%, would align with Stage 0-1, while volume of 5% or greater is considered lymphedema.[7] The Academy of Oncologic Physical Therapy Clinical Practice Guideline on the Diagnosis of Upper Quadrant Lymphedema Secondary to Cancer makes specific recommendations for the diagnosis of lymphedema that would include either absolute volume change or percentage change.[12] A percentage change more accurately reflects relative change; a 2 cm increase may be visible in smaller arms and practically undetectable in larger arms; furthermore 2 cm in a small arm may be significantly greater percentage change than in a larger arm.

Emerging technologies can address the limitations that water displacement and circumferential measures pose in a clinic to measure limb volume. Valid, reliable, and efficient methods may result in earlier identification of BCRL, track volume changes of the arm, and be more readily available in clinics. Portable 3D scanners may meet this need. Similar to perometry in image generation, which has established validity and reliability, portable 3D scanning is significantly less expensive and likely within the reach of clinics to obtain. More time efficient than circumferential measures, more cost efficient and smaller than perometers, portable hand-held 3D scanners that prove to be valid and reliable may facilitate widespread clinical use, increasing early identification of lymphedema. In addition, the ease of use and decreased time associated with these newer methods compared to water displacement could lead to better and more effective monitoring of limb volume in patients who are at risk for developing lymphedema. This would allow for earlier intervention, which can significantly reduce the effect of lymphedema on functional activities as well as a decrease in treatment costs.[3] Given the need for more efficient, yet cost-effective and easy to use valid and reliable tools to measure limb volume, the purpose of this review was to evaluate the psychometric properties of 3D imaging for measuring limb volume in identifying lymphedema.

Methods

Research Question

The research question that shaped the search strategy was formulated using the PICO framework. The preferred *population* of interest focused on those with breast cancer-related lymphedema, however as 3D imaging is a developing technology, any study examining limb volume in adults was of interest. The only exception to this included limb volume of residual limbs in a population of individuals with amputations as the authors felt a complete limb was a better reference standard for the population of interest. The *intervention,* assessment in this question, was 3D imaging. The *comparison* of primary interest was water displacement methods of volume measurement, however studies which reported other comparison measure in addition to water displacement were still included. Finally, the *outcome* of interest was measurement of limb volume.

Search Strategy

A comprehensive literature search with the assistance of a librarian was conducted in **October** 2019 using bibliographic databases including PubMed, CINAHL, Cochrane Library and Google Scholar. **The search initially was intentionally focused on breast cancer-related lymphedema and 3D imaging in a broad sense, and included MeSH terms: "Breast Cancer Lymphedema/diagnosis" OR "Breast Cancer Lymphedema/diagnostic imaging" OR "Lymphatic Vessels/diagnostic imaging" OR "Lymphedema/diagnosis" OR "Lymphedema/diagnostic imaging" AND "3D imaging" AND "adult." Given the small number of overall articles in the initial search, the search was expanded to "3D imaging" AND "lymphedema" to ensure all possible studies were included. Additional key words included** "limb volume," "perometry," and "water displacement" with and "lymphedema." Perometry was a specific search as it is a method **of 3D imaging using infrared scanners to measure** limb volume and studies investigating it did not initially appear in the literature search.

Reference lists of included articles were reviewed for additional studies. **Duplicate studies were removed based on final search lists using a reference management software.**

Selection Criteria

Four reviewers (N.B., M.W., M.V., R.K.) executed an independent literature search and reviewed titles and abstracts of articles from individual searches. Only peer reviewed, full-text articles that focused on evaluating the psychometric properties of 3D imaging to measure limb volume were included. Based on evidence that circumferential measures using a truncated cone overestimate limb volume, and that water displacement is considered the gold standard reference standard, only articles that **included** water displacement for comparison were **selected**.[10, 11] Inclusion dates were January 2000 to **October** 2019. Studies were excluded if the reference standard against which the 3D systems were compared did not include water displacement, were editorials or commentaries, or were not available in English. All studies were initially screened based on title and abstract, followed by full-text review of potential articles.

Data Extraction

Three general categories of 3D scanning of the limb are presented in the literature. Each study was categorized into one of these methods: Multi-camera Systems, Stationary Systems, or Portable Systems. The following data were extracted from each study: population, number of subjects, reference standard(s) used, study quality, and relevant psychometric properties. These psychometric properties included reliability, validity, accuracy and sensitivity to change, and clinical utility. Criterion-related (concurrent and predictive) and construct (convergent and discriminant) validity values were reported when available, as well as measures assessing accuracy and responsiveness to change such as minimal detectable change (MDC) and minimal clinically important difference (MCID).

Quality Assessment

After inclusion, articles were assessed for bias. The Scottish Intercollegiate Guidelines Network (SIGN) Methodology Checklist (Supplemental Online Material - Appendix) was used to assess bias of each study.[16, 17] The SIGN is based on the QUADAS2 (Bristol University) bias assessment, and includes 4 domains covering patient selection, index test methodology, reference standard choice and methodology, and flow and timing of the study.[18] Each domain is further divided into risk of bias and applicability to question investigated. The responses from each box are combined to assess the overall methodological quality of the study as "high", "acceptable", or "low." **Each article was reviewed for bias using the SIGN Methodology Checklist independently by two of the four authors. In the case of differing assessment, discussion took place until consensus on bias was reached.**

Data Analysis

For the purpose of this review, the following criteria were applied to determine the strength of the psychometric properties: excellent reliability = >0.90; good reliability = 0.76-0.89; moderate reliability = 0.50-0.75; and poor reliability <0.50.[19] The quality assessment combined with the strength of the psychometric properties were used to determine an overall strength of the evidence.

Results

The initial search for publications resulted in 130 articles; with an additional manual bibliographic searching resulting in an additional 21 potential articles. With duplicates removed, 127 underwent title and abstract screening; 100 articles were excluded resulting in selection of 27 articles for full text review. After completion of full text review, 13 total

articles fitting the inclusion criteria were selected. While multiple other studies examined the psychometric properties of 3D scanners, many used circumferential measurements as the reference standard, and were therefore excluded from this review. Additionally, studies examining 3D volume measurements of residual limbs in populations of those with amputations were excluded, as these limbs are different than full limbs of adults with **lymphedema**. See Figure 1 for the PRISMA diagram detailing study selection.[20] Table 1 identifies clinical feasibility of each measurement method including cost, portability, time to complete, and ease of calculation.

Types of Scanners

Table 2 provides details of included studies, by category. Study population, participant type and number, relevant psychometrics, and study quality are identified within each category.

Multi-camera Systems. Five studies reported on 3D scanning using multiple cameras: one study compared a fifteen camera system to water displacement,[21] a second compared a three-camera system to circumferential measures, water displacement, and ultrasound,[8] and three other studies examined the Vectra 3D 6-camera system.[22, 23, 24] All but one study included participants with BCRL; **the remaining study** examined healthy adults. All of the studies in this category were graded high quality using the SIGN Methodology Checklist.

Stationary Systems. Three studies reported on 3D scanning using stationary systems. Two studies validated the Perometer against water displacement measures.[10, 25] One other study examined a self-positioning laser scanner attached to a computer in comparison to WD measurements.[26] All studies compared healthy adult controls to individuals with lymphedema; two studies included women with BCRL and the third included individuals with primary or secondary lymphedema of the lower extremity. All studies were graded acceptable[10, 25, 26] as they used case-control methods. While this is often the study design necessary to determine discriminant validity, case-control studies tend to exaggerate diagnostic accuracy.[17]

Portable Systems. **Five** studies reported on 3D scanning using portable systems: one study compared a digital laser scanner camera to circumferential and water displacement methods,[27] one study compared a structure made with aluminium with two visible LED light sources, a Kinect sensor (Microsoft Corporation, Redmond, WA), and two electronic CMOS (complementary metal-oxide semiconductor) cameras to WD,[28] another used infrared depth scanners with Kinect sensors,[29], **two other studies** used a portable, infrared 3D imaging system.[30, 31] **Four of the five** studies included only healthy adults while the remaining study examined adults with filarial lower extremity lymphedema. **Four of the five** studies using a portable system were ranked as high quality; the other was acceptable.

Reliability

Multi-camera Systems. Reliability of the multi-camera systems was excellent, with correlation values exceeding 0.90 for both intra- and inter-rater reliability. In examining Bland-Altman plots of repeated 3D measures, high agreement was noted. Using paired-samples t-tests, differences were not significant ($p>0.05$). Overall, the ability of multi-camera systems to provide reliable measures of limb volumes is excellent.

Stationary Systems. Of the three studies reviewed that used stationary 3D imaging systems, two reported a reliability measures for 3D imaging and WD and while the final study also included the reliability of CM in addition to 3D imaging and WD. Both intra- and inter-rater reliability correlation coefficients exceeded 0.90 for 3D imaging in all studies. This was similar in the single study using concordance correlations, with values >0.90 for both intra- and inter-rater reliability.

Portable Systems. The reliability of portable systems was evaluated either by the Pearson's or intraclass correlation coefficient, Bland-Altman plots for limits of agreement, or by coefficients of variation. All methods resulted in good to excellent reproducibility, with reported standard error of the measure (SEM), except for a single study that found a larger variance in the SEM.[29]

Validity and Accuracy

Concurrent validity was examined in all studies with a consistent reference standard (WD) used in each. No study reported on predictive, convergent, or discriminant validity. The Bland-Altman plots of accuracy generally showed good agreement between 3D imaging and WD, however, one study did note decreased agreement with increased limb volume.

Multi-camera System. All multi-camera systems examined demonstrated excellent concurrent validity in comparison to water displacement methods, with correlation values exceeding 0.98.

Stationary Systems. Using concordance statistics, the stationary systems demonstrated high levels of concordance in excess of 0.90. Only one study examined diagnostic accuracy in this category of scanners, and the results indicated that the Perometer values were less than CM and greater than WD.

Portable Systems. These systems demonstrated excellent criterion-related validity in comparison to water displacement with correlation values exceeding 0.98. Further validation with circumferential measures as with skin thickness ultrasound was also excellent. Two studies examined diagnostic accuracy. Bland-Altman analyses showed no difference with WD and no proportional errors, while the other noted that 3D imaging underestimated volume as limb size increased.

Discussion

The primary purpose of this review was to investigate the psychometric properties of 3D analysis to measure limb volume. While the included articles evaluated multi-camera, stationary, and portable systems, all systems demonstrated acceptable to excellent psychometric qualities. While the analysis of the psychometric properties in this review do indicate that this technology can accurately and reliably measure limb volume, there are still limitations to clinical adoption of 3D scanning.

The multi-camera systems demonstrate both high reliability and excellent validity, but these systems require space and time to use. Some systems can quickly scan a limb, but the processing of the scan is dependent on operator manipulation, which takes additional time. To use the Vectra 3D Scanner, each side of the limb is scanned (medial and lateral) separately, and then stitched together.[22, 23] This step can introduce errors in accuracy, especially in a busy clinic. The scanner described by Hameeteman, et al,[21] scans the upper part of a limb and the lower part of a limb separately, and then the images are combined. This process also introduces human error. The stationary systems investigated in this study include the Perometer, which remains expensive, and with a lack of true portability, inefficient for clinical use. The other 3D scanner used has limitations in portability as it requires a fixed plexiglass panel for reflectors that are used for spatial reference.

The portable scanners show the greatest promise for clinical adoption, but the technology presented in the reviewed studies is quickly out-dated. Two of the studies used an older model of the Microsoft Kinect sensor which is no longer commercially available. While a newer version has since been released, this is not yet adapted to a clinical purpose. Even with such a scanner, the image was processed by software (Skanect 3D Scanning Software, Occipital, San

Francisco, CA) that required end-user processing. The single study in the portable scanner category that uses a currently available scanner (Structure Sensor, Occipital, San Francisco, CA) in a convenient manner also includes software specifically designed to measure limb volume (Lymphatech, Atlanta, GA).[30] This technology appears to be the most promising to develop into a commercially available device that is validated prospectively in a population of individuals with lymphedema.

The intent of the investigation was to determine if there are valid, reliable, and feasible methods to measure limb volume with the goal of using this technology within a population with lymphedema. As 3D imaging is an emerging technology in the medical community, current research is limited to reliability and validity, often in a healthy population. Often initial studies examining the psychometric properties of measurement tools begin with healthy populations, however, it is essential that additional research on those with lymphedema take place, especially to evaluate the diagnostic accuracy and responsiveness of the tool.

While all of these methods appear to have good reliability and validity, the concern that there is no universal method to diagnose BCRL remains. This issue may lead to varying measurements or undiagnosed lymphedema. In addition to having valid and reliable measurement tools to measure limb volume, a universally accepted diagnostic criteria is needed. Further research and expert consensus is needed to identify diagnostic cut points for lymphedema.

Limitations

This systematic review has several limitations that make the findings difficult to use to effect clinical change of practice for limb volume measurement. First, the search took place in

March 2019. It is possible that more current studies have since been published. Secondly, while the Perometer is often accepted as a reference standard for other limb volume measures, many of the original Perometer validation studies used CM as the reference standard. As CM is known to overestimate limb volume, the findings of this review could not be compared to these other studies. This ultimately limited the number of studies included in the final analysis. Since none of the methods of 3D scanning included a full range of psychometric studies, no one method emerges as the best method to adopt clinically.

It is clear that technology is rapidly advancing, and that 3D imaging holds the promise of efficient and accurate scanning to measure limb volume. Further research must investigate both the scanners and the software to rigorously test the psychometrics of these systems. This, along with an objective consensus on what constitutes lymphedema, is essential to address the unmet need to identify those at risk for and with early lymphedema to prevent the development of irreversible lymphedema.

Conclusion

The purpose of this systematic review was to investigate the psychometric properties of 3D imaging to measure limb volume, with the intent of determining whether this newer technology might address the flaws present with water displacement and circumferential tape measure limb volume measurement. The significant results of this review help to show that using newer methods of measurement **are accurate to measure limb volume**. **Future research in those with breast cancer-related lymphedema is necessary to evaluate diagnostic accuracy and responsiveness before adoption of this method of measurement can take place.** The limitations to both water displacement and circumferential measurements can be addressed by using a portable 3D scanner.

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