Development and Clinical Evaluation of a Computerized Limb Volume Measurement System (CLEMS)

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Limb edema is a common problem in both rehabilitation and acute care settings. In the past, attempts to determine an optimal management strategy for limb edema have been limited by the lack of accurate, noninvasive, rapid, clinical tools for quantifying limb volumes. The water displacement method is slow and difficult to use in the clinical setting. Furthermore, water displacement requires that the limb be in a dependent position. The tape measure method is unreliable because it is difficult to position the tape measure on a swollen limb. The development and evaluation of a new tool called the computerized limb volume measurement system (CLEMS) is described. The shape and volume of a limb or limb segment can be rapidly measured by CLEMS, independent of limb position. The limb volumes generated by CLEMS were compared to volumes determined by water displacement and by a tape measure. Volumes of eighteen legs (plaster, nonedematous and edematous) were measured using CLEMS, water displacement, and the tape measure. In all cases, the CLEMS and water displacement methods showed close agreement. CLEMS was found to be a reliable and valid new method of determining limb volume; whereas, the tape measure method was found to be invalid. This new tool allows clinicians to measure the efficacy of different treatment strategies in the management of limb edema.

KEY WORDS: Device; Edema; Equipment design; Extremities

Limb edema is a problem in rehabilitation and acute care settings. For patients with burns or gross cardiopulmonary failure, knowledge of the changes in the volumes of limb segments could be indispensable in optimal fluid management.1, 2 In the rehabilitation setting, accurate information about the amount of edema could clearly affect rehabilitation outcome expectations. For example, a patient might be unable to move his leg because he has insufficient strength to overcome the weight of the extra fluid in the limb. Edematous tissues are known to be poorly oxygenated.3 They heal slowly and often become the site of infection.4 In addition, limb edema can be accompanied by pain that can interfere with treatment and trigger spasticity in some patients.

Many treatments for edema are used in the clinical setting, but these have been poorly supported by research. Studies to determine optimal management strategies for limb edema have been limited by the lack of a valid, reliable, rapid, noninvasive, and clinically useful measurement tool. The two most commonly used methods (water displacement and tape measure) are very difficult to use with the disabled population. Water displacement is slow, difficult to use with individuals who have paralyzed, sometimes spastic limbs, and requires the limb to be in the dependent position. A tape measure is difficult to place circumferentially with even tension on an edematous limb. Volume calculations based on tape measure circumferences rely on a model of the leg as a truncated cone.

We are interested in assessing edema management strategies. Because of a lack of a suitable clinical measurement tool, we felt obliged to develop an accurate assessment tool before we could evaluate treatment efficacy. Thus, the computerized limb volume measurement system (CLEMS) was developed by a team of engineers and clinicians at the G.F. Strong Centre in Vancouver.

CLEMS has three parts—a mechanical arm, a digitizer, and a personal computer. The mechanical arm consists of five linkages instrumented with optical encoders. The end linkage is a hand-held stylus that is traced over the portion of the body being measured.

Twelve data streams are taken from the leg in longitudinal traces and are converted into transverse cross-sections. Software in the digitizer receives and processes information from the encoders, and records the changing position of the stylus tip in the form of data streams.

The information is then processed by a locally developed software package on a standard XT compatible computer. The first step involves dividing a data stream into 1cm increments based on the use of a longitudinal grid and a straight line fit between points in the data stream. This process is repeated on all data streams. A series of 1cm thick cross-sectional slices is then formed by connecting the twelve data streams at every corresponding increment.

The second step determines the shape of each cross-sectional slice. Thirty-six points at 10° increments are calculated about the centroid of each cross-sectional slice. The volume of each cross-sectional slice is computed individually. The total volume of the limb, then, is the summation of the volumes of the slices.
Two different approaches are taken to approximate the shapes of the calf and foot. In areas of convexity, such as the calf, a radial coordinate system rather than a Cartesian coordinate system is used. The circumference between neighboring points of a cross-section is considered to be a proportionally distorted arc of a circle. This circumference is used to determine the new shape. In relatively noncylindrical areas, such as portions of the foot and ankle, the circumference between trace points is considered to be a straight line.

The graphics portion of the software allows the operator to rapidly view the computer-simulated image of the leg. At the same time, the actual tracings are shown superimposed on the computer graphics (figure). The operator can easily select one of nine possible angles to view the image. In this way, all areas of the limb can be scanned for potential tracing errors.

The tracing process is rapid (less than ten minutes), and the only requirement of the patient is to remain still for two to three minutes. The patient's limb can be traced in any position of comfort (supine, sitting, or standing). The system has the capability of measuring both upper and lower extremities. In this study, however, only below-knee volumes were measured.

**METHODS**

The reliability of the CLEMS hardware was periodically assessed during the development stages and showed high reliability. The reliability of the entire hardware and software system was evaluated over three sessions spaced two days apart. The mean of three trials was used in each session. The same operator measured volumes of a variety of different types of legs (plaster, nonedematous, and edematous). The sessions were scheduled no less than two days and no more than four days apart for each of the subjects. Measurements were taken at the same time of day for each subject.

Validity studies consisted of a comparison of three methods of volume measurement. One of the methods, the water displacement method, was regarded as the "gold standard" in volume measurement. CLEMS volumes and tape measure volumes were compared to the water displacement volumes. Sequential volumes of the same limb segment were obtained first with the water displacement method (the "gold standard"), next with CLEMS, and then with a tape measure.

Validity studies were completed on the same number and variety of legs as in the reliability studies. Clinicians referred the patients with lower limb edema to the study. They all had persistent, pitting edema. The diagnoses of the patients varied. Two were spinal cord injured, one had multiple sclerosis, one had adult cerebral palsy, and one had congenital lymphedema. All five subjects had no known vascular disease. In all cases, lower limb volumes distal to the fibular head were measured.

The water displacement volumes were determined using a standard water-filled tank with an overflow valve. CLEMS measurements were obtained as previously described. The tape measure volumes were determined using two circumferential measurements, one taken around the malleoli, and the other at the same proximal point used in the water displacement and CLEMS measurements (at the level of the fibular head). The distance between the two circumferential measurements was also determined with the tape measure. Volumes were calculated using the equa-
tion for the volume of a truncated cone as previously described in the literature.\(^5,6\)

This work was given ethical approval by the University of British Columbia Clinical Screening Committee, and all subjects signed informed consent forms.

RESULTS

The table shows the high intraclass correlation coefficients for the CLEMS reliability studies. Since movement of the subject and variable degrees of skin distensibility were expected to introduce some error into the system, it is not surprising that measurements of the plaster legs showed the highest correlation coefficients \(r = .999\). An analysis of variance comparing the means of the three sessions showed that there was no significant difference between the three sessions \(f_{2,34} = .713, p = .497\).

The validity studies compared the water displacement method, CLEMS, and the tape measure method. The mean leg volume as determined by the water displacement method was 3176.99cc (SD = 844.42); by CLEMS, 3163.86cc (SD = 789.36); and by the tape measure method, 2538.49cc (SD = 693.28). The correlation coefficients for the water displacement method and CLEMS was high (.992); whereas, the correlation coefficients of both the water displacement method and CLEMS to the tape measure method were low (.318 and .341). The results of an analysis of variance of the three measurement systems indicated that the means of the three methods were significantly different \(f_{2,34} = 9.18, p = <.001\). Newman-Keul multiple comparisons, as a followup, showed that the means of both the water displacement method and CLEMS means were significantly different from those of the tape measure.

DISCUSSION

CLEMS appears to be both valid and reliable. In nonedematous and edematous patients (despite measurement error due to skin distensibility and patient movement), CLEMS appeared to be as accurate and reliable as the water displacement method. CLEMS has obvious advantages, however, over the water displacement method. These include speed, ease of measurement, and the ability to measure the individual in different positions. Measurements can also be taken over dressings and pressure garments.

In all cases, the tape measure method, which uses the equation for a truncated cone, was found to be inaccurate in quantifying limb volume. This may be due to the exclusion of the volume of the foot and ankle from the calculation of total volume. Also, in large volume legs, the model of a truncated cone does not fit the actual leg shape, even in the calf portion.

Previous clinical studies have focused on patients with congenital edema and postsurgical lymphedema. The measurement tool was the tape measure.\(^5,6\) There was no control for time of day or patient position or activity, even though there is evidence\(^6\) for the importance of these factors in determining limb volume. It is possible that edema of differing etiologies (vascular or neurologic) may behave differently with respect to patient position and activity. Therefore, any conclusions based on studies of patients with vascular edema may not apply to individuals with edema in conjunction with neurologic injury and no vascular pathology.

CONCLUSION

We have introduced a new tool for the measurement of limb volumes. CLEMS is accurate, reliable, noninvasive, and rapid. It can easily be used in the clinical setting for measuring lower limb volumes. This new tool allows us to study lower limb volume responses to position, exercise, and time of day in a way that was previously not possible. The question of how the individual with neurologic injury copes with fluid shifts in the extremities can now be examined. This tool allows us to assess accurately the effect of edema treatment strategies, and may lead to a better understanding of the underlying pathology in neurologic edema. The tape measure method using the equation for a truncated cone is not an accurate representation of lower limb volume.

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REFERENCES


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