Pilot study to evaluate a novel three-dimensional wound measurement device

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Abstract
As the burden of diabetes continues to grow and treatment standards require careful tracking of wound progress, clinicians increasingly need to rely on technological improvements in wound measurement technologies to track the progress of their treatments. This study aims to determine the accuracy of a new three-dimensional wound measurement (3DWM) device against laser-assisted wound measurement (LAWM) devices and traditional methods of wound measurement. Using several wound models, we demonstrate that the 3DWM device measures wound area, depth and volume similarly to the other methods tested. This is especially apparent when changes in wound measurements were compared between the two devices. Differences between the two technologies were apparent when analysing wound measurement time and measurement repeatability. There was a significantly lower incidence of error in measurements between the 3DWM device and the LAWM device. Finally, the measurement time was significantly faster with the 3DWM device compared to the LAWM device. Together, these data demonstrate that the 3DWM device provides an accurate and reproducible method for measuring changes in wound healing similar to other available technologies. Further, the use of the 3DWM device provides a faster and more consistent measurement, which is critical for clinical application and use.

Introduction
Chronic wounds, if untreated or mismanaged, have various detrimental effects including reduced patient quality of life (pain, reduced ambulatory activity, etc), increased morbidity and mortality and significant health care costs (1). It is estimated that chronic wounds affect 6-5 million patients in the United States alone, and the cost to the health care system is enormous, with estimates exceeding $50 billion per year (2–9). As the burden of diabetes, especially diabetic foot wounds, continues to grow and treatment standards require careful tracking of wound progress, clinicians will increasingly need to rely on technological improvements in wound measurement technologies to track the progress of their treatments. In the treatment and monitoring of a chronic wound, accurate and repeatable measurement of the wound provides indispensable data for the patient’s medical record. These data help determine the treatment course and progress of the wound and present a relevant clinical data point through which health care practitioners are able to communicate. The goal of any medical technology is to be safe, accurate and cost-effective; however, these three goals must equal or exceed the status quo if the device is to be considered an effective tool in a clinician’s toolbox (10–13).

In recent studies, laser-assisted wound measurement (LAWM) devices have been established as the next step...
in which medicine and wound care become intertwined with technology. In previously published studies by our group, we assessed the accuracy of a LAWM device in measuring cylindrical wounds (both artificial and porcine) that were to be accurately measured by hand (14,15). Although these measurements were relatively accurate, depth measurements were inaccurate by a consistent amount. In further studies, we demonstrated that the LAWM device could be used to calculate change in wound measurements (percent differences) accurately with no statistically significant differences compared with standard measurements. The current study aims to measure the accuracy of a new three-dimensional wound measurement (3DWM) device (16). This system comprises a tablet with an attached structure sensor, which measures 3D wound dimensions at the point of care. The measurements by the 3DWM device are compared to those by a previously tested LAWM device and traditional methods along with other methods that currently cannot be replicated clinically (14,15).

Methods

Wound model creation

To compare measurements of area, depth and volume, three irregular wound models were created using Play-Doh®, Hasbro, Pawtucket, RI and were labeled wound 1, 2 and 3 (Figure 1A). To create a model that simulates a healing wound, two models (Wounds A and B) were created (Figure 1B). For each of these models, the surface was made a different color from that of the interior wound tissues. After measurements with each device were taken, Play-Doh® was added to the wound model to simulate both filling and closure (each modification was plotted to simulate 1 week of wound healing). All wound measurements were plotted over time. In addition, each measurement was calculated as a percent of the starting measurement (percent of time 0) to compare change over time.

Area, depth and volume measurements

Wound areas were obtained by photographing each wound three times with a digital camera and a ruler placed in the field of the photographed image. Using National Institutes of Health (NIH) ImageJ, Bethesda, MD (17,18), the wound area from each photo was obtained, setting the scale for each measurement using the ruler in the captured image. Wound areas from the LAWM device (Silhouette Star™, Aranz, Christchurch, NZ) and the 3DWM device (eKare inSight™, eKare, Fairfax, VA) were obtained as per the manufacturer’s instructions. The depth of each wound was measured using a ruler at three independent sites chosen randomly within the wound model. The three measurements were averaged to give an average wound ruler depth measurement. To obtain maximum depth, three sets of three measurements were taken. The greatest values from each set of three were averaged. Average and maximum wound depth from the LAWM and the 3DWM devices was obtained by following the manufacturer’s instructions. To measure wound volume, the wound models were weighed, filled with water to the model surface and weighed again. The volume of the water was determined from a standard curve created from plotting the weights of known volumes of water. This was repeated three times. These wound volume measurements were compared with the average wound volume obtained from the LAWM and 3DWM devices as per the manufacturer’s instructions.

Measurement time

Each device was set up to capture the wound image (the time for this setup was not captured in our data). Measurement time was recorded as the time (seconds) from the initial wound acquisition by the LAWM and 3DWM devices to the data display when used as per the manufacturer’s instructions. The time for each measurement was averaged from three independent measurements for each of the three wound models.

Measurement error

Measurement error was calculated as the average standard error of the mean (SEM) between repeated measures for each evaluator for each device for wound models 1, 2 and 3. This was calculated for area, average depth, maximum depth and volume measurements.
Figure 2 Wound measurements of (A) area, (B) volume, (C) average depth and (D) max depth using laser-assisted wound measurement (LAWM), three-dimensional wound measurement (3DWM) and traditional measurements. *P > 0.05 was considered statistically significant. Statistical difference between 3DWM and LAWM is indicated by * and between 3DWM or LAWM and traditional measurement methods by #.

Statistical analyses
The repeated measurements obtained with each device (three each) were averaged, and SEM was calculated for each wound measurement. A paired t-test was used to determine if wound measurements (area, depth, volume and error) were different for each measurement device. Specifically, data from the 3DWM device was compared with the data from the LAWM device and hand-held methods. Wound healing over time (area, depth, volume) and percentage change in all measurements were analyzed by two-way Analysis of Variance (ANOVA). *P > 0.05 was considered statistically significant. The statistical difference between the 3DWM and LAWM devices is indicated by * and between 3DWM or LAWM and traditional measurement methods by #. All data were analyzed using Microsoft Excel 2010 for Mac (Redmond, WA) and GraphPad Prism 6 (La Jolla, CA) statistical software.

Results
Area, volume, and depth
In the three wounds measured for area, there was no difference between the measurements from the 3DWM and LAWM devices (Figure 2A). However, in wound 2 and 3, the area measured by the 3DWM and LAWM devices was less than the measurement from NIH ImageJ. The 3DWM measurement device measured a slightly higher volume than the LAWM and water measurement (Figure 2B). Average wound depth measurements were higher when measured with a ruler than a 3DWM or LAWM device (Figure 2C). In addition, the 3DWM device measures a slightly greater average depth than the LAWM. Maximum depth measurements varied slightly between the three measurement methods for two of the wound models measured (Figure 2D).

Change in area, depth and volume
In two healing wound models, area, maximum and average depth and volume measurements were compared between the LAWM and 3DWM devices (Figure 3). Data are presented as measurements over time (left) and measurement as % of time 0 over time (right). In Wound A, the only measurement for wound-healing trajectory that differed between the two devices was for maximum depth. In the healing trajectory for Wound B, only the volume measurement differed. However, there was no statistical difference between the devices for any of the measurements when change from time 0 was calculated.

Measurement time and error
The measurement time (from wound imaging to data acquisition) was significantly different between the LAWM and 3DWM devices for all wounds measured (Figure 4). Data show that it takes more than twice the time to acquire and calculate wound measurements with the LAWM as compared to the 3DWM device (approximately 2 minutes as compared to 45 seconds). In addition, the LAWM device measurement time increases with increasing wound size because of the need to trace the perimeter of the wound. The 3DWM device took the same amount of time to measure a wound irrespective of wound size. Further, the average SEM for all measurements was statistically lower when data was obtained from the 3DWM device as
Figure 3 Wound measurements over time (left) and change in wound measurements over time as a percent of Day 0 for 2 wound models measured using laser-assisted wound measurement (LAWM) and three-dimensional wound measurement (3DWM) devices; $P > 0.05$ was considered statistically significant. Statistical difference between 3DWM and LAWM is indicated by *.
FIGURE 4 Average wound measurement time for three independent wound models as measured by laser-assisted wound measurement (LAWM) and three-dimensional wound measurement (3DWM); $P > 0.05$ was considered statistically significant. Statistical difference between 3DWM and LAWM is indicated by * and between 3DWM or LAWM and traditional measurement methods by #.

FIGURE 5 Average error (standard error of the mean [SEM]) between measurements for area, volume, average depth and maximum depth as measured by laser-assisted wound measurement (LAWM) and three-dimensional wound measurement (3DWM) devices; $P > 0.05$ was considered statistically significant. Statistical difference between 3DWM and LAWM is indicated by *.

Discussion

There is a critical need for efficient and cost-effective tools that measure and manage the care of complex wounds. Currently, physicians rely on crude measurement techniques, such as rulers and photographs that must be analyzed after the patient visit. Between positioning difficulties, contamination and using multiple tools, there are too many hurdles to providing a consistent way of measuring areas and volumes of wounds. More novel devices aim to meet the goal of any medical technology in that it is safe, accurate and cost-effective (10–13). LAWM devices represent the next step in which medicine and wound care become intertwined with technology. Several studies have indicated that LAWM devices provide accurate measurements, low inter- and intra-rater variability and a relatively easy-to-use system (10,19–21). In two previous studies by our group, we validated a LAWM device and demonstrated its ability to accurately assess changes in wound area, depth and volume. In addition, the use of this type of device provides an objective assessment of wound healing without having to come in contact with the patient’s wound, thus reducing the risk of contamination.

In this study, we compared the accuracy and precision of a 3DWM device to a LAWM device and traditional wound measurement methods. Measurements from three independent evaluators were performed on different wound models. The data presented in this study demonstrate that the measurement of area and depth by the 3DWM device is as accurate as the measurements from the LAWM device. The volume measurement obtained from the 3DWM device was slightly higher than those obtained from the LAWM device and the water volume measurement method, and there were some statistical differences in average depth measurements between the two devices. In the clinical setting, this information could be useful when trying to calculate percentage changes in wound healing where absolute numbers are not as important as the percentage difference between wound depths measured at different time intervals (22,23). Several authors have suggested using percentage wound area reduction as a surrogate marker to determine wounds that are likely to heal after 1, 12 and 16 weeks of therapy. The change from baseline (% of Day 0 measurements) rather than the absolute values has been the focus of this work (22). To this end, when calculated against the baseline of a healing wound model, all measurements collected were equivalent between the two devices. Together, these data demonstrate that the 3DWM device can accurately assess wound-healing trajectory, measured by area, depth and volume, as compared to the LAWM device and traditional methods.

One of the most striking differences between the LAWM and 3DWM measurement devices is the ease of use. One-handed operation, the automation in wound identification and the software simplicity are substantially better in the 3DWM device than the LAWM device. This is most apparent in the measurement time for each device. The 3DWM device takes approximately one-third of the time taken by the LAWM device to obtain measurements. In addition, the error between repeated measures was less for all measurements taken with the 3DWM device than the LAWM device.

Conclusion

The LAWM device relies on lasers that only detect defined points in the wound bed while the 3DWM device captures the topology of the entire wound bed using structured light 3D-sensing technology. This likely allows more consistency between measurements, thus reducing inter- and intra-evaluator error. Overall, we believe that this device is equivalent to other measurement systems currently on the market with respect to measurement accuracy. However, it far exceeds available systems because of reduced error and its simplicity of use.
References

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