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SYMPOSIUM

Validation of a Laser-Assisted Wound Measurement Device for Measuring Wound Volume

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Abstract

Background:

Accurate and precise wound measurement is an essential part of the medical record when monitoring a patient with a chronic wound. This study was designed to determine if a new device, a laser-assisted wound measurement (LAWM) device, provides valid measurements for wound area, depth, and volume.

Methods:

We compared four methods to evaluate the area and volume of 12 wounds of differing size and depth that were created on the dorsum of a sacrificed pig. We evaluated the LAWM device, digital photograph assessment with National Institutes of Health ImageJ software, measurements of depth with a ruler, and weight-to-volume assessment with dental paste. We then sought to cross validate this data with further analyses obtained from these measurements using a Play-Doh®-based wound as a model for constant area with different depths.

Results:

We demonstrate that the LAWM device measures wound area accurately. Depth (and therefore volume) measurements, however, are artificially low. This inaccuracy is the same for shallow and deep wounds.

Conclusions:

The inaccuracy in the depth and volume measurements with the LAWM device results in an artificially low measurement. However, this may not affect percentage difference measurements. Further studies will need to be performed to determine if this device can accurately determine wound changes in the clinical setting.

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Introduction

There is increasing pressure on health care professionals to validate interventions and provide rationale to support their practice. This is especially true in the field of wound care. Accurate and precise wound measurement is an essential part of the medical record when monitoring a patient with a chronic wound. It provides objective data that demonstrate wound progress or deterioration, helps in the selection of treatment regimens, and augments

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Abbreviations: (LAWM) laser-assisted wound measurement, (NIH) National Institutes of Health, (RD) ruler depth

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communication between health care professionals. Reliability and reproducibility are of paramount importance in this regard.

Currently, practitioners find themselves measuring wounds using rudimentary tools such as rulers, wound tracings, and digital photography.[1–3] These modalities are inaccurate, difficult to use, and often require wound contact and risks contamination. New three-dimensional scanning devices are expensive, cumbersome, and time consuming and may not provide any significant improvement in accuracy.[4–6] There have been a few handheld devices that have demonstrated promise, but lacked the accuracy that wound documentation requires.[4,7–12] This study was designed to determine if a new laser-assisted wound measurement (LAWM) device provides valid measurements for wound area, depth, and volume. We compared four methods to evaluate the area and volume of 12 wounds of differing size and depth that were created on the dorsum of a sacrificed pig. We evaluated the LAWM device digital photograph assessment with National Institutes of Health (NIH) ImageJ software, measurements of depth with a ruler, and weight-to-volume assessment with dental paste. We then sought to cross validate this data with further analyses obtained from the these measurements using Play-Doh® (Hasbro)-based wounds as a model for constant area with different depths.

Materials and Methods

Porcine Wound Creation

Using a scalpel, 12 wounds were made on the dorsum of a porcine cadaver. These wounds were roughly circular in nature and were full thickness through the skin and subcutaneous tissue, down to the muscle fascia (**Figure 1A**).

Model Wound Creation

Sixteen wound models of equal area and decreasing depth were created with Play-Doh (example images shown in **Figure 1B**). A rolling pin and guides were used to achieve consistent thickness of the Play-Doh. A circular cutter was used to remove a cylindrical volume of Play-Doh, which was performed in blocks with increasing depth. The areas of each of the 16 wounds were equivalent.

Measures of Wound Area

Each wound was photographed three times with a digital camera with a ruler in the photographed image. Using NIH ImageJ, the wound area from each photo was obtained, setting the scale using the ruler in the image.

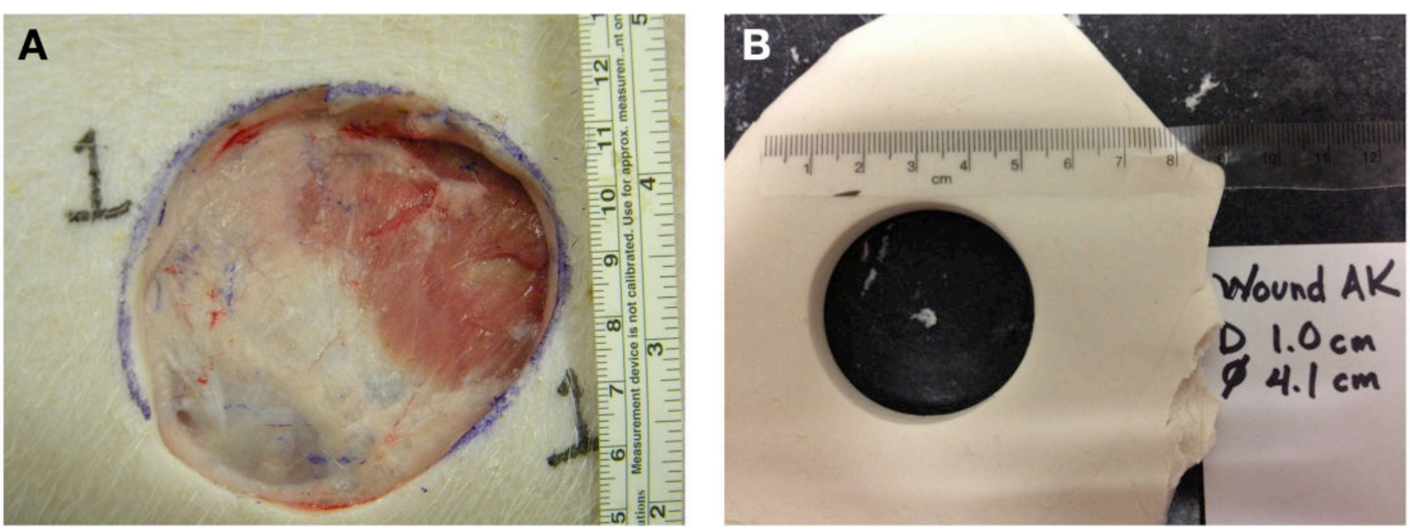

Figure 1. Example wounds. **(A)** Wound excised in porcine dorsum. **(B)** Artificial wound models using Play-Doh.

Wound area from the LAWM device (Silhouette Star™, Aranz, Christchurch, NZ) was obtained using the manufacturer's instructions.

Measures of Wound Depth

The depth of each wound was measured using a ruler at three defined sites around the wound. For each wound, the measurements were taken at approximately 12, 4, and 7 o'clock around the periphery of the wound. The three measurements were averaged together to give a mean wound ruler depth (RD) measurement. Average wound depth from the LAWM device was obtained using the manufacturer's instructions.

Measures of Wound Volume

The wounds were filled with Jeltrate® (Pearson Dental Supply Co, Sylmar, CA) fast-set dental paste per the manufacturer's instructions and allowed to solidify. The paste mold was then removed and weighed. Volume of the paste was determined from calculation of weights with known volumes. This was repeated three times. Wound volume was also calculated from wound area obtained with NIH ImageJ and the average RD as explained earlier. These wound volume measurements were compared with the wound volume obtained from the LAWM device using the manufacturer's instructions.

Data Analysis and Statistics

The repeat measurements obtained with each device (three each) were averaged, and standard error of the mean was calculated for each wound. Student paired *t*-test was used to determine if wound measurements (area, depth, volume, and error) were different for each measurement device. $P > .05$ was considered statistically significant.

Results

The Laser-Assisted Wound Measurement Device Measures Wound Area, but not Depth and Volume, Accurately

Data are presented as the average measurement for each wound and demonstrate that the measurements of only 4 of the 12 wounds assessed were statistically different (**Figure 2A**). For those wounds that had differences in measurements, the difference was less than 15% of wound area. To analyze the capability of the LAWM device to measure wound depth, 12 wounds were each measured four times (as earlier). Each wound was also measured four times with a ruler in defined points around the wound edge. Data are presented as average depth for

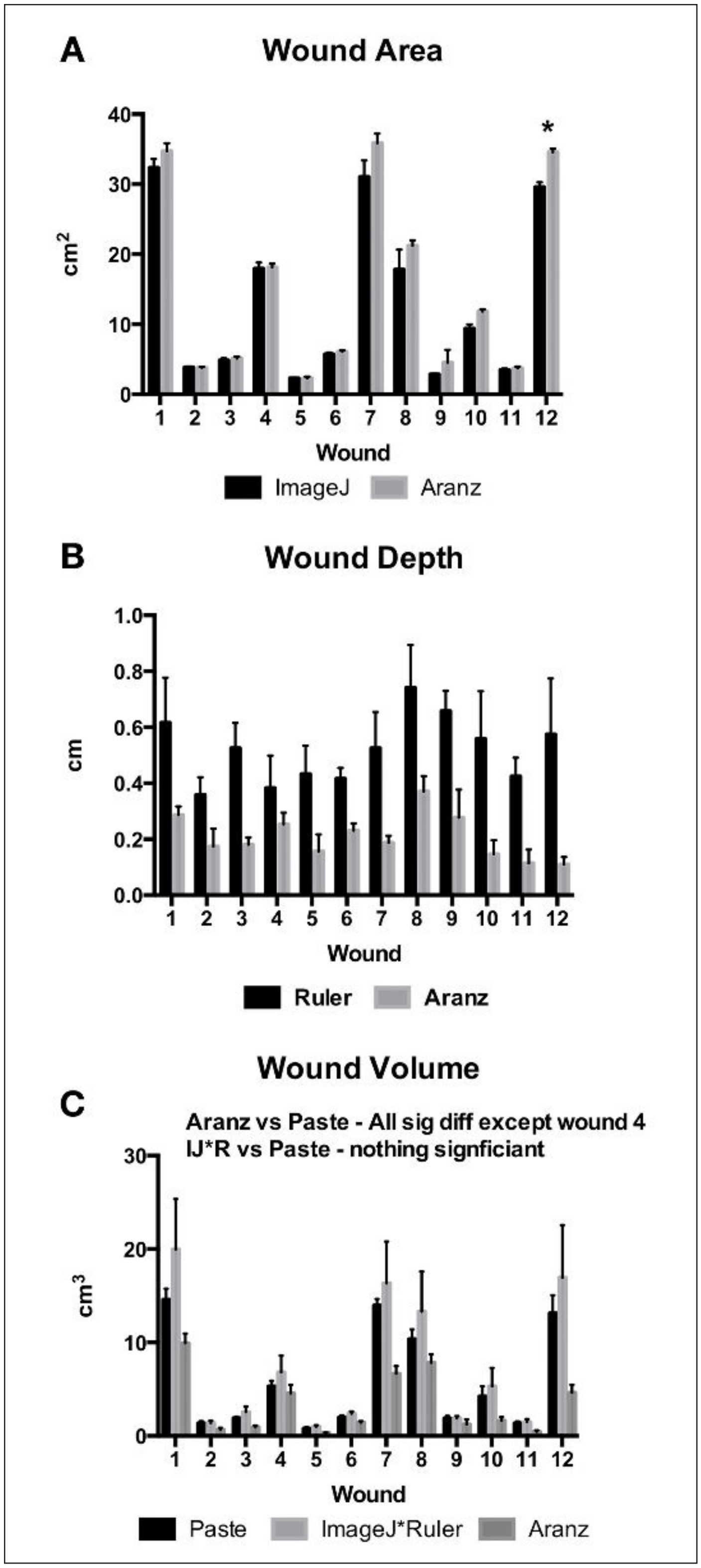

Figure 2. Porcine wound analyses. **(A)** Wound area measurements using NIH ImageJ and Aranz Silhouette Star. **(B)** Wound depth measurements using a ruler and Aranz Silhouette Star (all significantly different except wound 4). **(C)** Wound volume measurements using dental paste, ImageJ*Ruler, and Aranz Silhouette Star. $P < .05$ is considered significant. sig diff, significantly different. $P < 0.05$ is denoted by an *.

each wound and demonstrate that the average depth measurements of all but one of the 12 wounds assessed were statistically different between the two methods of measurement (**Figure 2B**). Measurements obtained with a ruler demonstrate a deeper measurement than what is measured by the LAWM device in all 12 wounds measured. The capacity to measure wound volume is very important clinically. Volume can be calculated using area and depth measurements. Ruler measurements along with area analyses of photography (from the earlier measurements) were used to calculate volume (ImageJ*Ruler). In addition, impression molds of each wound were taken with dental paste and volume of each mold calculated. The volume measurements obtained from these two methods were the same for all 12 wounds measured (**Figure 2C**). When these control volume measurements were compared with the volume data from the LAWM device, it demonstrated that the LAWM device gave a low volume measurement for the majority of the wounds measured (12 out of 12). These data suggest that the volume measurements obtained with the LAWM device are significantly different from the actual wound volume due to an inaccurate assessment of wound depth.

Artificial Model of Wound Healing Replicates Observations in Porcine Model, and the Error between Measurement Methods Is Constant for Deep and Shallow Wounds

To better understand the error observed in the porcine wound experiment, we developed an artificial wound model. We created 16 wounds with constant area (**Figure 3A**) and decreasing depth (**Figure 3B**), ranging from 4.5 to 0.5 cm deep. Similar to the porcine data, the LAWM device produces wound depths that are lower (shallower wounds) compared with a ruler measurement. Thus, the LAWM device measurements of volume are also artificially low compared with using ImageJ and ruler measurements (**Figure 3C**). Together these data demonstrate that we can create a simple wound model to further study the accuracy of the LAWM device. For each of the sixteen wound models, the ratio of the LAWM device depth to RD was determined and linear regression was performed. The ratios and resultant trend line of each are shown in **Figure 4A**. The extremely low coefficient of determination (R^2) indicates that the difference between the two measurement methods does not change whether the wound is shallow or deep. The coefficient of determination is also extremely low in the case of volume measurements (**Figure 4B**), indicating that the difference in volume ratio is not a function of depth.

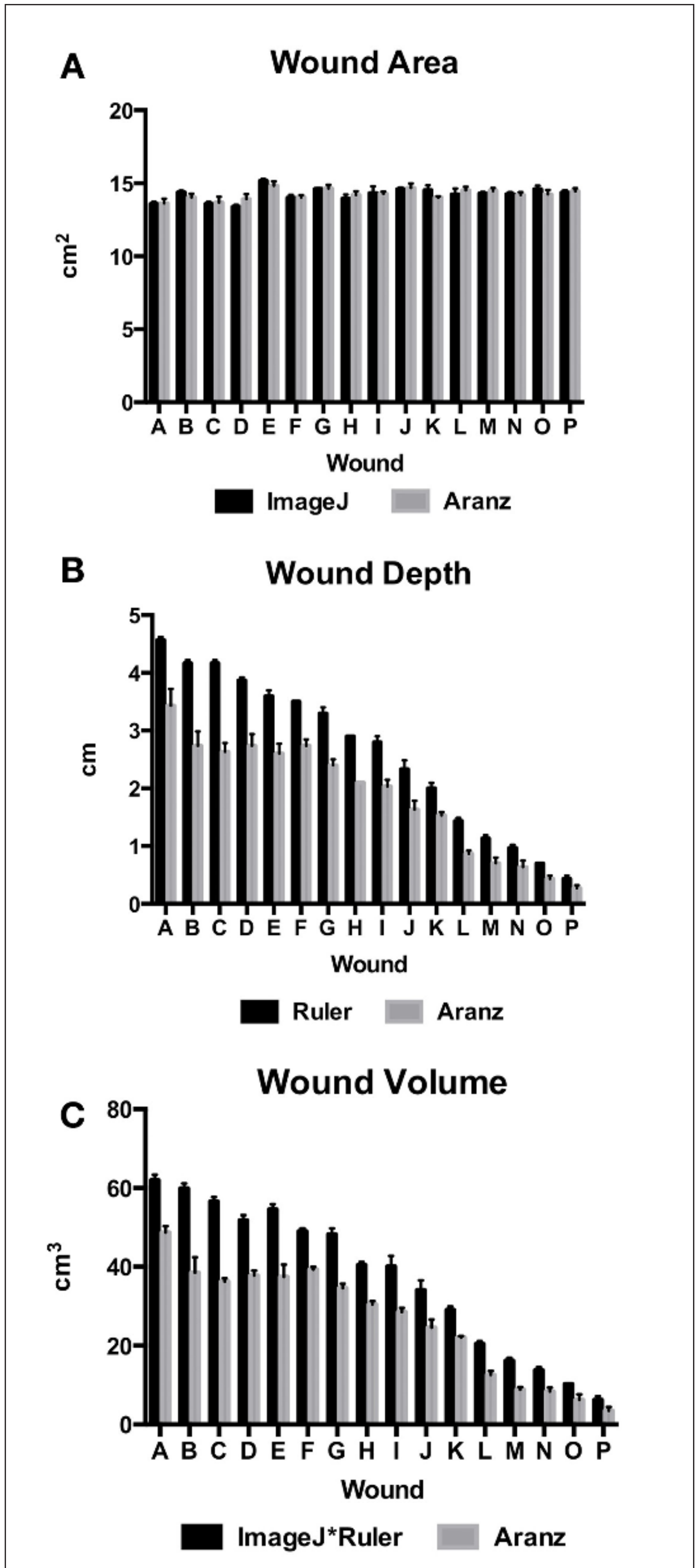

Figure 3. Wound model of decreasing depth. **(A)** Wound area measurements using NIH ImageJ and Aranz Silhouette Star. **(B)** Wound depth measurements using a ruler and Aranz Silhouette Star (all significantly different). **(C)** Wound volume measurements using ImageJ*Ruler, and Aranz Silhouette Star (all significantly different). $P < .05$ is considered significant.

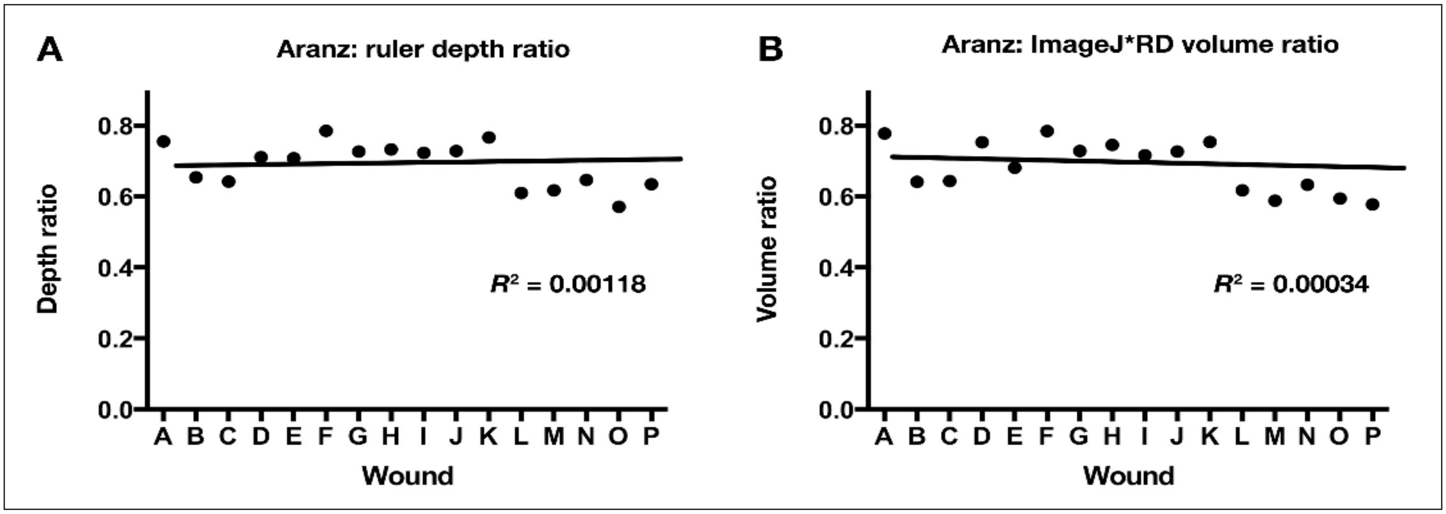

Figure 4. Ratios of different measurement methods. **(A)** Ratio of depth measurement using Aranz Silhouette Star and ruler. **(B)** Ratio of volume measurement using Aranz Silhouette Star and ImageJ*RD measurement.

These data demonstrate that the inaccuracies in the depth and volume measurements from the LAWM device are independent of wound depth.

Discussion

Physicians and nurses are under increasing pressure to document clinical outcomes using fewer resources and in a shorter amount of time. These demands can only be met with the use of more efficient and cost-effective tools. In this study, we sought to validate the accuracy of the LAWM device for measuring wounds compared with digital photographs and clinical measurement with a ruler. The LAWM device is a handheld, noncontact device for measuring and documenting wound surface area, depth, and volume. Tools to measure a patient's wound quickly and accurately are overdue. Between positioning difficulties, contamination, and using multiple tools, there are too many hurdles to providing a consistent way of measuring areas and volumes for wounds. Clinicians must determine if the additional cost and time of a sophisticated three-dimensional measurement tool, such as the LAWM device, is significantly more accurate than traditional approaches.

This study aimed to determine the accuracy of the LAWM device to other commonly used measurement methods. These analyses did not directly assess the precision, or the reproducibility, of the LAWM device. Our data demonstrate that the LAWM device is accurate in measuring wound area. The mechanism by which area is obtained with the LAWM device and NIH ImageJ is very similar, where the clinician traces around the edges of the wound and the software calculates the area. The depth measurements, however, are greater when assessed with a ruler versus the LAWM device despite the fact that the error associated with repeat measurements was equivalent. The LAWM device measurements ranged from ~20% to ~60% of the measurements from a ruler but did demonstrate a consistent difference as shown by the correlation coefficient shown in **Figure 3A**. Similar differences were observed when comparing the LAWM device volume measurements with other methods. The majority of the wounds were measured to have a smaller volume with the LAWM device than the paste or ImageJ*Ruler depth calculation. We can conclude that, while the true depth value is not accurate, the calculated LAWM depth is consistently and predictably lower. 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.[13,14] 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 rather than the absolute values have been the focus of this work.

Another important point of these analyses is the dependency of the LAWM device to be perfectly perpendicular to the wound being measured. It is possible that, if the wound is imaged from an angle, more variability could be introduced in the measurement. From a clinical standpoint, getting the device perpendicular to a patient's wound at the bedside or in the clinic may not be realistic. There may be other variables that need to be adjusted to produce more accurate readings. Further studies will need to be performed to understand these types of limitations.

The absolute value of wound volume is not as clinically relevant as the accurate measure of change. The conclusions that can be reached from volume measurements correlate directly with those of depth, as volume is a function of depth. While this study demonstrated that there was significant variability in the difference between the LAWM device volume measurement and those from the other measurements, further controlled research needs to be performed to gauge the accuracy of the LAWM device to assess volume change.

Conclusions

As independent investigators of the LAWM device, we have concluded that the device does an excellent job calculating the area of wounds as compared with conventional and proven techniques. However, when calculating wound depth and volume, we found great inconsistencies in the device's ability to measure the true depth and therefore volume of wounds. We have shown, however, that, while the device does not give accurate true depth measurements, it does give depth measurements that are consistently off whether the wound is shallow or deep. We have speculated as to why this might be the case, but without knowing exactly how the device is measuring the wound depths, we will not know for sure. More investigations are needed to better elucidate the method of depth measurements of the LAWM device to hopefully be able to troubleshoot and provide conclusive evidence to support its use in the clinical setting.

Disclosures:

Lawrence A. Lavery has research grants from KCI, Osirus, Health Point, Thermotek, Integra, Glasko Smith and Kline, Convatec, and Innovative Therapies Inc., and is on the speaker's bureau for Shire, KCI, and Innovative Technologies Inc. He is a consultant/advisor for Innovative Therapies Inc. and PamLabs. He has stock ownership in Diabetica Solutions and Prizm Medical and holds patents with Diabetica Solutions. Kathryn Davis has grants from Convatec and Innovative Therapies Inc.

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