Iterative design and testing of a hand-held, non-contact wound measurement device

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Abstract: A variety of wound measurement techniques are available to clinicians. Options range from relatively simple and inexpensive to complex, expensive devices. An iterative design approach was used to evaluate and improve performance and clinical utility of a new wound measurement device (WMD). The design was based upon a commercially available Smartphone. Accuracy was assessed using bench testing and reliability of area measurements was determined using multiple evaluators. Clinical utility was investigated by deploying the WMD during wound rounds in a rehabilitation hospital. Accuracy testing revealed an average error <2% at 0° or skew and an average error of 4.28% at 10° of skew. The intra-rater reliability exceeded 0.975 for all raters and inter-rater reliability was 0.966. Clinical utility testing provided the opportunity to address several usability concerns including the software interface and computation times.

The accuracy and reliability of a new, non-contact wound measurement device exceeded that of other manual techniques and were, at least, equivocal to other computer-based technologies. Some limitations of using a Smartphone were identified by the clinicians that can be addressed by the more advanced processing power of newer technology. Overall, the WMD was shown to have the potential as a useful clinical tool.

Introduction

Accurate, consistent and regular measurement of the size of a wound is vital in objectively describing the progress of wound healing. Size assessment assists with modifying the treatment regimen. In addition to the clinical implications, regular tracking of wound size has become important in terms of litigation and insurance coverage. The standard practice for the treatment of wounds includes monitoring the size of the wound at regular intervals. A variety of wound measurement techniques are available to clinicians. Options range from...
relatively simple and inexpensive to complex, expensive devices. To be clinically useful, wound measurement devices should be reliable, repeatable and accurate. Other usability issues include: the ability to measure wounds quickly, reduction of the potential for contamination of the device and patient, ease of portability, and overall ease of operation.

The most widely used method for measuring wounds is the ruler based method. Maximum measurements in two perpendicular directions are taken using a simple ruler. This method of measurement models the wound as a rectangle. The Kundin Gauge [1] is another ruler based device measuring models the wound as a rectangle.

A second low-cost, low tech method is the tracing method. Two sterile transparent sheets are laid on top of the wound, and the wound is outlined on the transparency sheet. The lower sheet that is in contact with the wound is disposed. The sheet with the tracing is then placed over a grid, and the area is approximated by counting the number of squares on the grid covered by the wound outline. The area can also be estimated with the use of a planimeter [2–4].

More advanced techniques can be roughly categorized as vision-based technologies and software-based systems.

Vision-based technologies utilize either stereophotogrammetry (SPG) or structured lighting to obtain wound images. With stereophotogrammetry, two or more photographs of the same wound are taken from slightly different angles. These images are reconstructed using a computer to produce a 3-D model of the wound. The wound border is then traced on the computer image, and the computer software determines the area and volume of the wound [5,6]. In the structured light method, a specific light pattern is projected on the wound, and it is photographed at a known angle. A computer is then used to calculate the area and volume based on this image [7,8].

Software-based systems use digital photographs of a wound to measure its area [9]. Digital images are loaded into the software and the clinician traces the border to obtain the area. Typically, the clinician places a target on the body to provide the computer with a scale upon which area can be calculated.

Several studies have compared the performance of different measurement systems and technologies [2,5,6,10,11]. Accuracy is typically determined by measuring a wound model of known area. Reliability is assessed using multiple evaluators to calculate the inter- and intra-rater reliability. Repeatability has also been reported and consists of reporting the precision using variability of repeated measurements. Reliability and repeatability of wound measurement is generally reported more often than accuracy, especially when measuring real wounds. Measuring accuracy requires a true measure of wound area so is typically assessed using models of known shape and size.

Thawer et al. [11] compared the reliability of measurements recorded using manual transparency tracing and a software-based system using digital photographs. This assessment was based on chronic lower extremity human wounds and excisional wounds in laboratory rats. The inter-rater reliability of measuring the small animal wounds was much greater using the computerized technique (r = 0.99) than the manual tracing method (r = 0.77). Inter-rater reliability of the larger human wounds was equivocal across techniques with each exceeding 0.91. Intra-rater reliability for both the manual and computerized techniques exceeded 0.98 for the human and animal wounds.

Bulstrode et al. [5] compared stereophotogrammetry to direct tracing and simple photography using ulcer models built from plaster casts and 10 actual leg ulcers in a clinical environment. Stereophotogrammetry measurements had a >99% accuracy with a precision of <2% between actual and measured surface areas of the ulcer models. Simple photography and tracing yield lower accuracy and precision: the mean error for simple photography was 11.4%, with a precision of 21.0%, whereas the mean error for direct tracing was 11.7% with a precision of 18.2%. Bulstrode et al. reported that stereophotogrammetry was also 10 times more precise in the clinical setting. During testing with real ulcers, the 95% confidence intervals for precision of stereophotogrammetry, simple photography, and direct tracing were reported as percentages of their mean surface area values. The mean 95% confidence interval for SPG was 3.36%, while the precision for simple photography was 28.6% and 37.8% for direct tracing.

Langemo [6] compared the performance of four different 2-D techniques using three wound models. The techniques compared a ruler, planimetry, computerized digital imaging for measuring length and width, and computerized tracing for measuring area. Multiple raters measured 3 wound models made of Plaster of Paris with known areas and reflecting L, pear, and circle shapes. Data was
used to calculate accuracy, bias, precision and reliability.

Accuracy was calculated by normalizing the difference between known and measured surface areas. Absolute error ranged from 17 to 45%. The two methods that used a rectangular approximation typically over-estimated the areas, whereas the two techniques that traced the borders underestimated the areas [6] (Table 1).

Inter- and Intra-rater reliability also varied across techniques (Table 1) with the computerized area tracing method reporting the highest Inter-rater reliability of 0.87 and manual tracing having the highest Intra-rater reliability. Langemo et al concluded that techniques with relatively high Intra-rater reliability but low Inter-rater reliability suggests that nurses had systematic error in measurement so either over- or under-measured the area.

Plassman et al. [10] reviewed the literature and compared various techniques for wound measurement in terms of precision (repeatability) values for different wound sizes. The comparison is summarized in the following table. (Table 2).

### Study objective

This article describes an iterative design process used to develop a new wound measurement device (WMD). Design objectives included the ability to photo-document and measure the surface area of wounds quickly and with no patient contact, ability to fit into a lab coat pocket for portability, a cost of goods of <$200 permitting a retail cost of between $500-$750, and accuracy and reliability exceeding that of commonly used wound measurement techniques.

### Methods

An iterative design approach was used to evaluate and improve performance and clinical utility. Therefore, multiple iterations of hardware and software were developed and deployed in response to testing and feedback. Accuracy was assessed using bench testing and wound models of known area. The reliability of area measurements was determined using multiple evaluators who manually circumscribed a cohort of wound images. Finally, clinical utility was investigated by deploying the WMD during wound rounds in a rehabilitation hospital.

### Hardware description

The Wound Measurement Device (WMD) utilizes a machine vision technique to calculate wound area. The prototyping platform was based upon a commercially available AT&T Tilt Smartphone equipped with a digital camera. Custom software, called WoundSuite, enables the calculation of the area of the wound or skin lesion via a simple graphical user interface. The casing, shown in Fig. 1, was designed to house the Smartphone and four laser diodes required to calibrate distance between the device and the wound bed.

The decision to use a Smartphone for this prototype was based upon the convenience of utilizing a small camera with a touch screen- two requirements of the WMD. One drawback of this decision was that the casing to house the lasers increased the size and mass of the device compared to a standalone PDA or Smartphone. The prototype measured 9 ½ × 19 × 4 cm with a mass of 0.58 kg.

Four laser diodes are arranged in a square with the camera lens lying in its center. (Fig. 1). These lasers are used to determine two parameters necessary to calculate wound area- distance and skew. After an image is taken, the WoundSuite software locates the four laser points using an intensity thresholding algorithm. The relative

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<th>Wound Size</th>
<th>Kudin guage</th>
<th>Transparency Tracing</th>
<th>Photography</th>
<th>Stereo-photography</th>
<th>Structure Lighting</th>
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<td>&lt;10 cm²</td>
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<td>11%</td>
<td>12%</td>
<td>2%</td>
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<td>10–40 cm²</td>
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locations of each laser is then used to calculate distance from the target plane and skew angle using known geometric relationships. A full description of the approach used to determine distance and skew has been reported previously [12].

Briefly, when the device is held parallel to a flat target plane, there is no skew and the four projected laser dots would form a perfect square. Given the known separation of the lasers, a relationship can be defined between pixel size and an area on the target. If the device is held at an angle relative to the target plane, the lasers do not form a perfect square which is recognized by the software and accommodation is made in the calculations.

**Accuracy**

The accuracy of the WMD was evaluated over a range of distances and skew angles using two images of known area. The images consisted of square and oval shapes printed in black ink on white paper; both had an area of 15 cm². The prototype WMD was mounted on a stand that had the capability of changing the device height from and angle to the target surface (Fig. 2). Digital images were taken at heights ranging from 13 cm to 25 cm, at intervals of 2 cm. Images were taken with skew angles at 0, 5 and 10°. Therefore, the total image set consisted of 7 different heights and three skew angles.

For each captured image, the border of the wound was traced manually on the screen by a single investigator. The area as reported by the WMD was recorded in cm² along with the wound border image coordinates, calculated camera skew, and detected laser locations. Accuracy was calculated using the equation 

\[
\frac{\text{true area} - \text{measured area}}{\text{true area}}
\]

**Reliability**

Four clinicians with wound care experience were invited to test the reliability of measuring area with the wound measurement device. The device was loaded with images of 19 pressure ulcers. All images were in color, with wound borders varying from well to poorly defined. For each image, the clinicians manually traced the wound border on the touch screen using a stylus (Fig. 3). Corrections to the border tracing could be made by dragging the green nodes. Additionally, clinicians had the option to erase and retrace the wound border from scratch. Each clinician measured all wounds on
two different days separated by at least 3 days. Clinicians were not provided with their tracing areas but the WMD recorded them for analysis. Reliability was determined using intraclass correlation coefficients (ICC) calculated by SPSS using a two-way mixed effects model.

Clinical utility
Clinical testing was included to assist with improvement of the design of the device. Three clinicians, a physical therapist, nurse practitioner, and WOCN nurse participated in evaluating the system. Each clinician was trained on the proper use of the device. Forty-five subjects were recruited from both the inpatient and outpatient areas of a large neurological rehabilitation and acute care hospital. Individuals with pressure ulcers were asked by their wound care clinicians to participate in the trial of this new device. Subjects were at least 18 years old, primarily male and from a mixture of ethnic groups. The wounds photographed were of various sizes, anatomical locations and stages of healing. An IRB-approved information sheet was reviewed with each individual.
participant prior to any procedures being conducted and consent was obtained prior to implementing any study procedures.

Each wound was measured according to the standard practice of the hospital using the ruler based method and recorded on data sheets. A photo was taken by the clinician using the wound measurement device. The clinicians were instructed to position the four laser points around the perimeter of the wound insuring that both the wound and all lasers were captured (Fig. 4). They were also instructed to try and maximize the size of the wound on the screen and to avoid large skew angles between the device and surface of the body/wound. The subject was instructed to not look directly at the laser points at any time.

After the image was captured and accepted, the stylus was used to trace the wound border on the screen. (Fig. 3) The clinician was able to make corrections to the border tracing by dragging on the green nodes or re-tracing the wound. Once the wound border trace was completed, the device software processed the image to calculate the surface area of the wound based on the defined borders. The actual image, the tracings and the calculations were all saved in the device and each image was assigned a unique photo identification number.

The clinicians participating in the trial were asked to provide feedback on the user interface and overall device usability. This feedback was utilized to make usability changes to the device and assist in further development. In addition, clinicians were asked to log notes on any unusual occurrences or problems they encountered during the use of the device. Finally, ruler and WMD area information were collected for comparison.

**Results**

**Accuracy**

At a skew of 0°, the average error between the calculated and known areas for the square and oval shapes was 1.90%, with a range in error of 0.4%—3.55%. At a 5° skew, the average error was 1.76%, with a range of −0.4% to 4.6%. With a 10° skew angle, the average error was 4.28%, with a range from 2.14% to 5.62%.

**Reliability**

The intra-rater reliability data showed that all the raters had a reliability of at least 0.975 during the three trials. The inter-rater reliability data demonstrates agreement among the three clinicians. For the first trial, the overall reliability for the three raters was 0.966, and for the second trial, the overall reliability was 0.978.

**Clinical utility**

The foci of the clinical testing were to obtain feedback on device usability in order to improve design and to compare areas measured using the wound measurement device to measurements using the traditional ruler method.

Throughout the course of the usability testing, participating clinicians were asked to provide feedback on their experiences to assist with modifications in the design of the device. Issues raised included battery problems, software bugs, and lengthy processing times. During the trial, software and hardware changes were made to address these issues.

During the study, 28 images were identified that had both ruler and WMD measurements. Since the ruler method captures the maximum length and width of a wound, the area reported by the WMD was expected to be different in certain cases. Of the 28 images, the WMD reported greater area than ruler measurements in 50% of the cases. On average, the WMD area reported measurements exceeding the rectangular area by 17.4%. For the other 14 images, for which lesser areas were reported, the WMD reported areas that were less than the rectangular area by 23.7%.

Five example wound images with superimposed device data are shown below. The processed data
illustrates the automatically identified laser dots and the clinician-traced border. A rectangle reflecting the length and width measured by a ruler is added for comparison with the selected wound border.

**WMD area exceeding ruler measurements**

Two examples are shown as representative of the WMD reporting a greater area than the ruler-measured rectangle (Fig. 5). In these cases, the wound border appeared to be judged slightly different within the two measurement methods. The first example is of a small sacral wound where the WMD reported an area of 0.75 cm² while the ruler measurement was 0.5 cm². The second example represents a more pronounced difference in area. The WMD reported an area of 6.96 cm² whereas the ruler based area was 1.95 cm² (1.3 × 1.5 cm). This illustrates a case in which the clinician included the periwound when circumscribing the wound with the WMD, but only included the open area when measuring with the ruler.

**Ruler exceeding WMD area**

In the other half of the ulcers, the ruler based area exceeded the WMD area. In many of these cases, the differences resulted from the ruler method modeling the wound as a rectangle whereas the WMD method was better able to capture the actual shape.

Fig. 6a illustrates a pear-shaped wound with a measured length and width of 5.5 cm and 2 cm, resulting in a rectangular area of 11 cm² with the wound measurement device reporting an area of 7.89 cm². The shape of the ulcer resulted in rectangular measurements that exceeded the wound boundary. An oval wound measured 4.5 cm and 3.2 cm, yielding a rectangular area of 14.4 cm² (Fig. 6b) with the wound measurement device reporting a similar area of 14.78 cm². The areas are quite similar given that the border and rectangle nearly overlap. Irregularly shaped wounds such as that shown in Fig. 6c, can be difficult to measure with a ruler. In this case, the measured length and width are each 2 cm, resulting in an area of 4 cm². The wound measurement device...
reported an area of 2.2 cm². The size of the irregularly shaped wound was over-estimated when using modeling it as a simple rectangle.

**Discussion**

The machine vision approach utilized to measure wound area met the design criteria by exhibiting better accuracy and reliability than the most common wound area measurement technologies as reported in literature. The WMD demonstrated better accuracy than all four techniques reported by Langemo et al. [6] and demonstrated better accuracy than the ruler and transparency techniques reported by Bulstrode et al. [5]. Bulstrode et. al reported that stereophotogrammetry had error <1% whereas the WMD had an average error of 1.9% at 0° skew. Bulstrode et. al did not report error at other skew angles. Both the inter- and intra-rater reliability were very high when using the WMD and exceeded the reported reliability of ruler, tracing and other photography-based techniques [2,6,8,10].

As mentioned, participating clinicians continuously offered feedback to assist with modifications in the design of the device. Most of the issues

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*Figure 6* Examples of ruler measurement exceeding WMD tracing. A. Pear-shaped ulcer. B. Oval shaped ulcer. C. Irregularly shaped ulcer.
identified were resolved through modifications to the device hardware and/or software and improved user education and training. However, a few areas continue to be a challenge when using the device in the clinical setting.

Laser detection is critical to device operation and a few problem situations were identified. Uneven ambient lighting or glare on the skin can hinder laser detection by the software. The inability to find a laser can also occur if the wound exceeds the geometric layout of the lasers resulting in one or more lasers being projected into the wound bed. To optimize detection, software algorithms were refined to better identify laser point centroids. Future modifications may include the option to manually select laser points to address cases where the software is unable to detect one or more lasers.

Projection of lasers on curved body sites or at high skew angles can also be problematic. Area calculation is based upon the assumption that all four lasers projected onto a plane are equidistant from the device. Two situations can violate this assumption: high skew and curved body parts. The accuracy of skew up to 35° has been deemed acceptable with error <7.5% [12]. The software was modified to warn the user in situations of high skew angles in hopes of avoiding highly skewed images. Highly curved body parts such as heels, ankles or elbows can also affect accuracy. Lasers may not project equidistantly from the camera and the curved wound bed is treated as planar by the camera. This latter limitation exists with all two-dimensional measurement techniques including software systems that digitally measure photographs [10,13,14].

Other clinician comments concerned the form factor of the device. Although the device is fairly small and portable in nature, it is still heavier and larger than a standard digital camera. This can make picture taking with one hand cumbersome and difficult especially in relation to the position of the subject and visibility of the wound. If this device segues into commercialization, one option would be to design a platform that can house the camera, touch screen, lasers, and illumination LEDs in a compact package with greater processing ability than offered by Smartphones. However, the increased processing power and smaller form factor of newer Smartphones may permit the next version of the WMD to meet the identified suggestions of a smaller device.

The responsiveness of the touch screen changed over time resulting in multiple attempts being needed to trace the wound border. This appeared to result from limitations in the processing power of the AT&T Tilt since the problem tended to occur with more processing-intensive situations. Relatively, many of the Smartphone functions remained which periodically caused confusion when navigating to the WoundSuite application from the main menu. Each of these problems was reflective of the prototype platform used for the device and should be ameliorated by the development of the next generation.

Finally, clinicians asked about the possibility of measuring wound depth as well as area. This lead to discussion about the associated costs and complexity of adding such a feature and resulted in very useful information of clinician priorities. While the current WMD design is limited to surface area measurement, concurrent development is focusing on incorporating depth measurement into this hardware platform. It has not yet been tested in a clinical environment.

Conclusion

The accuracy and reliability of a new, non-contact wound measurement device was shown to be better than manual techniques and, at least, equivocal to other computer-based technologies. Like manual methods, the device is capable of providing surface area information immediately after use so has some benefit from techniques that require post-processing.

Clinicians raised several usability issues that resulted from the prototypical nature of the WMD. These included size, processing time, and camera features. These factors appear to be a result of using the AT&T Tilt as the prototyping base. The future goal is to design a more powerful hardware platform that will overcome these limitations.

Conflict of interest statement

None of the authors have a financial or personal relationship with the project’s sponsor. One author is listed as one of four ‘inventors’ on a related patent application with the assignee being Georgia Tech.

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