Clinical Usability of a Wound Measurement Device

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Abstract—

Objective: Monitoring wound size is an integral component to the assessment and treatment of chronic wounds. Conventional methods, such as ruler measures and transparency tracings, for measuring wound size often have low accuracy and reliability. Newer high tech methods, while more reliable and accurate, are often expensive and difficult to use. The objective of the study was to design a wound measurement device (WMD) with the following features: ease of use, low cost, non-contact, time-saving, hand-held, reliable, and battery operated.

Design: The performance of the WMD was evaluated in two rounds of bench testing for accuracy and reliability, followed by a single round of clinical testing to assess ease of use.

Participants/Methods: Bench testing of the WMD was completed to assess for accuracy over distance from the wound surface, as well as camera angle skew. The performance in terms of inter- and intra-rater reliability was also assessed. Three clinicians participated in the clinical trial portion of the study. 45 subjects were recruited. General usability and ease of use was measured through the use of written surveys and verbal feedback from the participating clinicians.

Results: Intra-rater reliability of presented images for which each clinician was asked to interpret and trace the wound exceeded 0.975. Inter-rater reliability of these same images was 0.966-0.978. Accuracy measures based on two black and white shapes with known areas had an average 2.65% error rate.

Conclusions: Both intra- and inter-rater reliability proved to be significantly higher than conventional methods, such as ruler measures and transparency tracings. The WMD was easy to use for the clinician.

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***Key Words*—wound measurement, pressure ulcer, chronic wounds, digital image processing, wound area**

Introduction

Accurate, consistent and regular measurement of the size of a wound is vital in objectively describing the progress of wound healing. This 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 accurate and reliable. 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.

This article describes the design, performance and clinical testing of a new wound measurement device (WMD). Design objectives included the ability to photo-document and measure wounds quickly 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 techniques.

Background

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 [6] is another ruler based device using three disposable paper rulers set at orthogonal angles to measure length, breadth or width, and depth of the wound. This method models the wound as an ellipse with the area calculated as A=length x breadth x 0.785.

A second low-cost, low tech method is the transparency tracing method. Two sterile transparent sheets are laid on top of the wound, and the wound is outlined on the top 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 [7, 9, 11].

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 [1, 8]. 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 [5, 15].

Software-based systems use digital photographs of a wound to measure its area. 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 [1, 7, 8, 14, 18]. Accuracy is typically determined by measuring a wound model or 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 considered more important than accuracy when monitoring wound progress. The comparison of the measures over time is what defines wound healing progress. In addition, measuring accuracy is complicated by the need for a true measure of wound area. Clinically, that is difficult since defining a wound's border is dependent on the judgment of the clinician who performs the measurements.

Thawer et al. [18] 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. [1] 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 [1].

Langemo [8] compared the performance of four different 2-D techniques using three wound models. The techniques compared include ruler, planimetry, computerized digital image tracing 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 including L, pear, and circle shapes. Data was used to calculate accuracy, bias, precision and reliability.

Relative bias was calculated by normalizing the difference between known and measured surface areas using the equation: (mean surface area for technique- known surface area)/(known surface area). The two methods that used a rectangular approximation of area had positive bias meaning that they typically over-estimated the area, whereas the two techniques that traced the borders under-estimated the areas [8].

For inter-rater reliability, the digital area tracing method reported the highest ICC value at 0.87, followed by the digital length x width method at 0.53, and the manual tracing and ruler methods at 0.3 each. For intra-rater reliability, Pearson correlation coefficient was reported and results varied across shape. The manual tracing methods had reliability exceeding 0.85. The coefficients of the two manual length x width methods were similar with the digital length x width ranging between 0.52-0.75 and the ruler method between 0.48 and 0.68. The digital area method reported coefficients less than or equal to 0.4. In summary, Langemo found that the computerized digital tracing method had the highest inter-rater reliability but the lowest intra-rater reliability. This digital area tracing technique also had the least bias and best precision compared to the other 2-D area measurement techniques [8].

Plassman et al.[14] 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 1).

WOUND SIZE	KUNDIN GAUGE	TRANSP. TRACING	PHOTO-GRAPHY	STEREO-PHOTOGR.	STRUCT. LIGHT
< 10 cm²	25%	11 %	12 %	2 %	8 %
10 - 40 cm²	20%	8 %	11 %	2 %	6 %
> 40 cm²	20%	7 %	10 %	1 %	5 %

Table 1. Precision of five area measurement techniques (95% confidence intervals as percentages of the respective areas).

System-level description

The Wound Measurement Device (WMD) utilizes a machine vision technique to calculate wound area. The prototyping platform is 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 white casing, shown in Figure 1, was designed to house the smartphone and four laser diodes required for distance calibration of the device to the wound bed. The four laser diodes are arranged in a square with the camera lens in the center and are aligned such that the square is perpendicular with the z-axis of a flat surface. This design gives a known structure to the projected laser points to allow for the calculation of certain properties of the image. The digitized image is presented to the clinician who circumscribes the border using the touch screen, and the software calculates the surface area (Figure 1).

Figure 1. Device from side/top view. The mobile computing platform and laser are mounted within a casing to permit single handed use.

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 measures 9 ½ x 19 x 4 cm and has a mass of 0.58 kg. The overall design objective is for a dedicated WMD that is designed and packaged for this purpose.

Camera System and Operation

The four laser diodes on the platform 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 locations of each laser is then used to calculate distance from the target plane and skew angle using known geometric relationships.

When the device (and camera) is held parallel to a flat target plane, there is no skew. The four laser dots projected onto the target plane would then form a perfect square. Figure 2 shows the geometry of the basic laser system with no skew. The target plane in the diagram represents the wound surface, and the laser ray represents a single laser projection from the device surface to the target plane. The values x', f, and θ are explained in terms of the equation below. Figure 3 defines the geometry when camera skew is introduced. The device is represented by the rectangle in the upper right, with the camera center at the origin of the 3-D axes. The full view frustum of the camera on the target plane is drawn from the 3-D origin. The two smaller rectangles on either side of the device represent the laser diodes, and the laser rays from the diodes to the target plane are shown.

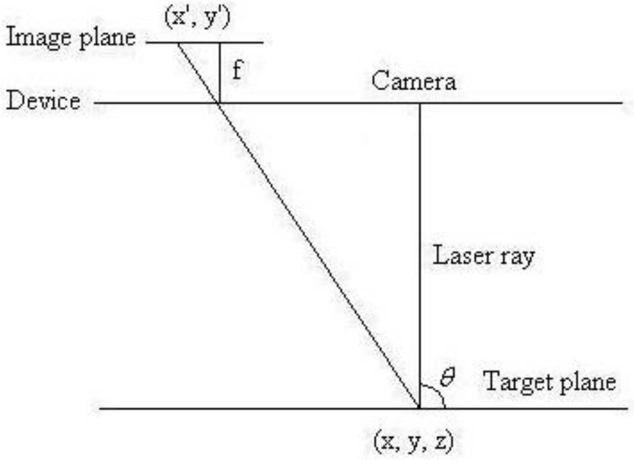


Figure 2. Basic geometry of system with device camera and lasers.

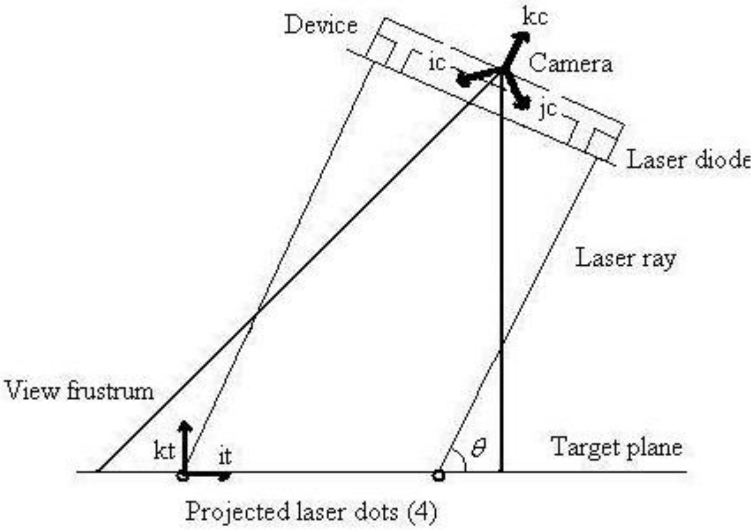


Figure 3. Geometry of system with skew introduced.

$$[x, y, z] = \frac{d}{(f\cot(\theta) - x')}[x', y']$$

The equation above describes the relationship between the real world coordinates (x,y,z) and image coordinates (x’,y’,z’) of a point in the system. The real world coordinates (x,y,z) are with respect to the camera coordinate system, where the 3-D origin is represented by the center of the camera. The coordinate pair (x',y') represents the 2-D coordinates of a pixel within an image. It is important to note that the center of the camera may not be exactly the same as the center of an image. The conversion from image to real world coordinates is based on the values d, f, and θ, which are calculated once during calibration of the device. The parameter, d, represents the real world distance in the x-axis from the camera center to each of the four lasers, f represents the focal length of the camera, and θ denotes the angle of the laser ray to the target plane. In the zero skew case where the camera is held parallel to the target plane, θ is 90 degrees. As the camera skew is increased, the value of θ decreases.

Skew correction involves calculation of the orientation at which the image was taken and then reshaping of the image so if it were taken from the correct orientation. Correction of an image is shown in Figure 4. This step is necessary, because if the device is held at an orientation that is not parallel to the wound bed when the picture is taken, then the resulting image will be skewed. This skew can result in an incorrect area calculation if left uncorrected. The impact of skew on accuracy was tested using an earlier hardware platform but the same skew correction method was used in this study [2]. A model wound with known dimensions was measured at four distances and skew angles between 0º and 35º. Accuracy across distance and skewness ranged from 5%-7.5% with a coefficient of variation (repeatability) of <4%.

Figure 4. Before and after skew correction.

Methods

Performance and clinical utility were tested using multiple approaches. Accuracy was tested 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.

I. Accuracy Testing

The accuracy of the WMD was evaluated over a range of distances and skew angles using two images of known area. The technique followed that used to test an earlier version of the WMD [2]. The images consisted of square and oval shapes printed in black ink on white paper; both had an area of 15cm^2. The prototype WMD was mounted on a stand that had the capability of changing the device height from and angle to the target surface (Figure 5). 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 degrees. Therefore, the total image set consisted of 7 different heights and three skew angles.

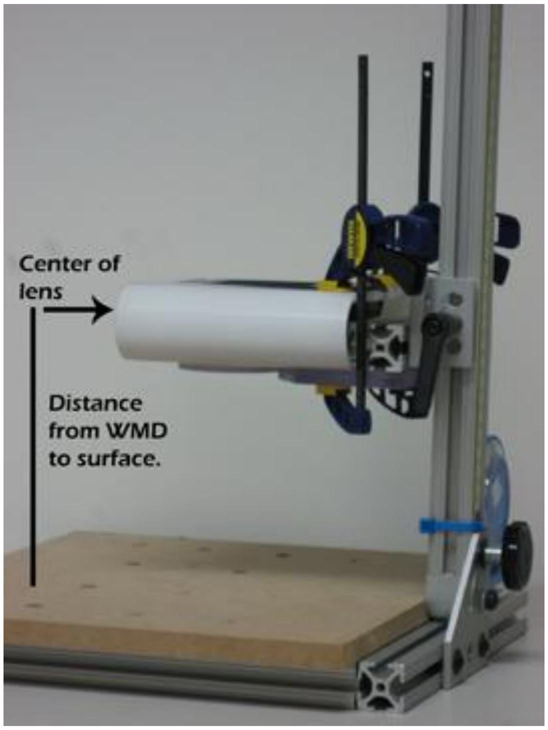
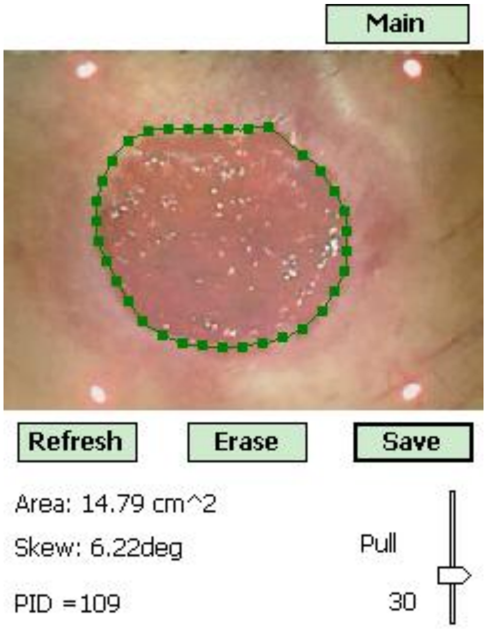


Figure 5. Alignment stand used during testing at various heights and skew angles. Device is mounted at a fixed height in cm and skew angle, and images printed on paper are placed on the wooden board.

For each captured photo, 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 cm^2 along with the wound border image coordinates, calculated camera skew, and detected laser locations.

II. Reliability Testing

Four clinicians 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 (Figure 6). 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 the area of their tracings but the WMD recorded them for analysis.



Area: 14.79 cm^2
Skew: 6.22deg
PID =109
30

Figure 6. Once the image is captured, the clinician uses the stylus to trace the border of the wound, and the software automatically calculates the area based on the border. The clinician can resize the border or erase to redraw from scratch as needed.

III. Clinical Testing

Participants

Three clinicians, a physical therapist, nurse practitioner, and WOCN nurse participated in evaluating the system. Forty-five subjects were recruited from both the inpatient and outpatient areas of a large neurological rehabilitation and acute care hospital. Individuals with areas of skin breakdown 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 participant prior to any procedures being conducted and consent was obtained prior to implementing any study procedures.

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 using the wound measurement device. Clinicians were instructed to position the four laser points around the perimeter of the wound and to avoid a large skew angle between the device and surface of the body/wound. The subject was instructed to not look directly at the laser points at any time (Figure 7).

Figure 7. Photo-documentation using the wound measurement device. The four laser points are lined up outside of the wound borders with special attention to the skew angle between the camera and the surface of the skin.

Once the photo image was captured and accepted, the stylus was used to trace the wound border on the screen. 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 Photo ID (PID) number.

The clinicians participating in the trial were asked to provide feedback on ease of use regularly. A clinician usability questionnaire was used to guide the areas of feedback. 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 degrees, 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% to 3.55%. At a 5 degree skew, the average error was 1.76%, with a range of -0.4% to 4.6%. With a 10 degree skew angle, the average error was 4.28%, with a range from 2.14% to 5.62%.

Reliability

The intra-rater reliability data shows that none of the raters had reliability under 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 and to compare areas measured using the wound measurement device to measurements using the traditional ruler method. During the study, 28 images were identified that had both ruler and WMD measurements and met an established skew threshold of 40 degrees. 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%.

WMD area exceeding ruler measurements

Two examples are shown as representative of the WMD reporting a greater area than the ruler-measured rectangle. The first example is of a small sacral wound where the WMD reported an area of 0.75 cm^2 while the ruler measurement was 0.5 cm^2. Figure 8 indicates the border as identified by the clinician and the area defined by the ruler length x width measurements.

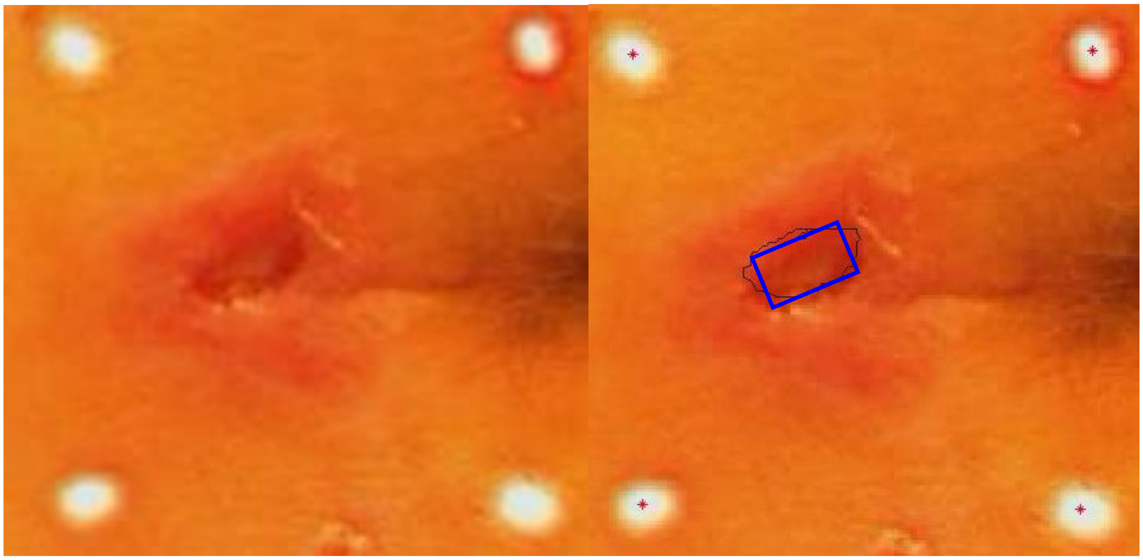


Figure 8. Original image is on the left. The processed image with lasers identified (red stars), and border drawn (black), and ruler-based rectangle (blue) is on the right. The length and width are 1cm and 0.5cm, and the WMD area is 0.75cm^2.

The second example represents a more pronounced difference in area (Figure 9). The WMD reported an area of 6.96 cm^2, where as the ruler-based area was 1.95 cm^2 (1.3 x 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.

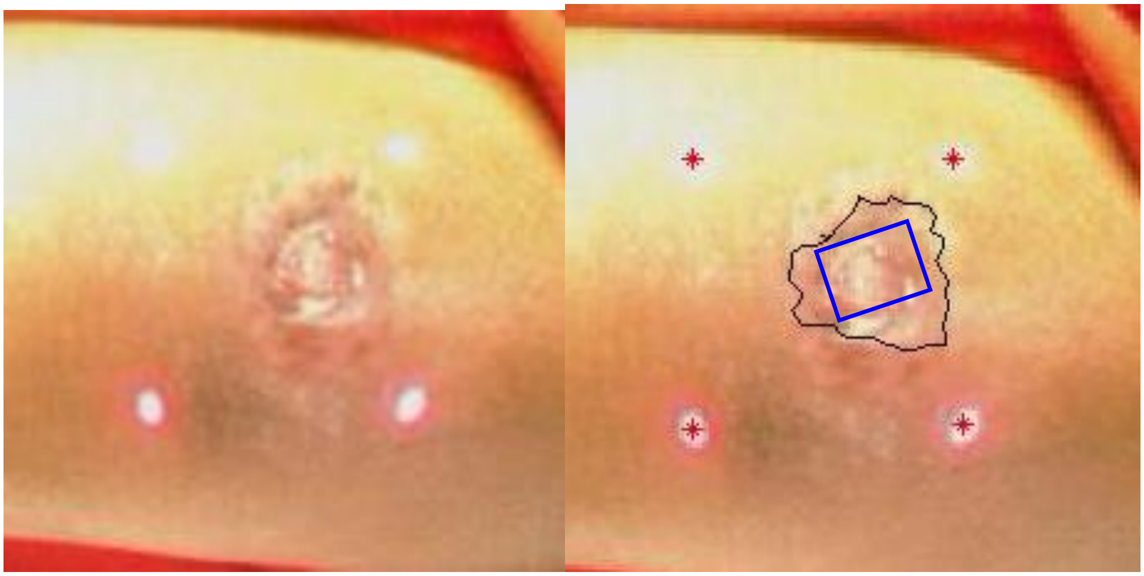


Figure 9. Original image is on the left. The processed image with lasers identified (red stars), and border drawn (black), and ruler-based rectangle (blue) is on the right. The length and width are 1.3cm and 1.5cm, and the WMD area is 6.96cm^2.

Ruler exceeding WMD area

In the other half of the ulcers, the ruler based area exceeded the WMD area by up to 54.2% for irregularly shaped wounds. For oval or near-rectangular wounds, the WMD border more closely matched the ruler based rectangular border with a difference as low as 0.7%. On average, the WMD reported area differs from the ruler-based area by 23.7%. This difference reflects the variance in wound sizes and shapes with respect to their ruler-defined rectangles.

Three example wound images with superimposed device data are shown below. The post-processed data includes the automatically identified laser dots in red and the clinician-traced border. A rectangle based on length and width ruler measurements is added for comparison with the selected wound border.

Figure 10 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 cm^2. The wound measurement device reported an area of 7.89 cm^2.

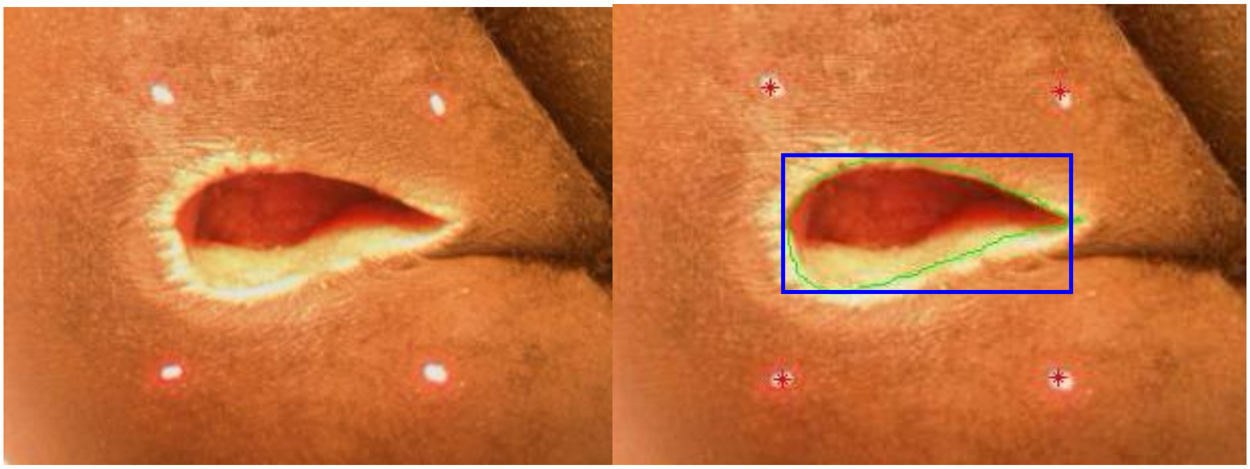


Figure 10. Original image is on the left. The processed image with lasers identified (red stars), border drawn (green), and ruler-based rectangle (blue) is on the right.

Figure 11 illustrates an oval wound with measured length and width of 4.5 cm and 3.2 cm, yielding a rectangular area of 14.4 cm^2. The wound measurement device reported a similar area of 14.78 cm^2. The areas are quite similar given that the border and rectangle nearly overlap.

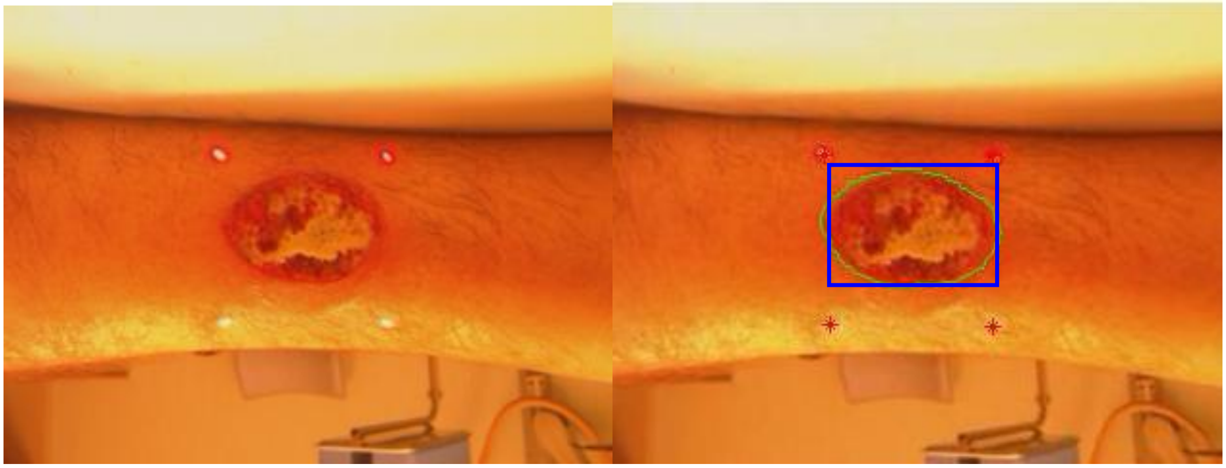


Figure 11. Original image is on the left. The processed image with lasers identified (red stars), border drawn (green), and ruler-based rectangle (blue) is on the right.

In Figure 12, the measured length and width are each 2cm, resulting in an area of 4 cm^2. The wound measurement device reported an area of 2.2 cm^2. The rectangular area easily encompasses the selected wound border.

Figure 12. Original image is on the left. The processed image with lasers identified (red stars), border drawn (green), and ruler-based rectangle (blue) is on the right.

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. The WMD demonstrated better accuracy than the ruler and transparency techniques reported by Bulstrode, et. al [1]. Bulstrode, et. al reported that stereophotogrammetry had error <1% whereas the WMD had an average error of 1.9% at 0 degrees 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 [7, 8, 14, 15].

Throughout the course of the clinical testing, participating clinicians were asked to provide objective feedback on their experiences. Most of the issues identified have been improved or resolved through modifications to the device hardware and/or software and improved user education and training. For example, battery problems, software bugs, and lengthy processing times were rectified and improvements were made to software navigation and operation. However, there are several general areas that continue to be a challenge when using the device in the clinical setting.

Laser detection is critical to device operation. 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% [2]. 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 [4, 12, 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. As mentioned, the goal for a commercial product includes the design of a dedicated platform that can house the camera, touch screen, lasers, and illumination LEDs in a compact package with greater processing ability than offered by smartphones.

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. Finally, many of the smartphone functions remained which caused confusion for some of the clinicians in terms of 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 a dedicated hardware platform.

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 overall goal is to design a dedicated hardware platform that will overcome these limitations. Additional development is focusing on incorporating a depth measurement capability by projecting a laser line across the wound bed.

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