Evaluation of a Novel Three-Dimensional Wound Measurement Device for Assessment of Diabetic Foot Ulcers

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Objective: The initial wound measurement and regular monitoring of diabetic foot ulcers (DFU) is critical to assess treatment response. There is no standardized, universally accepted, quick, reliable, and quantitative assessment method to characterize DFU. To address this need, a novel topographic imaging system has been developed. Our study aims at assessing the reliability and practicality of the WoundVue[®] camera technology in the assessment of DFU.

Approach: The WoundVue system is a prototype device. It consists of two infrared cameras and an infrared projector, and it is able to produce a three-dimensional (3D) reconstruction of the wound structure. Fifty-seven diabetic foot wounds from patients seen in a multidisciplinary foot clinic were photographed from two different angles and distances by using the WoundVue camera. Wound area, volume, and maximum depth were measured for assessment of reliability. Thirty-one of these wounds also had area calculated by using the established Visitrak[™] system, and a correlation between the area obtained by using both systems was assessed.

Results: WoundVue images analysis showed excellent agreement for area (intraclass correlation coefficient [ICC]: 0.995), volume (ICC: 0.988), and maximum depth (ICC: 0.984). Good agreement was found for area measurement by using the WoundVue camera and Visitrak system (ICC: 0.842). The average percentage differences between measures obtained by using the WoundVue from different angles for assessment of different sizes and shapes of wounds were 2.9% (95% confidence interval [CI]: 0.3–5.4), 12.9% (95% CI: 9.6–35.7), and 6.2% (95% CI: 2.3–14.7) for area, maximum depth, and volume, respectively.

Innovation: This is the first human trial evaluating this novel 3D wound measurement device.

Conclusion: The WoundVue system is capable of recreating a 3D model of DFU and produces consistent data. Digital images are ideal for monitoring wounds over time, and the WoundVue camera has the potential to be a valuable adjunct in diabetic foot wound care.

Keywords: chronic wounds, diabetes, devices

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INTRODUCTION

FOOT PROBLEMS IN diabetes are common and carry a substantial physical, physiological, and financial burden for affected patients. It is estimated that patients with diabetes have an almost 25% lifetime risk of developing a foot ulcer and ~2% of patients develop new foot ulcers each year.^{1,2} More than 50% of these ulcers become infected and many require hospitalisation.¹ Diabetic foot care accounts for a substantial proportion of health care expenditure, and the majority of this expenditure arises through prolonged and severe ulceration.³ Diabetic foot complications are the most common cause of “non-traumatic” lower limb amputation, and it has been estimated that on a global scale a lower limb is lost every 20 s as a consequence of diabetes.⁴

The treatment of diabetic ulcers is complex and requires a multidisciplinary team. The principles of management include wound care, management of infection, revascularization if required, and off-loading, with the aim of achieving expeditious wound healing, prevention of ulcer recurrence, and ultimately avoiding amputations.⁵

As part of wound management, it is essential to obtain accurate and reproducible wound measurements. A thorough initial wound assessment provides baseline data about the status of the wound and is important in developing a treatment plan.⁶

CLINICAL PROBLEM ADDRESSED

Repeated wound measurements at clinical encounters is valuable for assessing the effectiveness of treatment and can be a predictor of longer-term ulcer healing. In a prospective study of patients with diabetic foot ulcers (DFU), the percent change in foot ulcer area after 4 weeks of observation was a good predictor of healing at 12 weeks.⁷ Recent recommendations from the International Working Group for the Diabetic Foot recommend consideration of revascularization if the wound in patients who were initially assessed as having adequate perfusion has not significantly improved within 6 weeks of optimal wound care.⁸ Thus accurate wound assessment is an essential component of diabetic foot management.

The ideal method of wound measurement should be practical, comfortable for the patient, accurate, and, most importantly, reproducible. In clinical practice, it is important to be able to reassess wounds regularly to track changes in size, depth, and appearance over time. The measurement methods most commonly used include simple ruler

assessment, acetate tracing, and digital imaging methods.⁹

Ruler-based techniques to calculate area are simple and inexpensive but inconsistent and are not very reliable for irregular or large wounds. Acetate tracing is performed by placing a transparent film over the wound and tracing the outline with a permanent marker, allowing more accurate area calculation when the wound is irregular. The area can be obtained by placing the wound trace on a metric grid and counting the number of squares of a known area. However, it is time consuming and inaccuracies may arise when deciding the value of partial squares. Alternatively, the wound outline can be retraced onto a digital tablet, which calculates the area.⁹ One example of digital planimetry device that has been validated is the Visitrak™ system (Smith & Nephew Wound Management, Inc., Largo, FL).¹⁰

Digital photography is also commonly used. The wound can be photographed with a ruler or a marker of known dimensions placed at the skin near the wound edge and the image transferred to a computer, and planimetric software can be used to calculate the area. However, inaccuracies due to parallax may occur.¹¹

More recently, new methods of wound measurement using laser scanners, stereophotogrammetry, and structured light technique have become available. Eykona®, Silhouette® and the InSight® cameras are examples of these new technologies with the potential to provide a more comprehensive evaluation of the wound, including assessment of volume.^{12–15} The WoundVue® system is a new prototype device that uses the principle of stereophotogrammetry to provide a three-dimensional (3D) assessment of the wound (Figs. 1 and 2).

The purposes of this study were to determine reliability of the WoundVue camera for area, volume, and maximum depth measurements and to assess the agreement between area measurements obtained by using the WoundVue camera and the Visitrak system.

MATERIALS AND METHODS

Ethical approval was granted from Central Adelaide Local Health Network Human Research Ethics Committee, and written informed consent was obtained from all participants.

Patients with DFU were enrolled from multidisciplinary diabetic foot clinics at the Queen Elizabeth Hospital and Lyell McEwin Health Service, or they were admitted under the Vascular Surgery service at the Royal Adelaide Hospital, all within

Figure 1. WoundVue[®] camera. The system consists of a Microsoft Surface Pro Tablet, 3D-camera, a pair of LED lights, and tailor-made software. 3D, three-dimensional.

the metropolitan Adelaide region, South Australia, from June to November 2018.

Digital documentation of wounds was obtained by one of the clinicians involved in the study (G.P.) by using the WoundVue camera. G.P. received a formal 30-min training session on the device before the research. The WoundVue system is a prototype device developed by the machine learning department at The University of Adelaide in collaboration with LBT Innovations Limited (Adelaide, South Australia).

The camera system consists of two infrared cameras that image the wound from two different vantage points and an infrared projector that casts a textured light pattern onto the wound. The textured light pattern facilitates matching pixels in the first image with corresponding pixels in the second image. Once corresponding points have been established, the process of triangulation determines the range of all points in the image, thus producing a 3D reconstruction of the wound (Fig. 3). The theoretical foundations and practical algorithms that underpin the 3D reconstruction from a pair of images are well established and docu-

mented in the computer vision and photogrammetry literature and can be found in Hartley and Zisserman and Filko *et al.*^{16,17} After the user helps delineate the wound bed in the input image, the wound bed in the 3D model is closed with an artificial surface to facilitate the computation of the area, volume, and maximum depth of the wound.

Fifty-seven wounds were photographed with the WoundVue camera from two slightly different angles and distances for assessment of intra-rater reliability. All the photos were taken by the same clinician (G.P.) from an appropriate position where the target ulcer was placed close to the center of the frame for both right and left cameras. The objective was to assess consistency in measurements when the photos were taken in satisfactory but not identical circumstances. Subsequently, two clinicians (G.P. and B.K.) independently assessed all the images and outlined wound edges. Thirty-one wounds that were photographed also had area measured by using Visitrak system by the same clinicians involved in the study (G.P.).

Wound images were downloaded and processed by the Australian Institute for Machine Learning

Figure 2. 3D reconstruction of foot wound. The *left panel* is an image of the wound, and the *right panel* shows the concomitant 3D reconstruction and metric measurements.

Figure 3. Triangulation of a cube. The cube is imaged from two different vantage points, and pixels in the first image are matched with pixels in the second image. For example, the corresponding corners of the cube in both images are identified and matched. To determine the depth of the corner of the cube, one casts a ray from the optical center of each camera such that it passes through the image at the location of the corner pixel. The two rays intersect in 3D space, and the depth can then be determined from the point of intersection. The same process can be applied for each pixel in the image to recover the depth of the entire scene.

(AIML—University of Adelaide) where area, volume, and maximum depth measurements were obtained.

Statistics

Intraclass correlation coefficient (ICC) estimates and their 95% confidence intervals (CIs) were calculated. In accordance with Koo and Li¹⁸ recommendations, ICC values >0.90 were indicative of excellent agreement, whereas values between 0.75–0.90 and 0.50–0.75 portrayed good and moderate agreement, respectively.

A two-way mixed-effects, absolute agreement, measurement model was used for assessment of WoundVue intra- and inter-rater reliability and a one-way random effect model was used to assess the agreement between the different instruments (WoundVue and Visitrak).

One-sample *t*-test of the differences of measurements obtained by using the WoundVue system was performed to assess average percentage difference between wound dimensions acquired from photos taken from slightly different angles.

All statistical analysis was performed by using SPSS statistical package version 25 (IBM SPSS Statistics for Windows, Version 25.0; IBM Corp., Armonk, NY).

RESULTS

Fifty-seven diabetic foot wounds of different shapes and sizes were photographed by using the WoundVue camera. The average wound area obtained was 5.7 cm², ranging from 0.4 cm² (small digital ulcer) to 30.0 cm² (forefoot amputation wound). Wound maximum depth and volume were on average 0.6 cm (max 5.6 cm and min 0.02 cm) and 1.2 cm³ (max 14.9 cm³ and min 0.003 cm³), respectively.

Excellent intra-rater (G.P.) reliability was found for area (ICC: 0.995 [95% CI: 0.991–0.997]), volume (ICC: 0.988 [95% CI: 0.979–0.993]), and maximum depth (ICC: 0.984 [95% CI: 0.975–0.990]) measurements obtained with the WoundVue camera between the two different images taken of the same wounds (Fig. 4).

Similarly, excellent inter-rater reliability for area (ICC: 0.983 [95% CI: 0.971–0.990]), volume (ICC: 0.978 [95% CI: 0.962–0.988]), and maximum depth (ICC: 0.975 [95% CI: 0.956–0.986]) was achieved when images were analyzed by two different assessors.

The average percentage differences between measures obtained by using the WoundVue from different angles for assessment of different sizes and shapes of wounds were 2.9% (95% CI: 0.3–5.4), 12.9% (95% CI: 9.6–35.7), and 6.2% (95% CI: 2.3–14.7) for area, maximum depth, and volume, respectively.

Thirty-one wounds that were photographed also had area measured by using Visitrak. The reason for the fact that not all wounds photographed had area measured with Visitrak is that this device was only available in one of the clinics initially and then became accessible to other settings during the research. A good agreement was found for area measurement by using the WoundVue camera and Visitrak system (ICC: 0.842 [95% CI: 0.700–0.920]) (Fig. 5).

DISCUSSION

An accurate and reliable measurement method of wound area and depth is important for appropriate wound documentation, assessment of progress, and determining the efficacy of treatment. An ideal measurement method should be consistent, easy to learn and use, cost efficient, and comfortable for patients.¹⁹

Figure 4. Intra-rater reliability of the WoundVue.

With the advent of new technologies, 3D cameras have become available and they have the potential to afford a more comprehensive assessment of wounds, providing not only measures of surface area and circumference but also wound volume.

There are 3D measurement systems commercially available. However, they have not yet had a

major impact in clinical practice. A major limiting factor for their widespread adoption remains the significant cost of purchase and maintenance of such devices. Examples are the Eykona camera (Fuel3D, Oxford, UK), Silhouette (Aranz, Christchurch, New Zealand), and InSight (eKare, Inc., Fairfax).^{12,14} These systems use different technologies to assess wound dimensions.

Figure 5. Correlation between WoundVue and Visitrak for area measurement.

The Eykona camera uses what is known as “photometric stereo” to construct a 3D model of the wound. Photometric stereo involves taking a sequence of photographs of the wound while holding the camera stationary but illuminating the wound from different directions. It turns out that one can construct a 3D model of the wound by analyzing the shading patterns in the series of wound bed images. The Eykona device requires the user to place a bespoke calibration target near the wound bed. The Silhouette device projects three red laser fanbeams onto the wound. One positions the device such that the three red laser lines intersect and form a star shape on the wound bed. Silhouette uses knowledge of the orientation and position of the lasers’ beams to determine the depth of pixels in the image that the laser falls on. That is, one obtains minimal depth information since one only has depth corresponding to three thin lines that project onto the wound. Consequently, one can expect a significant variance in depth and volume measurement since any three lines of the wound bed will lead to different reconstructions. The In-Sight and WoundVue device are similar in that they both project an infrared structured light pattern onto the wound to aid in constructing a 3D model and construct a volume measurement by taking into account the entire wound bed. However, the devices use different camera lenses, dot patterns, and algorithms to build the 3D models and produce the measurements. The choice of lenses is crucial since it influences the minimum wound size that a device handles.

This study describes an initial evaluation of the WoundVue camera in human subjects. The device

proved to be practical and provides a reliable method of wound assessment. It requires minimal training to operate the camera and software, and it can be easily deployed in routine clinical practice.

Results demonstrated excellent intra-rater reliability for area, volume, and maximum depth assessment for a range of wound shapes and sizes. Photos taken in the same clinical encounter but with the device positioned in different angles and distance from the wound provided consistent results with ICC above 0.980 for all the parameters. In addition, when the photos were analyzed by two assessors, there was excellent correlation for all parameters.

Wound area measurements obtained with WoundVue demonstrated a good correlation with wound area obtained by using the Visitrak system, with ICC 0.842. As demonstrated in Fig. 5, the correlation between the two systems was less strong for larger wounds. This was not surprising as the two systems use different methods to assess surface area. The WoundVue system evaluates surface area of the wound taking into consideration all the irregularities of the wound bed while Visitrak film grid, although malleable, is unable to conform precisely to the wound surface.

The proportional difference for area assessment using photos of real wounds with different shapes and sizes was from different angles and was very low (2.9%, 95% CI: 0.3–5.4), demonstrating high value of the WoundVue camera for area assessment. There was more variability for assessment of the other parameters. The highest variability was for maximum depth, 12.9% (95% CI: 9.6–35.7). This can be explained by the fact that the study included

several superficial wounds for which any variance in depth measurement resulted in a large proportional difference in this parameter. Examples are wounds that were <3 mm in depth for which 1 mm of difference between measurements, while not clinically important, resulted in more than 30% variance. The proportional difference in volume between measurements was 6.2% (95% CI: 2.3–14.7). This variance is viewed as acceptable considering that images were taken from slightly different angles and the cohort comprised real diabetic foot wounds with different shapes and sizes. The considerable variability in depth measurement, especially for superficial wounds, also affected volume measurements.

Assessment of wound volume is challenging. Slight movements of the patient or camera operator can change the appearance of a wound, especially if there is an undermined segment of the wound. Localization of the wound on a curved part of the body (*e.g.*, the heel) can make it difficult to correctly estimate wound size.¹⁵

The commercially available 3D cameras have been shown to be accurate for area assessment; however, they have not been sufficiently validated in terms of accuracy and reliability for volume assessment. Several validation studies were done in a controlled environment by using artificial or animal wound models^{12,14,20,21} that are much less complex than real wounds in clinical settings. Therefore, these results should be looked at with caution. A study using wound models compared volume measurement by the water displacement technique with measurement obtained by using Eykona and Silhouette devices. Both devices significantly overestimated wound volume compared with water displacement.¹⁴ More recently, Jørgensen *et al.* assessed 48 real wounds by using a novel 3D-Wound Assessment Monitor camera (prototype device) and compared wound volume obtained with the 3D device with volume obtained by injecting gel into wound cavity; a high agreement between methods was reported.²²

There are many advantages associated with the use of a 3D camera system such as WoundVue. It is a practical, efficient, and comprehensive way to assess wound size. It is noninvasive and, thus, causes no discomfort to patients. As the wound bed is not touched during assessment, there is no risk of infection and, importantly, cross-infection.

The potential for using this system in telemedicine is exciting.²³ This is particularly important in countries such as Australia where distance from expert assessment can be a critical factor in providing good care. In Australia, the prevalence

of diabetic foot disease is high in remote geographic areas, especially among the indigenous population.²⁴ Frequently, patients live hundreds of kilometers from specialized multidisciplinary foot clinics. The use of a reliable 3D camera system that provides high-quality imaging and measurements would allow enhanced communication between local teams (general practitioners and community nurses) and wound care specialists (specialist nurses, podiatrists, and vascular surgeons). A 3D photo of a wound is able to transmit more nuanced information that often cannot be easily captured in a wound description. As a result, routine follow-up care could be performed in a remote area with close liaison with a multidisciplinary service.

In addition to being able to provide wound dimensions, the WoundVue core machine-learning algorithms have been adapted to interpret tissue types. This innovative technology allows for an even more comprehensive wound assessment measuring, for example, the percentage of wound area with nonviable tissue in the base. Further studies need to be undertaken to validate this feature currently offered by the WoundVue system.

Limitations of this study include a small sample size, lack of Visitrak assessment in all patients, and the fact that we did not compare the volume and maximum depth measurements obtained with WoundVue camera with other methods. Ideally, wound depth should have been measured by using ruler or a depth probe and wound volume with saline or alginate cast. However, these methods can cause patient discomfort, are impractical to be performed in a busy diabetic foot clinic, and lack reproducibility.^{25,26} It would also be valuable to compare the measurements obtained with other 3D wound camera systems available. However, unfortunately the research team did not have access to other devices and none of the 3D camera devices commercially available has been proven to be particularly accurate for depth and volume assessment.

There are also limitations related to the device. As with all methods of digital wound measurement, the WoundVue camera is unable to assess undermined parts of a wound, and the presence of debris and clot in a wound may affect volume measurement. Further, assessment of wounds at points of curvature of the body represent significant challenges and some wounds may not be suitable for 3D reconstruction. The WoundVue Camera demonstrated restrictions for measuring depth and volume of shallow, flat wounds. However, for this type of wound, area assessment is clinically much more relevant.

Currently, the WoundVue camera does not provide the dimensions instantly and the device needs

to be connected to specific software on a desktop computer to generate the 3D model of the wound and wound measurements. Future development of the system should allow for immediate wound assessment within the device without the need to connect to external software.

KEY FINDINGS

- WoundVue camera has demonstrated excellent consistency for wound measurement in relation to area, maximum depth, and volume.
- Good correlation for area assessment between WoundVue and Visitrak, although this correlation was less strong for larger wounds.
- 3D wound measurement devices, such as WoundVue camera, has the potential to be a valuable adjunct in diabetic foot wound care.

INNOVATION

This was the first human study evaluating the WoundVue system. This system is capable of recreating a reliable 3D model of diabetic foot wounds, providing wound measurements. It has the potential to be a valuable adjunct in diabetic foot wound care, as digital images are ideal for monitoring wounds over time and for telemedicine application.

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LBT innovation provided the WoundVue device for conduct of the study. The authors declare no competing financial interests. The content of this article was expressly written by the author(s) listed. No ghostwriters were used to write this article.

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Abbreviations and Acronyms

CI = confidence interval
 3D = three-dimensional
 DFU = diabetic foot ulcers
 ICC = intraclass correlation coefficient