Clinical Evaluation of Portable Wound Volumetric Measurement Devices

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ABSTRACT

OBJECTIVE: Wound dimensional assessments are important in determining the progress of a wound and the effect of interventions on wound healing. The FastSCAN (FS; Polhemus Inc, Colchester, Vermont) and Silhouette Mobile (SM; ARANZ Medical, Christchurch, New Zealand) are portable devices that quantify surface area, depth, and volume of wounds. This study evaluated their reliability in producing accurate wound measurements.

DESIGN AND SETTING: This study was conducted at the Waikato Hospital, Hamilton, New Zealand.

PATIENTS AND INTERVENTION: Eleven vascular patients with a combined total of 16 wounds underwent simultaneous wound measurements using three-dimensional computed tomography (CT) reconstruction, FS, and SM.

MAIN OUTCOME MEASURE: The validity of FS and SM was tested against CT. Additionally, the interoperator reliability and intraoperator reliability of FS and SM were determined.

MAIN RESULTS: The intraoperator reliability and interoperator reliability for volume recordings of the SM were 0.97 and 0.97, respectively, and for the FS were 0.96 and 0.97, respectively. The FS and SM measurements were not significantly different from CT. The SM consistently produced smaller wound volume and depth measurements compared with CT. In contrast, overestimation was observed for FS when compared with CT. However, the volume measurements in one wound were anomalous, being 10 times larger than CT measurements. Excluding this wound, there were strong correlations in wound volumes for SM and CT ($r = 0.81$; $P \leq .0001$), for FS and CT ($r = 0.99$; $P \leq .001$), and for SM and FS ($r = 0.99$; $P \leq .0001$).

CONCLUSIONS: Measurements from FS and SM were comparable to CT. Therefore, SM and FS devices both offer the benefit of being noncontact portable devices that produce reproducible and reliable readings.

KEYWORDS: computed tomography, FastSCAN, Silhouette Mobile, wound dimension, wound measurement, wound size

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INTRODUCTION

The volumetric assessment of wounds is useful in monitoring wound healing response and research. Objective measurement can summarize the patient's progress and is valuable to healthcare providers for tracking wound progress and evaluating different treatment modalities. Validated methods for determining wound volume include wound molds, fluid installation, and the Kundin wound gauge (a three-dimensional ruler).[1–3] These tools can be messy, impractical, and time consuming and often involve wound contact, thereby increasing the risk of infection.[4] Digital photographic techniques incorporate sophisticated software that can provide accurate wound measurements; however, these are usually bulky, heavy, and expensive.[5,6] To date, standard techniques for wound measurement have not been established.

Computed tomography (CT) is highly regarded in clinical practice for measurement of dimensions.[7–9] It is considered to be the most accurate noninvasive modality, superior to magnetic resonance imaging.[10] Its reliability for volumetric assessment is excellent, with intraoperator reliability ranging from 91% to 100% and interoperator reliability between 90% and 100%.[11,12] Using this method, wound volume and depth are calculated via three-dimensional reconstruction. However, the use of CT scanning for repeat wound monitoring over a given time period consumes more hospital resources and poses a risk from radiation exposure.

The ARANZ Medical Silhouette Mobile (SM; Christchurch, New Zealand) is a handheld personal digital assistant (PDA)–based wound imaging and documentation device.[13] It combines a digital camera and structured lighting in the form of two laser beams to automatically correct for image scale and skin curvature, allowing quantitative, rapid, and noncontact wound measurements.[14,15] The SM device correlates measurements of wound surface area and depth with past measurements to give a graphic representation of the wound progress. The scanner has been used in clinical practices and trials in patients with leg ulcers;[16,17] however, there is limited independent evidence of its accuracy and reliability.[17–19]

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Only one independent study assessed its measurement of wound volume on artificial wounds.[19] The SM is US Food and Drug Administration–approved with 510k clearance.

The FastSCAN (FS) Cobra (Polhemus Inc, Colchester, Vermont) is another noninvasive handheld laser scanner. It uses a "class A" laser line scanner that sweeps repeatedly over the wound and two miniature handpiece cameras to record the three-dimensional spatial coordinates of the surface points.[20] This reconstructs a precise three-dimensional digital surface map of the ulcer and wound edge contour in real time. Advanced computer software, such as the FS Volumator program, can then quantify the wound volume. This appears to be the most practical, modern, and reliable device available for objective wound volume measurement that has been validated;[21,22] however, studies in human wounds are sparse. Based on a small study of 30 upper limbs in healthy volunteers without wound defects, interoperator reliability was up to 95%, and intraoperator reliability was 72%.[23] The latter statistic was attributed to poorer-quality scans. FastSCAN also appeared to overstate wound volume when compared with the fluid displacement method.[23] The FS device is not approved for medical use by the US Food and Drug Administration.

There are limited affordable and practical devices to provide objective wound volume measurements, and in addition there is limited information available concerning these current, innovative devices. Both the FS and SM are potential clinical tools that could prove beneficial to the medical profession if they can produce reliable and reproducible measurements of wounds.

METHODS

Vascular patients with open surgical wounds or ulcers of the lower limb at Waikato Hospital (Hamilton, New Zealand) were recruited from the ward and outpatient clinic between December 2009 and February 2010. Wound dimensions were measured using the FS and SM, and the readings were compared with three-dimensional CT reconstruction. Patients younger than 18 years with a history of severe dementia or known methicillin-resistant *Staphylococcus aureus* were excluded.

Consented participants underwent a targeted noncontrast CT scan of the lower limb focused around the region of the ulcers or wounds. The CT scan protocol was specifically developed for this study to minimize radiation risks. Prior to the CT scan, wound dressings were removed, and the wound was cleaned before being lightly covered in transparent cling film without causing distortion of the wound dimensions. This cover was removed after the CT scan but prior to assessments with FS and SM. The cling-film technique was adopted because packing and wound dressings would disrupt the wound-surface interface on CT imaging. The cling film also protected the wound from desiccation as a result of prolonged exposure to air.[24] A three-dimensional CT reconstruction of the wound was created with an imaging slice thickness of 1 mm.

Immediately following CT, the wounds were scanned by three different operators using the FS and SM laser devices with the patient lying supine (Figure 1). Each operator scanned the same wound 3 times with both devices to measure wound surface area (cm^2), maximum depth (cm), and volume (cm^3). The average values of the three repeated FS and SM readings from the three operators were used for comparison with similar CT measurements. The latter were calculated by processing the CT images and defining the wound edges with the Siemens imaging reconstruction software (Siemens AG, Munich, Germany) by a single operator. No wounds were specifically debrided during the scanning process.

Statistical analyses were performed using SPSS version 22 software (IBM Corporation, Armonk, New York). A type I error of 5% ($P \leq .05$, 2-tailed) was considered to be statistically significant. Descriptive statistics were described in terms of the range, mean, median, and SD. Student *t* test was used to compare the means of two groups of continuous variables, and Pearson correlation was used to test associations between continuous variables. Random systematic errors in assessing the reliability of the devices were expressed as a ratio of total variance to calculate the intraclass correlation coefficient (ICC).[25] The ICCs and the Bland-Altman test were used to assess interoperator and intraoperator variability. The study was approved by the local Northern Y ethics committee (NTY/09/08/080).

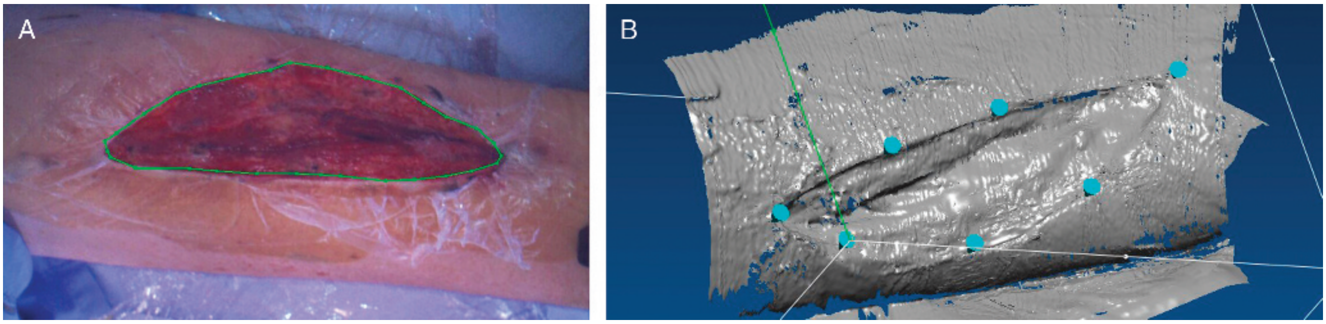
RESULTS

This study was completed with 16 wounds in 11 patients with peripheral vascular disease over a 20-week period. Nine patients were New Zealand Europeans, and 2 were Māori. The median age was 77 years. Wound locations included the toe (n = 4), foot (n = 5), heel (n = 1), calf (n = 4), leg stump following an above-knee amputation (n = 1), and medial thigh (n = 1). The average volume and depth measured by CT were 4.6 (0–23.5) cm^3 and 1.3 (0–4.9) cm, respectively (Table 1).

Evaluation of Intraoperator and Interoperator Reliability

Table 2 shows ICCs between 0.94 and 0.99 for the SM and FS, which indicate excellent intraoperator and interoperator reliability. Within Table 2, the average ICC is shown as the number within the brackets, whereas the single-measure ICC is detailed to the left of the brackets. The former indicated reliability when measurements were repeated three times or by three different operators. Wound depth was more variable than the other measures.

Figure 1.
INFECTED LOWER-LIMB SURGICAL WOUND



A, Silhouette Mobile image. B, FastSCAN image; blue stylus laser point outlines the wound boundary.

Correlation between SM and FS versus CT Reconstruction

The single mean values of the three repeated FS and SM readings from the three operators were used for comparison with CT. Table 3 shows the mean differences and SD of the wound surface area, maximum depth, and volume measurements when comparing the different modalities.

There was no statistically significant difference for wound volume measured by SM compared with wound volume measured by CT (Table 3). However, SM underestimated the wound depth compared with CT (-0.65 cm, $P = .04$). There was no statistically significant difference in any wound measurements obtained by FS and CT. While surface area measurements were not compared with CT, the surface area measurements from SM and FS were compared. Surface areas measured by SM were underestimated by 1.6 cm^2 ($P = .02$).

Although no statistically significant differences were detected when comparing wound volume of FS and SM with CT volume, the mean differences suggested that the FS volumes were overestimated by 14 cm^3 (compared with CT) and 16 cm^3 (compared with SM), respectively, with a large SD. In patient 10, the volumes measured by FS were approximately 10 times larger than measured by CT. This did not appear to be a technical error, because the FS recordings in this patient were similar in all the repeated measurements by the three operators. If patient 10 was excluded from the analysis, the difference in mean volume between FS and CT was –0.66 (SD, 1.2) cm^3 ($P = .10$), and the mean volume between SM and FS was –0.70 (SD, 2.0) cm^3 ($P = .30$).

Figure 2 shows the Bland-Altman plots used to compare measurements from SM and FS with the CT reconstruction. In these graphs, the x axis represents the average measurements for either wound volume or wound depth produced by CT and SM (Figures 2A, B) and CT and FS (Figures 2C, D). The y axis plots the subtracted difference in values between the two modalities tested in each graph and therefore the error. It can be observed from these graphs that for SM volume and depth a positive difference existed for CT. This implies that most CT outcomes were higher. A systematic bias could be deduced from this pattern of underestimation. For FS, in contrast, a pattern of overestimation was observed, as most points lay above the zero line in the Bland-Altman plots.

Table 1.
SUMMARY OF WOUND DIMENSIONS RECORDED BY CT, SM, AND FS

Wound Dimensions	Modality	Mean	SD	Range	Mean Excluding Patient 10	SD	Range
Surface area, cm^2	SM	7.9	12.7	0.4–50.9	8.1	13.1	0.4–50.9
	FS	9.3	16.2	1.2–57.3	9.4	17.0	1.2–57.3
Depth, cm	CT	1.3	1.7	0–4.9	1.0	1.7	0–4.9
	SM	0.62	0.65	0.1–1.9	0.59	0.66	0.1–1.9
	FS	1.7	3.8	0.1–13.1	0.52	0.35	0.2–1.1
Volume, cm^3	CT	4.6	6.7	0–23.5	4.2	6.6	0–23.5
	SM	3.7	6.4	0.1–22.8	3.7	6.6	0.1–22.8
	FS	18.1	51.6	0.1–173	2.7	6.4	0.1–20.6

Abbreviations: CT, computed tomography; FS, FastSCAN; SM, Silhouette Mobile.

Table 2.

INTRAOPERATOR AND INTEROPERATOR RELIABILITY OF SM AND FS FOR WOUND VOLUME, DEPTH, AND SURFACE AREA

		Intra-ICC (Average)	Inter-ICC (Average)
SM	Volume	0.97 (0.99)	0.97 (0.99)
	Depth	0.97 (0.99)	0.94 (0.98)
	Surface area	0.99 (1.00)	0.99 (1.00)
FS	Volume	0.96 (0.99)	0.97 (0.99)
	Depth	0.95 (0.98)	0.98 (0.99)
	Surface area	0.99 (1.00)	0.99 (1.00)

Abbreviations: FS, FastSCAN; ICC, intraclass correlation coefficient; SM, Silhouette Mobile.

There is a strong linear correlation for SM depth and SM volume when compared with CT, with Pearson correlation coefficients (r) of 0.81 and 0.88, respectively (Table 3). The correlation coefficients of volumetric and depth assessments of FS compared with CT were not significantly consistent.

However, by excluding patient 10, this yielded strong correlations between FS and CT (r = 0.99; $P \leq .0001$) and between FS and SM (r = 0.99; $P \leq .0001$; Tables 1 and 3).

DISCUSSION

This is a unique independent study that investigated both small and large wounds in a clinical setting and compared SM and FS with volumetric CT. A recent literature review by Khoo and Jansen[26] on various wound measurement techniques found only 3 studies on the use of structured light or laser approach to wound measurement, and all involved SM. Two of these, by Miller et al[17] and Hammond and Nixon,[18] demonstrated an interoperator and intraoperator reliability similar to that obtained from this research (0.998 and 0.990 for area and depth, respectively). Hammond and Nixon[18] (published by ARANZ Medical) investigated 5 wounds, and Miller et al[17] investigated 14. The SM device was not compared with other modalities, and wound volumes were not assessed. The third article, by Davis et al,[19] compared SM with its newer version, Silhouette Star, and found congruency in depth and volume measurements between the two devices when assessing dental molds, crafted porcine wounds, and cadaveric wounds.

Depth is an important factor in wound healing, with a large peripheral wound often signaling a better prognosis than a smaller but deep ulcer.[27] Current clinical methods for assessment of wound size, particularly depth, are often inadequate and inaccurate. Most clinicians prefer to use observational estimations or wound diameter measurements via tracing tools.[28] Three-dimensional CT reconstruction for measuring wound properties offers the advantage of sagittally visualizing the wound, defining the air-wound interface, revealing bone erosion, and identifying the presence of undermined wound or inflammatory tissue below the peripheral border. However, the major limitations of CT relate to the quality of the reconstruction software, an inability to capture small and superficial wounds, and inaccuracies in assessing wounds where dimensions are affected by pressure or dependency. An example was patient 10, who had a large open wound on the stump following an above-knee amputation. This patient's wound was compressed when the patient was lying supine in the CT scanner, potentially altering measurements (Figure 3). Scanning with the SM and FS was more flexible in that the patient could lie prone or in a lateral decubitus position, or the leg could have been elevated by an assistant so the wound could lie freely. The position should be consistent when monitoring wound progress. In addition, a small superficial ulcer was not detectable by CT, but SM and FS offered a more detailed measurement and were able to record this wound dimension.

The 3 operators underwent a 1-day training course in both devices prior to the study. However, there was a practical learning curve for the operators during the study with technical difficulties encountered. The FS and SM devices were not sensitive to wounds with undermined skin edges or deep wounds with small orifices. Therefore, operators had to be mindful of these limitations when scanning participant wounds.

Table 3.

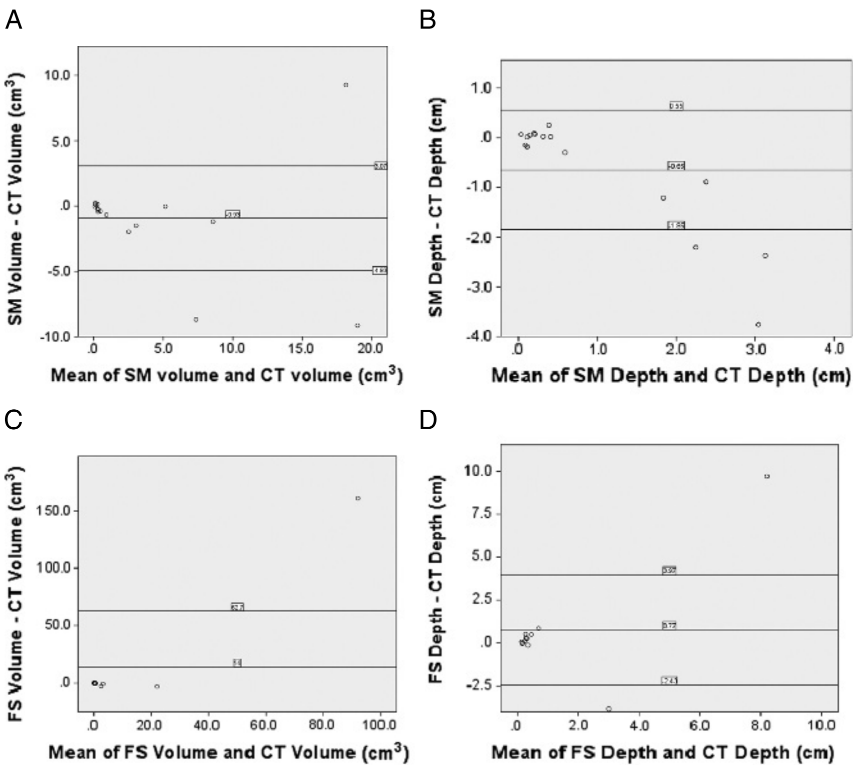
WOUND VOLUME (CM^3), DEPTH (CM), AND SURFACE AREA (CM^2) MEASUREMENTS USING THE SM AND FS COMPARED WITH CT, CALCULATED BY PAIRED-SAMPLES *T* TEST

Comparisons		Mean Difference	SD	*P*	Correlation Coefficients (r)	*P*	Correlation Coefficients Excluding Patient 10	*P*
SM vs CT	Volume	−0.93	4.0	.37	0.81	.0001	0.86	.0001
	Depth	−0.65	1.2	.040	0.88	.0001	0.87	.0001
FS vs CT	Volume	14.0	48.7	.36	0.45	.16	0.99	.0001
	Depth	0.77	3.2	.45	0.54	.09	0.58	.08
SM vs FS	Volume	−16.0	50.9	.32	0.19	.58	0.99	.0001
	Depth	−1.3	3.5	.26	0.65	.03	0.62	.04
	Surface Area	−1.64	2.0	.02	1.00	.0001	1.00	.0001

Abbreviations: CT, computed tomography; FS, FastSCAN; SM, Silhouette Mobile.

Figure 2.

DIFFERENCES IN VOLUME AND DEPTH MEASUREMENTS



A, Bland-Altman plot showing the difference in volume measurements between the Silhouette Mobile and computed tomography. B, Bland-Altman plot showing the difference in depth measurements between the Silhouette Mobile and computed tomography. C, Bland-Altman plot showing the difference in volume measurements between the FastSCAN and computed tomography. D, Bland-Altman plot shows the difference in depth measurements between the FastSCAN and computed tomography.

In considering the SM, potential inaccuracies arose with volume and depth measurements because these depended on the angles assumed by each operator and thus varied according to the location of the wound. Wounds located in highly curved areas, such as a toe amputation stump or at the heel, were difficult to capture because the laser lines from the SM were often disrupted without a flat surface bordering the wound.[29] In addition, interoperator and intraoperator reliability can be reduced when annotating small wound areas.[17]

The SM provides measurements without the requirement for another program or use of an external device such as a computer, whereas the FS images had to be processed with the DELTA software (Polhemus, Colchester, Vermont). This step added a new dimension of operator and software variability. Further, the SM was more convenient because it outlined the wound boundary on the PDA screen rather than a separate personal computer screen.

The accuracy of outlining the wound boundary using the optical stylus in FS was difficult for operators. Accuracy depended on the operator's ability to steady their hands and precisely click stylus points along the wound, which were then visualized on the personal computer screen. Nevertheless, accuracy in FS may be improved by outlining the wound completely with optical stylus points rather than using 10 to 15 landmarks in SM. This might explain the difference in surface area measurements between the SM and FS. The stylus points are crucial to carrying out the necessary calculations. Placing an excessive number of styluses around wounds could be counterproductive and produce erroneous results with the DELTA software failing to accurately represent the wound edges.

Quality of the FS images was affected by many factors, including the presence of blood and necrotic tissue within wounds (which appeared dark red, blue, or black). The FS laser does not register

Figure 3.
SILHOUETTE MOBILE IMAGE OF AN OPEN WOUND ON AN ABOVE-KNEE AMPUTATION STUMP (PATIENT 10)

black objects, resulting in patches and incomplete scans. Blood pooling within the wound also led to underestimation of wound depth and volume. Each FS scan quality also depended on ambient lighting, the patient's skin color, and the laser speed, contributing to the longer times required to complete the scans. The average time to complete a scan and process wound measurements is approximately 10 minutes. In contrast, it takes approximately 3 minutes to record wound surface area and depth for SM.[16] In addition, the presence of metal interference from the electromagnetic transmitter-receiver field disrupted the final FS scans. Efforts were made to adjust for metal objects, mainly by using a wooden trolley to transport the FS unit, but metal is commonplace in a hospital environment, including in beds, trays, heaters, and various medical equipment.

The technology behind FS appears to be more advanced and accurate in assessing wound dimensions than CT or SM. This device created a mirror image of the entire wound bed in detail (0.26 mm) from the wound boundary with the surrounding skin to the deepest crevices of the wound. The accompanying software then assessed the locations of each pixel's coordinate, which were used to extrapolate the dimensions of the cavity deficit. In contrast, the SM calculated volumes from up to 3 slices of depth measurements across a wound, and the cavity was assumed to be of a conical shape. This may explain the consistent underestimation observed in SM when compared with CT. The accuracy of wound depth and volume assessment in three-dimensional CT reconstruction depends on the thickness of the imaging slices. In considering this factor, FS imaging would appear to be more comprehensive in measurement of wound volume, and it is possible FS assessments provided a more correct volume than CT.

All three methods had subjective bias in their measurements. They are essentially three-dimensional imaging devices, where operators had to actively outline the wound boundary over the computerized image. The quality of the measurements was software dependent. All three modalities encountered a common problem that affected their accuracy, in that they all assume that the skin surface of a healed wound would have a flat surface. This was commonly not the case, for example, at the heel, which has a semispherical surface, or the calf, which has a curved surface. However, this should not affect monitoring the healing progress of an individual wound.

Compared with the FS, the SM is less expensive, more time efficient, and more portable, and the PDA can provide immediate report generation without the need for further computer analysis. For clinical use, data from the SM can be connected to the hospital or manufacturer's Internet database, Silhouette Central, therefore improving communication between clinicians. Based on these factors, the SM device is more appropriate for the clinical environment, as demonstrated by its current use in podiatric clinics and hospital wards for wound monitoring and comparison of wound intervention outcomes.

CONCLUSIONS

Despite the limitations of a small sample size and a learning curve for the operators, this study demonstrates that measurements from FS and SM were comparable with CT. However, future studies including more wounds are required to definitively recommend either the FS or SM devices.

The SM and FS devices both offer the benefits of noncontact portable devices that produce reproducible and reliable readings. However, the SM may be more practical for clinicians by offering the additional benefits of better efficiency, portability, and ability to generate an immediate report.●

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