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Clinical validation of a smartphone application for automated wound measurement in patients with venous leg ulcers

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Abstract

Chronic wounds are associated with significant clinical, economic and quality-of-life burden. Despite the variety of wound imaging systems available in the market for wound assessment and surveillance, few are clinically validated among patients of Asian ethnicity. We aimed to clinically validate the accuracy of a smartphone wound application (Tissue Analytics [TA], Net Health Systems Inc, Florida, USA), versus conventional wound measurements (visual approximation and paper rulers), in patients of Asian ethnicity with venous leg ulcers (VLU). A prospective cohort study of patients presenting with VLU to a specialist wound nurse clinic over a 5-week duration was conducted. Each patient received seven wound measurements: one by a trained wound nurse clinician, and three separate wound measurements using TA on each of the iOS and Android operating systems. Inter-rater and intra-rater reliability between clinical and TA-based measurements were analysed using intra-class correlation statistics, with values of <0.5, 0.5 to 0.75, 0.75 to 0.9, and >0.9 indicating poor, moderate, good and excellent reliability, respectively. 82 patients (51% males), with a mean age at 65.8 years, completed the 5-week study duration. 25 (30%) had underlying diabetes mellitus. Chinese, Malay and Indian ethnicity comprised 68%, 12% and 11%, respectively. The VLU healed in 26 (32%) of patients within the study period. In total, 358 wound episodes with 2334 wound images were analysed. Inter-rater reliability for length, width and area between wound nurse measurements and TA application measurements was good (range 0.799-0.919, $P < 0.001$). Separate measurements of intra-rater reliability for length, width and area within the iOS or Android systems were excellent (range 0.967-0.985 and range 0.977-0.984 respectively, $P < 0.001$). Inter-rater reliability between TA used on the iOS and Android systems was also excellent (0.987-0.989, $P < 0.001$). Tissue Analytics, a smartphone wound application, is a useful adjunct for wound assessment and surveillance in VLU patients of Asian ethnicity.

KEYWORDS

chronic venous insufficiency, machine learning, venous ulcers, wound imaging, wound management

Key Messages

- this study aimed to clinically validate measurements of venous leg ulcers (VLU) using the Tissue Analytics (TA) artificial-intelligence assisted imaging system, by comparing them against traditional wound assessment measurements by a trained wound nurse, through the use of intra-class correlation statistics
- there was good inter-rater reliability for VLU length, width and area between wound nurse measurements and measurements derived from TA (range 0.799-0.919, $P < 0.001$)
- there was excellent intra-rater reliability for VLU length, width and area across repeated measurements within each of the iOS or Android systems (range 0.967-0.985 and range 0.977-0.984, respectively, $P < 0.001$)
- inter-rater reliability between the use of TA on iOS versus Android systems was also excellent (0.987-0.989, $P < 0.001$)

1 | INTRODUCTION

Chronic venous insufficiency (CVI) is a serious but often overlooked health care problem, with varicose veins afflicting an estimated 5% to 30% of adults.[1,2] A serious downstream consequence of CVI is the development of venous leg ulcers (VLUs), which occur in an estimated 20% of patients with CVI.[3,4] VLUs create a notable socioeconomic impact, causing reduced quality of life, loss of productive work hours and large financial burden on the health care system.[5-8] This is further exacerbated by their high recurrence rate of 17% in 1 year.[9]

The management of VLUs is multidisciplinary; health care professionals must address the active ulcer as well as the background of CVI. Venous hypertension, the commonest aetiology of VLUs, is typically treated with compression bandaging, but interventions may also extend to surgical options such as endoluminal laser treatment, radiofrequency ablation and sclerotherapy.[10] In addressing the ongoing ulcer, wound care is a crucial pillar of VLU management and is typically overseen by specialised wound care nurses.[11] Continued assessment of healing progress is traditionally done via manual wound measurements; however, technological advancements in recent years have led to the development of numerous digital wound imaging and assessment systems. Some of these systems have been tested and validated in the clinical setting.[12-15] The advantages of such systems lie in their contactless nature, which helps to reduce infection risk; ease of use via smartphones and tablets; reduction in time spent on wound measurement; remote monitoring of wounds via patient-uploaded images; and seamless integration into electronic health records services.[16-18]

Nevertheless, a systematic review in 2020 found that the majority of commercially available wound assessment systems have yet to be reviewed in the literature with regards to measurement accuracy.[19] Even fewer of these systems have been clinically validated in patients of Asian ethnicity. This study aims to bolster existing literature on commercially available wound imaging systems, by clinically validating a 3-dimensional (3-D) enabled, machine learning-based imaging system (Tissue Analytics [TA], Net Health Systems Inc, Florida, USA) against traditional wound measurements in patients with VLUs.

2 | METHODS

This was a prospective cross-sectional study on patients with VLUs from June 2020 to March 2021 in a single-centre, university-affiliated tertiary hospital in Singapore. Inclusion criteria were all patients aged 21 years and above with VLUs. Exclusion criteria were patients who were pregnant, breastfeeding, had leg ulcers of non-venous origin such as primarily arterial ulcer or neuropathic ulcer, or did not have capacity to consent. Mixed arterio-venous ulcers were also included. This study was approved by a local institutional review board (National

Healthcare Group Domain Specific Review Board Ref No: 2020/00148). Written consent was obtained for all patients included in the study with appropriate translations as required for non-English speakers.

2.1 | Study protocol

The study protocol is shown in Figure 1. Patients were identified and recruited from the outpatient wound clinic. Baseline demographics and clinical profile were collected from medical records prior to the study. All participants in this study were subjected to a standardised VLU management pathway with standardised follow-up. The approximate study duration for each patient was five clinic visits or until complete resolution of the ulcer, whichever was earlier. No additional clinic visits were required for the purpose of this study. During each clinic visit, wound measurements were recorded traditionally by a trained specialised wound nurse and electronically by a dedicated research coordinator using the TA imaging system. Wound episode was defined as the wound images taken at each clinic visit. In total, seven wound images would be taken at each wound episode: one with a digital camera by the specialised trained wound nurse, and three on each of the Android and iOS platforms by the research coordinator.

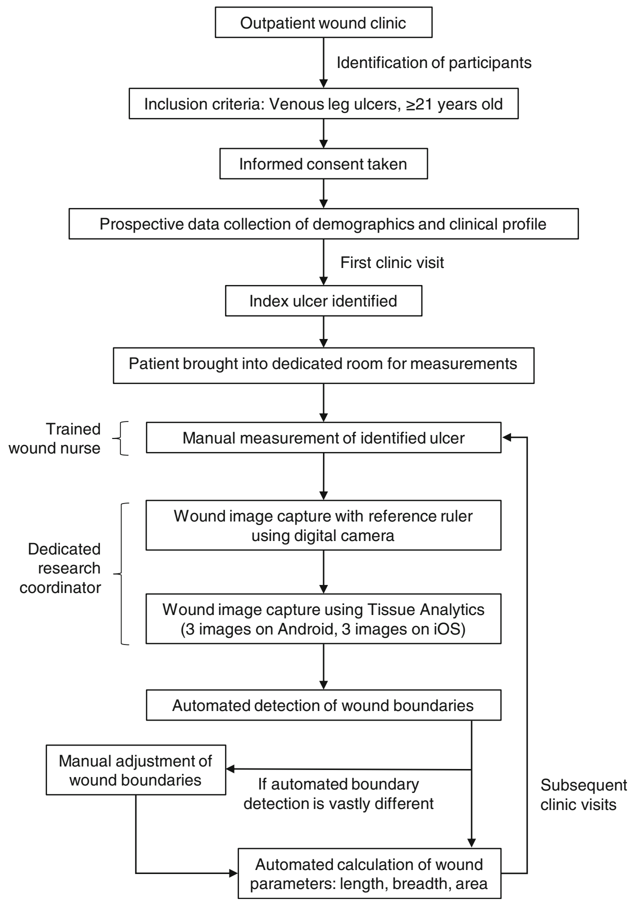

FIGURE 1 Study protocol for participation recruitment and standardisation of wound measurement process

2.2 | Tissue analytics wound imaging system

Tissue Analytics (TA) is a non-contact, digital wound assessment and documentation tool that can be run as a smartphone application on both iOS and Android devices. Image capture is performed by placing a small green dot next to the patient's wound. This dot allows the study team to normalise for environmental conditions such as irregular room lighting, distance from the wound and camera skew angle. Approximately five seconds of video footage of the wound is captured. The application then uses machine learning and computer vision to generate a 3D rendering of the wound. Machine learning is applied using trained algorithms which are used to automatically define the borders between wounds and healthy skin. Altogether, this allows measurements of the ulcer volume and depth with sub-millimetre resolution.

2.3 | Standardisation of ulcer measurement

If a patient had multiple VLUs, an index ulcer was identified for the purpose of this study during the first clinic visit, and this was monitored during subsequent clinic visits. When patients arrived at the clinic, they were directed to a dedicated room with adequate lighting from the ceiling prior to consultation with the doctor. Measurement of the index ulcer was performed in this room. All participants were positioned sitting on a chair with their feet overhanging. Wound measurements were first taken traditionally by a specialised trained wound nurse, then using TA by a dedicated research coordinator.

Each instance of manual wound measurement was performed by either of two trained specialised wound nurses. Both nurses had more than 2 years of experience in wound care and management. Standardisation of measurements was performed prior to the conduct of the study. Tracing paper was first placed over wound, then a sterile marker pen was used to outline the wound. Using this tracing, the length (defined as the longest axis) and width (defined as longest axis perpendicular to the length) of the wound were measured. The tracing paper was placed over the graph paper with 1 cm × 1 cm squares, and wound area was obtained by counting the number of grids within the outlined boundary.

FIGURE 2 Venous leg ulcer on a patient, for measurement using the Tissue Analytics application

Following completion of the manual measurements, the wound nurse left the dedicated treatment room and a dedicated research coordinator would then enter the room to perform the next set of measurements, to reduce inter-investigator bias. Both the wound nurse and research coordinator were blinded from each other's observations so as to reduce bias. The research coordinator first took a photograph of the wound using a digital camera (Canon PowerShot G7X), with a reference ruler laid over the wound. Then, the research coordinator took three images of the wound using TA running on an iOS device (iPhone 11, iOS 13) and three images using TA running on an Android device (XiaoMi Mi Max 2, Android 7.0), for a total of seven images per wound. An optical zoom of 1.0x was used to capture images at approximately 40 cm from the wound, and a green dot was included in the field of view as a reference for the software (Figure 2). Each repeat image of the same wound involved repositioning of the research coordinator and the patient. The wound length, width and area were automatically calculated based on the image boundaries determined by the imaging system. Automated boundary detection was difficult or vastly different from the actual wound boundaries in a small select group of wound images in view of (a) poor colour contrast with patients' skin tone (with darker complexion posing a greater challenge to the software artificial intelligence), (b) wounds being too small (<1 cm), or (c) being located in areas where with large variation in skin contours (such as bony prominences on the malleolus). Manual adjustments were made to the wound boundary selection window in these circumstances.

2.4 | Sample size calculation

Sample size was calculated as per number of wound images (defined as wound episode) rather than the number of subjects as due to the cross-sectional nature of this study. Based on TA's internal validation, the baseline mean accuracy is 90%. Hence, assuming baseline correction (R_0) at 0 and alternative correlation (R_1) at 0.2, the sample size required for one correlation test with power 90% and alpha 0.05 is 258 wound images. For intra-rater reliability between TA on iOS and Android platforms, assuming baseline correlation (R_0) at 0 with alterative correction (R_1) at 0.2, sample size required for intraclass correlation with Power 90% and alpha 0.05 is 83. As such, the overall sample size required was 341 wound images.

2.5 | Statistical analysis

All statistical analyses were performed with SPSS version 25.0 (SPSS Inc., Chicago, III., USA). Statistical significance was determined by $P < 0.05$. Intra-class correlation statistics (ICC) was used to analyse intra-rater and inter-rater reliability.[20] Inter-rater reliability for length, width and area of VLU between the wound nurse measurements and measurements from TA running on either iOS or Android was analysed using two-way mixed effects model, absolute agreement and single measure. Intra-rater reliability for length, width and area between images taken by TA on the same device (for both iOS and Android systems) was also analysed using two-way mixed effects model, absolute agreement and single measure. Inter-rater reliability between the iOS and Android systems was analysed using two-way random effects model, absolute agreement and single measure. The two-way random effects model was used for inter-rater reliability between TA running on different devices, for generalising our results for all existing TA devices in the market.[21]

There is no standard definition or cut-offs for ICC to determine the extent of reliability. Hence, the following definitions were used in this study: ICC <0.5 indicates poor reliability, 0.5 to 0.75 indicates moderate reliability, 0.75 to 0.9 indicates good reliability and > 0.9 indicates excellent reliability.[22]

3 | RESULTS

3.1 | Patient demographics

A total of 82 patients were analysed. The mean age was 65.8 years, 42 (51%) were male, and the mean body mass index (BMI) was 29.1. The VLU healed in 26 (32%) of

TABLE 1 Demographics of patients included in the study

	Number of patients (n = 82)
Age	
Mean (SD)	65.8 (11.7)
Median (IQR)	66.5 (60.3-74.0)
Male gender, *n* (%)	42 (51%)
Ethnicity, *n* (%)	
Chinese	56 (68%)
Malay	10 (12%)
Indian	9 (11%)
Others	7 (9%)
Comorbidities, *n* (%)	
Diabetes mellitus	25 (30%)
Hypertension	49 (60%)
Heart disease	17 (21%)
Chronic kidney disease	7 (8.5%)
Cerebrovascular accident	6 (7.3%)
Peripheral vascular disease	77 (94%)
Varicose veins	39 (48%)
Previous venous surgery	28 (34%)
Previous skin/leg ulcers	75 (91%)
Location of ulcer, *n* (%)	
Anterior	10 (12%)
Medial	40 (49%)
Lateral	26 (32%)
Gaiter	3 (3.7%)
Ankle area	56 (68%)
Others	23 (28%)
Wound parameters, median (IQR)	
Length, cm	2.65 (1.53-4.65)
Width, cm	1.80 (1.00-3.45)
Area, cm^2	3.55 (1.40-9.23)

Abbreviations: IQR, interquartile range; SD, standard deviation.

patients within the study period. Table 1 summarises the relevant patient demographics.

3.2 | Wound episodes

A total of 358 wound episodes and 2334 wound images were analysed. Although each patient was theoretically expected to have seven images from each of five clinic visits for a total of 2870 images, the missing data of 536 images was due to: (1) patients withdrew from the study (140 images), (2) defaulted appointments (140 images), (3) complete resolution of ulcer before the end of the study period (256 images).

There was good inter-rater reliability between the measurements made by the wound nurse and with the TA running on both iOS and Android devices for ulcer length, width and area (range 0.799-0.919, $P < 0.001$ for iOS; range 0.803-0.914, $P < 0.001$ for Android) (Tables 2, 3).

There was excellent intra-rater reliability for length, width and area between three different images of the same wound taken by the same iOS or Android device running TA (range 0.967-0.985 for iOS and range 0.977-0.984 for Android, $P < 0.001$) (Table 4). Inter-rater reliability between TA running on the iOS versus Android was also excellent (range 0.987-0.989, $P < 0.001$) (Table 5). When analysis was stratified by ethnicity, inter-rater reliability between TA and wound nurse measurements in Malay and Indian patients (who had darker skin complexion) was numerically lower compared to Chinese patients (who had lighter skin complexion) (Table 6).

4 | DISCUSSION

Numerous wound imaging technologies are commercially available and they are becoming increasingly

TABLE 2 Inter-rater reliability between wound nurse and Tissue Analytics (iOS device) for the corresponding image

	Measurements, mean ± SD			Inter-rater reliability (95%CI)			*p* value		
	Length	Width	Area	Length	Width	Area	Length	Width	Area
TA on iOS	3.10 ± 2.21	2.27 ± 1.61	6.18 ± 7.99	0.919 (0.840-0.953)	0.846 (0.789-0.885)	0.799 (0.678-0.866)	<0.001	<0.001	<0.001
Wound nurse	3.55 ± 2.55	2.62 ± 2.27	9.13 ± 12.89						

Note: Length and width are expressed in cm; area is expressed in cm^2.
Abbreviations: 95%CI, 95% confidence interval; SD, standard deviation; TA, Tissue Analytics.

TABLE 3 Inter-rater reliability between wound nurse and Tissue Analytics (Android device) for the corresponding image

	Measurements, mean ± SD			Inter-rater reliability (95%CI)			*p* value		
	Length	Width	Area	Length	Width	Area	Length	Width	Area
TA on Android	3.11 ± 2.20	2.31 ± 1.65	6.38 ± 8.30	0.914 (0.843-0.947)	0.855 (0.808-0.890)	0.803 (0.701-0.864)	<0.001	<0.001	<0.001
Wound nurse	3.55 ± 2.55	2.62 ± 2.27	9.13 ± 12.89						

Note: Length and width are expressed in cm; area is expressed in cm^2.
Abbreviations: 95%CI, 95% confidence interval; SD, standard deviation; TA, Tissue Analytics.

TABLE 4 Intra-rater reliability within the same Tissue Analytics device (iOS or Android) on three different images obtained from the same wound

	Measurements, mean ± SD									Intra-rater reliability (95%CI)			p value		
	Image 1			Image 2			Image 3								
	Length	Width	Area	Length	Width	Area	Length	Width	Area	Length	Width	Area	Length	Width	Area
iOS	3.06 ± 2.15	2.26 ± 1.61	6.07 ± 7.88	3.07 ± 2.19	2.22 ± 1.58	6.05 ± 7.93	3.07 ± 2.22	2.27 ± 1.58	6.10 ± 8.05	0.985 (0.982-0.987)	0.967 (0.960-0.872)	0.974 (0.969-0.978)	<0.001	<0.001	<0.001
Android	3.09 ± 2.19	2.29 ± 1.67	6.29 ± 8.31	3.10 ± 2.23	2.30 ± 1.67	6.39 ± 8.51	3.08 ± 2.20	2.30 ± 1.62	6.29 ± 8.22	0.984 (0.981-0.987)	0.977 (0.973-0.981)	0.981 (0.977-0.984)	<0.001	<0.001	<0.001

Note: Length and width are expressed in cm; area is expressed in cm^2.
Abbreviations: 95%CI, 95% confidence interval; SD, standard deviation.

TABLE 5 Inter-rater reliability between Tissue Analytics on iOS versus Android devices on the average measurements of all three images taken using each device

	Measurements, mean ± SD						Inter-rater reliability (95%CI)			*p* value		
	iOS			Android								
	Length	Width	Area	Length	Width	Area	Length	Width	Area	Length	Width	Area
Image	3.10 ± 2.21	2.27 ± 1.61	6.18 ± 7.99	3.11 ± 2.20	2.31 ± 1.65	6.38 ± 8.30	0.989 (0.987-0.991)	0.988 (0.984-0.990)	0.987 (0.984-0.990)	<0.001	<0.001	<0.001

Note: Length and width are expressed in cm; area is expressed in cm^2.

Abbreviations: 95%CI, 95% confidence interval; SD, standard deviation.

relevant in clinical care.[23] Digital wound imaging systems have been shown to provide rapid, accurate and consistent measures of wound parameters.[19,24] Images stored on the electronic device can also be transferred to electronic medical records, enabling seamless monitoring of wound healing.[23]

The present study demonstrates favourable intra-rater reliability between images taken by the same device, inter-rater reliability between the two devices, and inter-rater reliability between TA and measurements by a wound nurse. This provides proof of the real-world efficacy of this imaging system, and its translatability to clinical practice. Moreover, with good inter-rater reliability between iOS and Android showing that the type of device does not affect reliability of the application, TA can be easily used by various institutions without need for special customisation. TA is also an application which can capitalise on developments in hardware technology. For instance, the use of Light Detection and Ranging (LiDAR) scanners in newer iPhone models, which allows for accurate depth perception, may circumvent current limitations in depth perception in the near future.[25]

The rapid capture of wound parameters (less than 5 s per wound) using a no-touch technique is a favourable alternative to conventional measurements by border tracing, which are time-consuming and may unwittingly introduce infection. These advantages may have wider implications in the care of patients with VLUs. Studies have observed a treatment period ranging from 80 to 117 days for VLUs, which necessitates multiple clinic visits.[26] Continued documentation of wound status, particularly the reduction in wound area, is helpful in determining the progress of healing and evaluating whether changes in management are needed.[27] Hence, reducing the time taken for each wound measurement is likely to translate into significant time savings, and a corresponding reduction in the economic cost of longer waiting times.[28] Nonetheless, despite the time savings documented in other studies, this study did not capture such data for comparison.[18,29]

Moreover, the digital nature of this system may aid in remote assessment of wounds. The COVID-19 pandemic was found to limit the ability to practice wound care under normal conditions, with higher rates of missed appointments and loss of contact with patients.[30] This could potentially worsens healing outcomes and may lead to patients presenting at a later date with larger, more serious, or infected ulcers.[31] Under such situations where physical attendance at the wound clinic is not desired by the patient or delayed by administrative policies, a digital application that can be downloaded by patients themselves may be helpful: patients can submit images of their wounds and the accompanying

TABLE 6 Inter-rater reliability between wound nurse and Tissue Analytics (iPhone), and between wound nurse and Tissue Analytics (Android) for the corresponding image in various races

Race	Mode of measurement	Measurements, mean ± SD			Inter-rater reliability			*p* value		
		Length	Width	Area	Length	Width	Area	Length	Width	Area
Chinese (n = 226)	iPhone	2.92 ± 2.22	2.09 ± 1.46	5.41 ± 7.64	0.931 (0.849-0.962)[a]	0.892 (0.855-0.919)[a]	0.871 (0.783-0.918)[a]	<0.001[a]	<0.001[a]	<0.001[a]
	Android	2.93 ± 2.25	2.12 ± 1.50	5.62 ± 8.17	0.929 (0.855-0.959)[b]	0.895 (0.862-0.920)[b]	0.883 (0.815-0.922)[b]	<0.001[b]	<0.001[b]	<0.001[b]
	Wound nurse	3.36 ± 2.50	2.28 ± 1.70	7.39 ± 10.46	-	-	-	-	-	-
Malay (n = 43)	iPhone	3.40 ± 2.12	2.66 ± 2.04	7.93 ± 8.70	0.887 (0.776-0.941)[a]	0.793 (0.587-0.893)[a]	0.774 (0.521-0.888)[a]	<0.001[a]	<0.001[a]	<0.001[a]
	Android	3.40 ± 2.05	2.75 ± 2.10	8.19 ± 8.95	0.874 (0.758-0.933)[b]	0.816 (0.641-0.904)[b]	0.801 (.566-0.902)[b]	<0.001[b]	<0.001[b]	<0.001[b]
	Wound nurse	3.86 ± 2.64	3.54 ± 3.59	12.26 ± 15.12	-	-	-	-	-	-
Indian (n = 39)	iPhone	3.68 ± 1.69	2.89 ± 1.40	8.06 ± 5.97	0.906 (0.713-0.961)[a]	0.838 (0.625-0.924)[a]	0.738 (0.236-0.893)[a]	<0.001[a]	<0.001[a]	<0.001[a]
	Android	3.75 ± 1.70	2.94 ± 1.39	8.43 ± 6.26	0.918 (0.781-0.963)[b]	0.852 (0.675-0.928)[b]	0.775 (0.321-0.909)[b]	<0.001[b]	<0.001[b]	<0.001[b]
	Wound nurse	4.12 ± 1.82	3.35 ± 1.73	11.98 ± 8.99	-	-	-	-	-	-
Others (n = 27)	iPhone	3.25 ± 2.76	2.31 ± 2.02	7.09 ± 11.10	0.897 (0.765-0.954)[a]	0.802 (0.602-0.906)[a]	0.688 (0.375-0.852)[a]	<0.001[a]	<0.001[a]	<0.001[a]
	Android	3.25 ± 2.53	2.34 ± 2.01	6.88 ± 10.22	0.873 (0.723-0.942)[b]	0.796 (0.597-0.902)[b]	0.647 (0.326-0.828)[b]	<0.001[b]	<0.001[b]	<0.001[b]
	Wound nurse	3.86 ± 3.41	2.98 ± 3.51	14.58 ± 24.82	-	-	-	-	-	-

Note: Length and breadth are expressed in cm. Area was expressed in cm^2.
Abbreviation: SD, standard deviation.
[a]Between wound nurse and Tissue Analytics (iPhone).
[b]Between wound nurse and Tissue Analytics (Android).

parameters onto the digital app, health care professionals can then evaluate the progress of healing remotely. For instance, a study by Barakat-Johnson et al in Australian patients during the COVID-19 pandemic, also using the TA wound imaging application, noted improvements in the areas of objective wound assessment, shared wound plans and patient adherence.[32] The completeness of wound documentation was improved relative to standard care ($P < 0.001$), and enhanced efficiency in providing virtual care was observed via qualitative surveys of patients and clinicians. Additionally, travel time savings of 35.9 min by car and 14 min by public transport, along with their corresponding cost savings, were observed in metropolitan patients. Although our present study did not perform such calculations, similar socioeconomic benefits are theorised to be applicable to the local context and may warrant investigation in future studies. The efficacy of remote monitoring using this system may complement the increase in teleconsultations during the COVID-19 pandemic for better wound care. The availability of images may also facilitate continuity of care between community-based wound care nurses and home care professionals.[33]

This study adds to the developing scene of the wound imaging industry and also showcases the competitive nature of the field. Previous studies have employed various contactless wound imaging systems, most of which were operated using a smartphone or tablet; these showed good agreement between manual and software-based measurements.[12-15,34] Nonetheless, prospective comparisons of the relative accuracies of these systems have yet to be performed.

The main strength of this study is its large sample size of 2334 wound images, which provides adequate data for analysis of reliability of the software. Multiple parameters of wound assessment (length, width and area) were also measured to provide a similarity to traditional clinical measurements and allow easy comparison of accuracy. The standardisation of wound measurements by specialised wound nurses, as well as the capturing of digital images by only one research coordinator, helped to reduce the risk of bias in this study. In addition, this is the first study of TA in patients of Asian ethnicity. As imaging systems tend to be validated in predominantly Western populations, and artificial intelligence software trained using datasets from these populations, it is imperative to verify the efficacy of the system in Asian patients who may have different skin colours and tones. The results of this study help to support the use of this system in a more global context.

Nonetheless, several limitations of this study should be mentioned. The study was limited to purely numerical measurements of the VLU (length, width and area); other functions such as wound depth and wound characterisation were not studied. Due to the inclusion of all races in this study, the inter-rater and intra-rater reliability was numerically lower in patients with darker skin tone. Qualitative characteristics such as the presence of slough, exudates, eschars and oedema were only assessable by the wound nurse. Hence, although TA offers rapid imaging and parameter calculation, its capabilities must also be paired with clinical assessment of wound status.

5 | CONCLUSION

This study of the TA mobile application in measuring the dimensions of VLUs demonstrated good to excellent intra-rater and inter-rater reliability when compared with traditional wound assessment and between the iOS and Android platforms. Hence, it is a suitable tool for monitoring of VLU healing progress when combined with clinical assessment. Future prospective studies should aim to measure other functions of the imaging software, such as depth measurements and wound characterisation, as well as the wider socioeconomic impact of its use.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

DATA AVAILABILITY STATEMENT

The research data is not publicly available. Special requests may be made to the corresponding author for request of data.

ETHICS STATEMENT

Ethics approval was obtained for this study (NHG DSRB 2020/00148-SRF0001).

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REFERENCES

1. Evans CJ, Fowkes FG, Ruckley CV, Lee AJ. Prevalence of varicose veins and chronic venous insufficiency in men and

women in the general population: Edinburgh vein study. *J Epidemiol Community Health*. 1999;53(3):149-153.
2. Eberhardt RT, Raffetto JD. Chronic venous insufficiency. *Circulation*. 2014;130(4):333-346.
3. Fowkes FG, Evans CJ, Lee AJ. Prevalence and risk factors of chronic venous insufficiency. *Angiology*. 2001;52(Suppl 1): S5-S15.
4. Rhodes JM, Gloviczki P, Canton LG, Rooke T, Lewis BD, Lindsey JR. Factors affecting clinical outcome following endoscopic perforator vein ablation. *Am J Surg*. 1998;176(2): 162-167.
5. Ruckley CV. Socioeconomic impact of chronic venous insufficiency and leg ulcers. *Angiology*. 1997;48(1):67-69.
6. Purwins S, Herberger K, Debus ES, et al. Cost-of-illness of chronic leg ulcers in Germany. *Int Wound J*. 2010;7(2):97-102.
7. Da Silva A, Navarro MF, Batalheiro J. The importance of chronic venous insufficiency. Various preliminary data on its medico-social consequences. *Phlebologie*. 1992;45(4):439-443.
8. Kaplan RM, Criqui MH, Denenberg JO, Bergan J, Fronek A. Quality of life in patients with chronic venous disease: San Diego population study. *J Vasc Surg*. 2003;37(5):1047-1053.
9. Gohel MS, Taylor M, Earnshaw JJ, Heather BP, Poskitt KR, Whyman MR. Risk factors for delayed healing and recurrence of chronic venous leg ulcers—an analysis of 1324 legs. *Eur J Vasc Endovasc Surg*. 2005;29(1):74-77.
10. van Gent WB, Wilschut ED, Wittens C. Management of venous ulcer disease. *BMJ*. 2010;341:c6045.
11. Simon DA, Dix FP, McCollum CN. Management of venous leg ulcers. *BMJ*. 2004;328(7452):1358-1362.
12. Chan KS, Liang S, Cho YT, et al. Clinical validation of a machine-learning-based handheld 3-dimens4.
13. Bowling FL, King L, Paterson JA, et al. Remote assessment of diabetic foot ulcers using a novel wound imaging system. *Wound Repair Regen*. 2011;19(1):25-30.
14. Chan KS, Chan YM, Tan AHM, et al. Clinical validation of an artificial intelligence-enabled wound imaging mobile application in diabetic foot ulcers. *Int Wound J*. 2022;19(1):114-124.
15. Malone M, Schwarzer S, Walsh A, et al. Monitoring wound progression to healing in diabetic foot ulcers using three-dimensional wound imaging. *J Diabetes Complicat*. 2020;34(2): 107471.
16. Quan SY, Lazarus GS, Kohli AR, Kapoor R, Margolis DJ. Digital imaging of wounds: are measurements reproducible among observers? *Int J Low Extrem Wounds*. 2007;6(4):245-248.
17. Samad A, Hayes S, French L, Dodds S. Digital imaging versus conventional contact tracing for the objective measurement of venous leg ulcers. *J Wound Care*. 2002;11(4):137-140.
18. Au Y, Beland B, Anderson JAE, Sasseville D, Wang SC. Time-saving comparison of wound measurement between the ruler method and the swift skin and wound app. *J Cutan Med Surg*. 2019;23(2):226-228.
19. Chan KS, Lo ZJ. Wound assessment, imaging and monitoring systems in diabetic foot ulcers: a systematic review. *Int Wound J*. 2020;17(6):1909-1923.
20. Liu J, Tang W, Chen G, Lu Y, Feng C, Tu XM. Correlation and agreement: overview and clarification of competing concepts and measures. *Shanghai Arch Psychiatry*. 2016;28(2):115-120.
21. Koo TK, Li MY. A guideline of selecting and reporting Intraclass correlation coefficients for reliability research. *J Chiropr Med*. 2016;15(2):155-163.
22. Portney LG, Watkins MP. *Foundations of Clinical Research: Applications to Practice*. Vol 892. NJ: Pearson/Prentice Hall Upper Saddle River; 2009.
23. Queen D, Perez C. What digital wound care could mean for those suffering from wounds. *Int Wound J*. 2018;15(4):501-502.
24. Wang SC, Anderson JAE, Evans R, et al. Point-of-care wound visioning technology: reproducibility and accuracy of a wound measurement app. *PLoS One*. 2017;12(8):e0183139.
25. Aleotti F, Zaccaroni G, Bartolomei L, Poggi M, Tosi F, Mattoccia S. Real-time single image depth perception in the wild with handheld devices. *Sensors*. 2021;21(1):15.
26. Simka M, Majewski E. The social and economic burden of venous leg ulcers. *Am J Clin Dermatol*. 2003;4(8):573-581.
27. Flanagan M. Wound measurement: can it help us to monitor progression to healing? *J Wound Care*. 2003;12(5):189-194.
28. Bailey NTJ. A study of queues and appointment Systems in Hospital out-Patient Departments, with special reference to waiting-times. *J R Stat Soc B Methodol*. 1952;14(2):185-199.
29. Nair HKR. Increasing productivity with smartphone digital imagery wound measurements and analysis. *J Wound Care*. 2018;27(Sup9a):S12-S19.
30. Tinelli G, Sica S, Guarnera G, Pitocco D, Tshomba Y. Wound care during COVID-19 pandemic. *Ann Vasc Surg*. 2020;68: 93-94.
31. Sallustro M, Florio A. The impact of COVID-19 pandemic on vascular leg ulcers. *Int J Low Extrem Wounds*. 2021;28: 15347346211010958.
32. Barakat-Johnson M, Jones A, Burger M, et al. Reshaping wound care: evaluation of an artificial intelligence app to improve wound assessment and management amid the COVID-19 pandemic. *Int Wound J*. 2022;25.
33. Buckley KM, Adelson LK, Agazio JG. Reducing the risks of wound consultation: adding digital images to verbal reports. *J Wound Ostomy Continence Nurs Off Publ Wound Ostomy Continence Nurs Soc*. 2009;36(2):163-170.
34. Liu C, Fan X, Guo Z, Mo Z, Chang EIC, Xu Y. Wound area measurement with 3D transformation and smartphone images. *BMC Bioinf*. 2019;20(1):724.

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