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Validity And Reliability of a Smartphone Application in Measuring Surface Area of Lower Limb Chronic Wounds

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ABSTRACT

Background: As the population ages, chronic wounds also raised, creating a load on the health system. Accurate documentation and continuous measurement of wounds have become critical.

Aim of the study: It was to determine the validity and reliability (VAR) of a smartphone application in measuring the surface area of lower limb chronic wounds.

Patients and Methods: A study of 61 patients (46 males and 15 females) with lower limb chronic wounds, aged from 40 to 70 years were selected from Cairo University Hospitals from March 2022 to August 2022. Patients were assessed by the manual planimetry method and a smartphone application (Imito AG, Switzerland). Wound evaluation using the Imito-measure application was performed twice by the principal investigator and by a co-investigator to test Inter-rater reliability (Inter-RR), intra-rater reliability (Intra-RR), and validity. Concurrent validity was investigated by determining the correlation between a smartphone application and the metric graph sheet by Pearson Product Moment Correlation Coefficient. Intra-RR and inter-RR were expressed in Intra-class Correlation Coefficients (ICCs).

Results: The validity, intra-RR, and inter-RR of the Imito-measure application were excellent with a strong positive significant correlation ($r = 0.998$, $p = 0.001$), ICC was 0.999, with 95% CI 0.998-0.999 and standard of measurement (SEM) of 1.83; ICC for measurement wound surface area was 0.999, with 95% CI 0.998-0.999 and SEM of 1.85, respectively.

Conclusion: The Imito-measure application showed excellent VAR for wound measurement, and it could be a selection to be used as an assessment tool in clinical practice.

Keywords: chronic wounds, wound assessment, Smartphone application, Validity, Reliability.

INTRODUCTION

A chronic wound is an unhealed wound that undergoes an organized and proper reparative process to maintain long-term anatomical and functional integrity. It can last from four weeks up to three months [(1)]. Worldwide, chronic lower limb ulcers found to affect nearly 3% over the age of 60 years and more than 5% of people aged above 80 years [(2)].

Chronic lower limb wounds are classified into vascular ulcers (venous and arterial ulcers), pressure ulcers, and diabetic foot ulcers [(3)]. Lower limb chronic ulcers are difficult-to-heal wounds on the foot or lower leg usually caused by diabetes mellitus, venous insufficiency, and arterial insufficiency [(4)].

There are many reasons why a wound should be evaluated so that measurements will indicate whether the wound is healing, getting worse, or remaining static [(5)].

Although measurement methods overestimate or underestimate the surface area of a wound or its volume, even so, they are useful in assessing wound healing. Wound area measurements need to be reliable, but not certainly accurate in assessing wound healing [(6)].

Tracing wound boundaries is one of the most popular methods for measuring the surface area of a wound. Sterile acetate paper or a transparent film is placed above wounds. The margins of the wound are then marked on sterile acetate paper or a transparent film. Then paper or film is placed on a milli-metric grid paper and then milli-meter squares inside the marked region are calculated [(7)]. Using a smartphone mobile application shows good feasibility when utilized as a point-of-care tool. Reliability and interrater agreement will be ensured when compared with a previously validated method [(8)].

In clinical trials, the utilization of the Imito-measure application has the advantage of overcoming the difficulties associated with the manual tracing method such as the material availability, problems with storing data, and the time required to calculate the wound surface area, and it is easily accessible since medical practitioners frequently use smartphones [(9)].

AIM OF THE STUDY

The aim of this study is to determine the validity and reliability (VAR) of a smartphone application in measuring the surface area of lower limb chronic wounds.

PATIENTS AND METHODS

Patients:

Sixty-one patients were diagnosed with chronic leg ulcers by a physician, they suffered from partial-thickness and full-thickness pressure ulcers, diabetic ulcers, and venous ulcers based on clinical investigations, they were selected from Cairo University Hospitals. Their age ranged from 40 to 70 years. They were evaluated by

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both methods of assessment the manual planimetry method and a smartphone application (Imito AG, Switzerland) specifically Imito-measure app. wound measurement by the Imito-measure application was performed twice by the principal investigator and by a coinvestigator to test Inter-RR, Intra-RR and validity. Concurrent validity was investigated by determining the correlation between the smartphone application and the metric graph sheet by Pearson Product Moment Correlation Coefficient. Intra-RR and Inter-RR were expressed in Intra-class Correlation Coefficients (ICCs).

Ethical consideration:

Ethical Committee approval (No: P.T.REC/012/003630) of the Faculty of Physical Therapy, Cairo University was obtained, as well as a written consent form was obtained before starting the study.

Inclusion and exclusion criteria:

The inclusion criteria were: lower limb chronic ulcers; Patients of both sexes and subjects' ages ranged between 40 and 70 years. The current study excluded patients with the following conditions; patients with acute lower limb wounds, patients which were Psychologically unstable, patients with ulcers in other body parts other than the lower limb, and patients with burn wound injuries.

Materials:

Smartphone application (Imito AG, Switzerland) specifically Imito-measure was chosen as the smartphone app. to measure the surface area of lower limb chronic wounds; Metric graph paper; fine -tipped marker to be used over the metric graph sheet; Touch screen pen for android phones to be used with the smartphone application; an adhesive calibration marker; plinth for the patient; pillows to support the patients; chair for the therapist; disposable clean plastic gloves; alcohol and some cotton to clean the area before the treatment and the treatment performed in quiet and air conditional room.

Procedures:

Firstly, each patient was assessed using the metric graph sheet to trace the margins measuring the surface area of the wound.

- The transparent grid paper was cleaned with alcohol before use and used for one time only (disposable).
- Then the grid paper was placed above the wound and the boundaries of the wound were traced using a fine pen marker in cm^2.
- Area of the wound was manually calculated by the principal investigator by counting the fully filled squares within the wound borders and grouping the partially full squares. this method was used as a reference method.
- Then, patients were placed in a suitable position to be assessed using the Imito-measure application, and an adhesive calibration marker (2cm) diameter was placed close to the wound to calibrate the image.
- The user must print the calibration marker which is freely available with the application.
- Then the camera of the smartphone was positioned approximately 20 to 30 cm away from and parallel to the wound and the marker, then a photo was taken.
- The photo was taken, using the application, then the wound margins were outlined manually on the screen using a touch screen pen for android phones to be more precise than using the investigator's fingertips.
- Then wound's length, width, and surface area measurements were automatically calculated and a report was sent via e-mail when requested.
- Following the completion of the procedure, the principal investigator left the patient's room, and a coinvestigator repeated the previous procedure to assess the wound's surface area. Both the principal investigator and coinvestigator were blinded from each other's observations to reduce bias and assure inter-rater reliability.
- The principal investigator then performed another evaluation with the application same as previously mentioned to examine intra-rater reliability.

Statistical analysis

Concurrent validity was investigated by determining the correlation between the smartphone application and the metric graph sheet by the Pearson Product Moment Correlation Coefficient. Intra-RR and inter-RR were expressed in Intra-class Correlation Coefficients (ICCs). Measurement error was expressed in the standard of measurement (SEM). SEM = pooled SD $\sqrt{}$(1-ICC). The level of significance for statistical tests was set at $p < 0.05$. All statistical measures were performed through the statistical package for social studies (SPSS) version 25 for windows. (IBM SPSS, Chicago, IL, USA).

RESULTS

Subject characteristics:

A total of sixty-one patients were analyzed and diagnosed with lower limb chronic wounds. Most patients were men with a reported percentage of 75%, and the study included 15 females with a reported percentage of 25%, their mean ± SD age was 56.29 ± 6.62 years, and the wound etiologies were mostly diabetic ulcers with (54%), venous ulcers (33%), pressure ulcers (13%).

Descriptive statistics of wound surface area:

The mean ± SD wound surface area of the measured wounds was 15.02 ± 14.11 cm² with a maximum value of 50 cm² and minimum value of 0.85 cm². The correlation between wound surface area that was measured by the smartphone application (Imito-measure) and that measured by the manual planimetry method (metric graph sheet) in the study group was a strong positive significant correlation (r = 0.998, p = 0.001) as shown in (Table **1**) and demonstrated in (figure **1**). There was also excellent Intra-RR when measured by the same investigator twice (Trial 1 and Trial 2) in measuring lower limb wounds surface area with; ICC 0.999, with 95% CI 0.998-0.999, and SEM of 1.83. (Table **2**, figure **2**). Smartphone application (Imito-measure) yielded an excellent inter-RR in the measurement of lower limb chronic wound surface area when measured by the principal investigator (rater 1) and a Co-investigator (rater 2); ICC for measurement wound surface area was 0.999, with 95% CI 0.998-0.999 and SEM of 1.85. (Table **3**, figure **3**).

Table (1): Correlation between wound surface area that was measured by a smartphone application and that measured by metric graph sheet:

Wound surface area (cm²)		r value	p-value	Sig
Smartphone application	**Metric graph sheet**	0.998	0.001	**S**

r value: Pearson correlation coefficient,
p-value: Probability value, S: Significant

Table (2): Intra-rater reliability of smartphone application in the measurement of wound surface area:

	r value	ICC	(95% CI)		SEM
			Lower bound	Upper bound	
Wound surface area (cm²)	**0.998**	0.999	0.998	0.999	1.83

r value: Pearson correlation coefficient
ICC: Inter class correlation coefficient value
CI: Confidence Interval; SEM: standard error of measurement.

Table (3): Inter-rater reliability of a smartphone application in the measurement of wound surface area:

	r value	ICC	(95% CI)		SEM
			Lower bound	Upper bound	
Wound surface area (cm²)	**0.998**	0.999	0.998	0.999	1.85

r value: Pearson correlation coefficient, ICC, Inter class correlation, coefficient value; CI: Confidence Interval , SEM, standard error of measurement

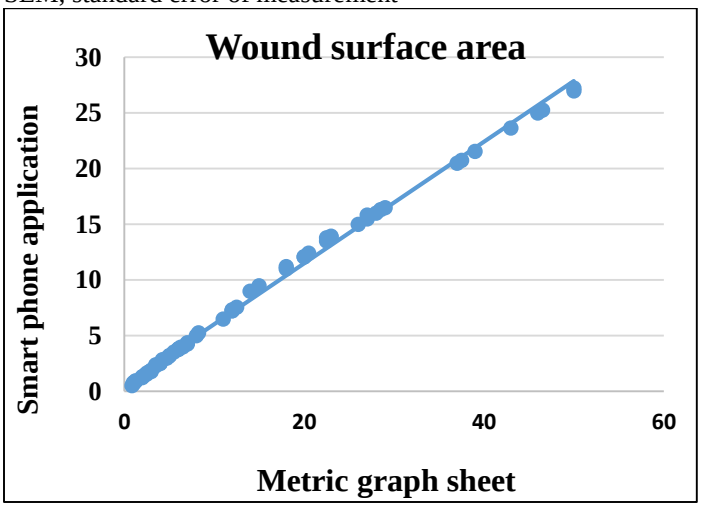

Figure (1): Correlation between wound surface area measured by a smartphone application and that measured by metric graph sheet.

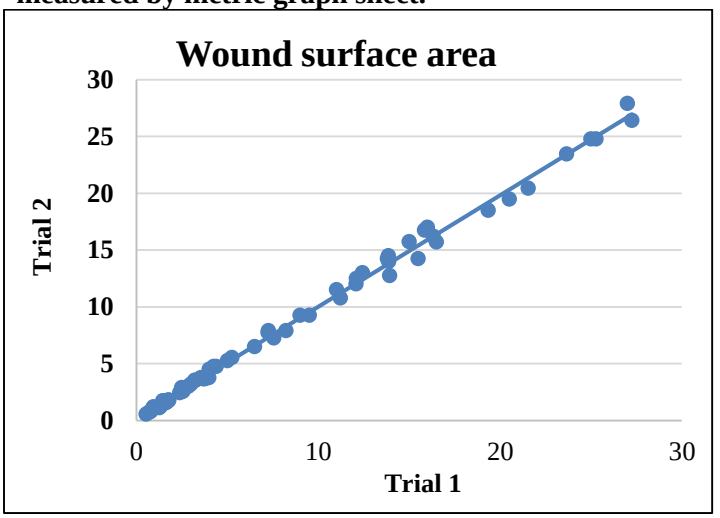

Figure (2): Correlation between trial 1 and trial 2 wound surface area that was measured by a smartphone application.

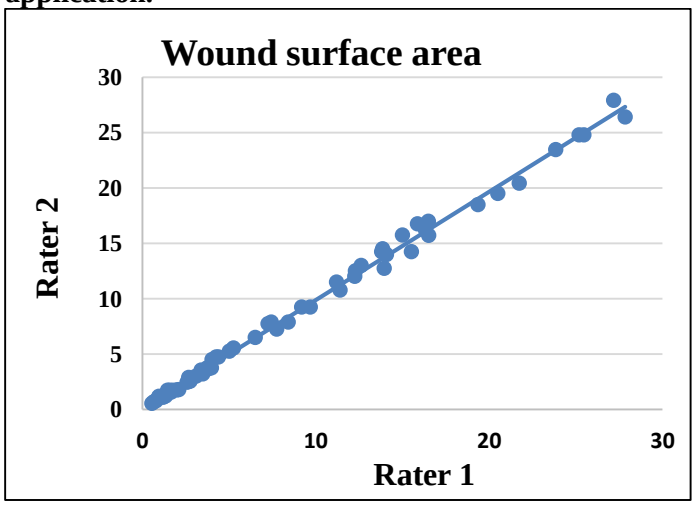

Figure (3): Correlation between rater 1 and rater 2 wound surface area that measured by a smartphone application.

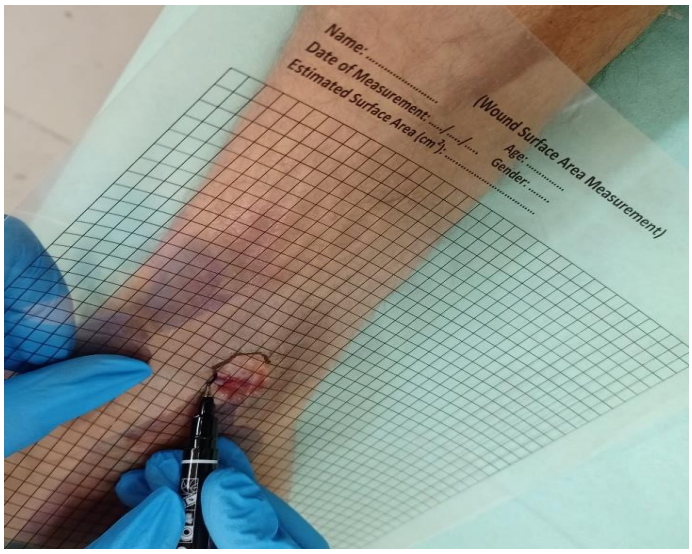

Fig.4 (a)

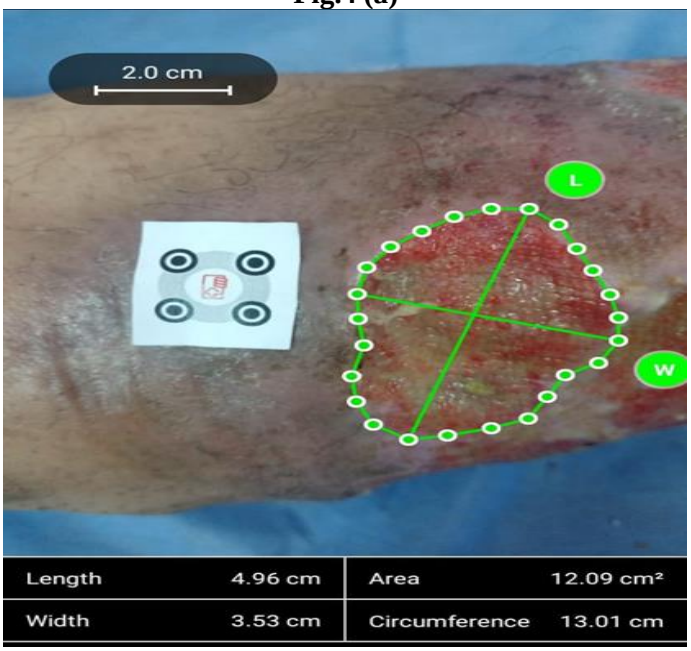

Fig.4 (b)

Figure (4) a: Image of wound tracing on a metric graph sheet. b: Image of the wound surface area automatically measured by the imito-measure app.

DISCUSSION

The results of this study agreed with Roger et al. who stated that accurate wound assessment is essential to establish a useful and practical wound care program. It is necessary not only to decide on a treatment plan based on wound status but also to determine the progression of healing or the deterioration of the wound[10].

The purpose of the study was to test the VAR of the Imito-measure application in measuring the surface area of lower limb chronic wounds. Sixty- one patients were assessed by both methods of assessment the manual planimetry method considered as (Reference method) and a smartphone application (Imito AG, Switzerland) specifically Imito-measure app. The correlation between wound surface area that was measured by the smartphone application (Imitomeasure) and that measured by the manual planimetry method (metric graph sheet) in the study group was a strong positive significant correlation ($r = 0.998$, $p = 0.001$). There was also excellent intra-RR (Trial 1 and Trial 2) in measuring the wounds surface area with; ICC 0.999, with 95% CI 0.998-0.999 and SEM of 1.83. Smartphone application (Imitomeasure) yielded excellent inter-RR in the measurement of wound surface area (rater 1) and (rater 2); ICC for measurement wound surface area was 0.999, with 95% CI 0.998-0.999 and SEM of 1.85. Thus Imito-measure application can be easily used by various institutions without the need for special customization.

Both the principal investigator and the co-investigator familiarize themselves with the smartphone application quickly, without any previous training, and used their mobile devices (Android-based smartphones). We found that the level of agreement between wound measurements obtained using the mobile application and wound tracing was higher in smaller, regular-shaped wounds and lower in larger, more irregularly shaped wounds. Further validation studies of larger and more irregular wounds could be helpful.

From the previously mentioned results, the data gathered indicates that the smartphone application Imito-measure is valid and reliable in measuring the area of chronic leg ulcers and accordingly we reject our hypothesis.

The positive correlation between wound surface area that was measured by a smartphone application and that measured by metric graph sheet as mentioned in table (**1**) come in agreement with the findings of **Do Khac *et al.*** [9] who stated using the Imito-measure app. demonstrated an excellent correlation between the application and the tracing method in pressure ulcer patients.one important difference from the study that used Imito-measure application in pressure ulcer patients was the size of the wounds. In our study, the wounds were significantly larger with a mean surface area of 15.02 cm^2 compared with 7.7 cm2 in the study using the Imito-measure app. in pressure ulcer patients.

Biagioni *et al.* [11] who studied Smartphone applications for wound area measurement and found that the Imito-measure app. provided useful and practical

surface area measurements with excellent validity and accuracy compared to digital photography and the ImageJ processing tools.

Jones *et al.* [12] who performed a systematic review to study the regulation and validation of smartphone applications in plastic surgery by creating a list of 2155 applications, of these only 172 were found to be specific for medical practitioners within plastic surgery including the Imito-measure app. which was found to be useful in wound care and met the MHRA definition of a medical device. Caution is recommended when using such medical applications.

Also, **Bodea *et al.*** [13] who studied the Clinical benefits of using a smartphone app. in assessing wound healing in a feline patient concluded that the Imito-measure smartphone app. appears to be helpful in wound assessment by being able to simplify the measurement of wound parameters. Its non-invasive nature might enhance clinical practice by avoiding animal discomfort when compared with traditional assessment techniques. Further research is required to approve the efficacy and accuracy of wound assessment of various wound types and animal species.

The excellent intra-RR and Inter-RR in the measurement of lower limb chronic wound surface area as mentioned in table (2) and table (3) were confirmed by **Aarts *et al.*** [14] who studied the VAR of two digital wound measurement tools for post-operative patients with Hidradenitis Suppurativa, comparing the inSight® 3D device and the Imito-measure wound app and recorded that the Imito-measure wound app. yielded excellent concurrent validity and reliability for the surface area measurement of concave wounds and is useful as an assessment tool in routine clinical practice.

The results of this study also came in line with **Guarro *et al.*** [15] who demonstrated that the pilot study showed that the digital measuring systems with the Imito-measure mobile application could be considered a flexible tool that could be applied in daily clinical practice and the statistics revealed that digital technology became highly reliable.

From the previous discussion of these results, it could be concluded that the results support that the Imito-measure application is valid and reliable in measuring the surface area of chronic lower-limb ulcers compared to the manual tracing method as mentioned in our study.

More research is needed to evaluate the effectiveness of smartphone applications for additional clinical indications, such as burns, arterial ulcers, erythematous skin eruptions, and surgical wounds.

CONCLUSION

Based on the scope and findings of our study, we concluded that the Imito-measure mobile application confirmed excellent concurrent validity and reliability for wound measurement and proved to be accurate, reliable, and practical for monitoring the healing progress of lower limb chronic wounds and that it is a suitable measurement tool to be used in daily clinical practice.

Conflict of interest: Nil
Source of funding: Nil

REFERENCES

1. **Järbrink K, Ni G, Sönnergren H *et al.* (2016):** Prevalence and incidence of chronic wounds and related complications: a protocol for a systematic review. System Rev., 5(1): 1-6.
2. **Agale S (2013):** Chronic Leg Ulcers: Epidemiology, Aetio-pathogenesis, and Management. Ulcers. 1-9.
3. **Nunan R, Harding K, Martin P (2014):** Clinical challenges of chronic wounds: searching for an optimal animal model to recapitulate their complexity. Dis Models Amp Mechan., 7(11): 1205-1213.
4. **Tollow P, Ogden J (2019):** The importance of relationships in treatment for chronic leg ulceration. J Health Psychol., 24(13): 1839-1849.
5. **Rivolo M (2015):** Clinical innovation: SEE & WRITE — a new approach for effective recording. Wounds Internat., 6(2): 6–10.
6. **Santamaria N, Ogce F, Gorelik A (2012):** Healing rate calculation in the diabetic foot ulcer: Comparing different Measurement Techniques. J Wound Ostomy Amp Continence Nur., 40(6): 590-593.
7. **Bilgin M, Güneş Ü (2013):** A Comparison of 3 Wound Measurement Techniques. J Wound Ostomy Amp Continence Nur., 40(6): 590-593.
8. **Wang S, Anderson J, Evans R *et al.* (2017):** Point-of-care wound visioning technology: Reproducibility and accuracy of a wound measurement app. PLoS ONE, 12(8): e0183139.
9. **Do Khac A, Jourdan C, Fazilleau S *et al.* (2021):** mHealth App for Pressure Ulcer Wound Assessment in Patients With Spinal Cord Injury: Clinical Validation Study. JMIR M Health U Health., 9(2): e26443.
10. **Rogers L, Bevilacqua N, Armstrong D *et al.* (2010):** Digital Planimetry Results in More Accurate Wound Measurements: A Comparison to Standard Ruler Measurements. J Diabetes Sci Technol., 4(4),799-802.
11. **Biagioni R, Carvalho B, Manzioni R *et al.* (2021):** Smartphone application for wound area measurement in clinical practice. J Vasc Surgery Cases Innov Tech., 7(2): 258-261.
12. **Jones O, Murphy S, Durrani A (2021):** Regulation and validation of smartphone applications in plastic surgery: It's the Wild West out there. The Surgeon, 19(6): e412-e422.
13. **Bodea I, Dîrlea S, Mureşan C *et al.* (2021):** Clinical Benefits of Using a Smartphone Application to Assess the Wound Healing Process in a Feline Patient – A Case Report. Topics Companion Anim Med., 42: 100498.
14. **Aarts P, van Huijstee J, Ragamin A *et al.* (2022):** Validity and Reliability of Two Digital Wound Measurement Tools after Surgery in Patients with Hidradenitis Suppurativa. https://www.researchgate.net/profile/Pim-Aarts/publication/3628765… ·
15. **Guarro G, Cozzani F, Rossini M *et al.* (2021):** Wounds morphologic assessment: application and reproducibility of a virtual measuring system, pilot study. Acta Biomedica Atenei Parmensis, 92(5): e2021227.