VALIDATING A NEW INSTRUMENT TO IMPROVE WOUND MEASUREMENT

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The objective measurement and assessment of wounds in clinical practice has previously proven to be time-consuming and difficult. We have developed a new device, the Clini-Rule, based on a similar instrument for perineal trauma assessment in midwifery (the Peri-Rule). This article reports early results from research to validate the Clini-Rule. To date, 42 participants have had wounds assessed. A strong level of agreement was found between the Clini-Rule measurements of two raters, and the surface area measurements correlated highly with a digitising pad. The Clini-Rule may now make wound assessment easier and more practical for both patients and nurses.

BACKGROUND Metcalfe et al (2002) developed a new tool for the assessment of perineal trauma and carried out a study to validate it. Following safety checks, the product has been licensed for sale in the UK and European Union as a Class 2b medical device.

Following the development of the Peri-Rule, we were interested to investigate whether a similar device might be used for the assessment of other types of wounds and trauma, for example pressure ulcers and leg ulcers.

As a result of this investigation, we developed a new instrument, known as the Clini-Rule.

Improving assessment

Wound assessment and evaluation of progress are important aspects of wound management (Dealey, 2005).

There is a growing need to improve the assessment of wounds and trauma through objective rather than subjective assessment, in order to confirm that the many expensive wound care products available do improve healing. In addition, with increasing risk of litigation, it is becoming essential to provide an accurate assessment of wounds, including pressure ulcers, to demonstrate the care provided and careful patient monitoring.

Previously, it has generally been recognised that there is no method of wound measurement that is accurate, repeatable, inexpensive and practical for everyday clinical use (Salcido, 2000).

The most widely used methods for measuring wounds are: linear measurements of length and width; wound tracing; and computer-based or digital planimetry.

THE CLINI-RULE

The Clini-Rule is a flexible, medical grade plastic tool and a specially designed assessment pro forma, which guides the nurse (or rater) with simple instructions on the measurements to be taken and recorded. The instrument also possibly allows depth to be measured if its use is carefully defined by specific instructions.

Using a simple algorithm, a wound’s surface area can be calculated by a computer programme that can be used on hand-held devices. The evidence suggests that, for many wounds and skin trauma, these simple measures are likely to be accurate and reliable and the most suitable for use in daily clinical practice (Keast et al, 2004).

AIM

Before the instrument can be used in clinical practice, it needs to be validated to assess the reliability of its measurements when used by different nurses. Our aim was therefore to validate the device between different nurses and to compare their assessments against a computer-based one. Here we report the early findings from the study currently in progress.

METHOD

The study was carried out in outpatient wound care clinics for the assessment and treatment of leg and foot ulcers and among inpatients with pressure ulcers, minor traumatic wounds and surgical wounds that have not healed. Following ethical approval, patients were given an explanation of the study and asked to sign a consent form if they agreed to participate.

The device used to measure the wound is 105mm long, 10mm wide and 4mm deep.
and has a mm scale measurement on the anterior surface. Before use, each device was cleaned and autoclaved at 130°C for three minutes in line with recommended NHS sterilisation procedures. This meant it could be used in direct contact with the wound, with minimal risk of wound contamination or infection, provided that the procedure was conducted aseptically. A pro forma was developed that guided nurses on measurements to be taken and recorded.

Procedure
Following removal of the dressing, one nurse (rater 1) was asked to use the Clini-Rule aseptically by wearing sterile gloves while making specific measurements, using the pro forma to guide how these should be taken and recorded. This nurse was asked to request a second nurse (rater 2) to independently repeat the assessment at the same clinic appointment, blinded to the results of the first. The first nurse also took a sterile wound tracing. The surface area dimensions were measured from the tracing using a digitising pad (Quantify One, produced by Klonk in Denmark).

Assessment pro forma
The pro forma guides the measurements to be taken and requests information on the shape of the wound and whether pain is felt.

If participants complained of pain during the assessment, they were asked to describe the level of pain experienced using a five-point rating scale: (i) very small amount; (ii) small amount; (iii) moderate amount; (iv) quite a lot; and (v) severe.

Pain was assessed first while using the Clini-Rule and second while making the wound tracing. General comments were also invited from patient participants and clinicians. The assessment pro forma cannot be made available at present because it is in the process of being trademarked.

Levels of agreement between raters’ measurements and assessments were determined using the kappa statistic (K). To evaluate differences in experiences of pain, a Mann Whitney U test was performed and correlations tested using Spearman’s rank correlation coefficient (rho or r).

RESULTS TO DATE
The device has so far been validated with 42 participants. Wound types varied, although mainly pressure ulcers and foot ulcers have been measured. The level of inter-rater reliability observed for all wound measurements gave kappa scores greater than 0.78 (p=0.001).

Based on the shape of the wound reported by rater 1 and the measurements recorded, an algorithm was developed to calculate the surface area of each wound. The surface area derived from the algorithm was compared with the surface area calculated by the digitising pad from wound tracings. These showed almost perfect correlations between the method using the Clini-Rule and assessment pro forma and that using the digitising pad (r 0.98, p<0.01).

Participants were more likely to report pain from the wound tracings than with measurements taken using the Clini-Rule (Mann Whitney U=2.17, P<0.03).

DISCUSSION
From the preliminary data, the Clini-Rule and assessment pro forma appear to provide a simple and effective method of assessing and measuring wounds. This device therefore has the potential to enable wound measurement to become a routine part of clinical practice, improving objective assessment of wounds and trauma.

The Clini-Rule and its assessment pro forma appear to give similar readings to the digitising pad, which suggest that they perform in a similar way. It is therefore likely that the pro forma guiding the measurement of the wounds and the subsequent calculation of the surface area is the essential component, because otherwise the measurements would be more haphazard and less likely to correlate consistently with results from the digitising pad.

Study limitations
To date, only 42 participants have had their wound assessed using the Clini-Rule. To ensure sufficient statistical power is achieved, ideally a total of 128 participants would be required.

REFERENCES


However, the device has already been licensed for use in clinical practice. This decision was based on the joint evidence of the data collated so far and the data obtained from the use of the Peri-Rule, on the grounds that perineal trauma requires similar measurements to other types of wound. The uniqueness of the Clini-Rule is in how that data is transformed to calculate surface area.

Work to recruit the remaining 86 patients for the validation of the Clini-Rule and further studies are needed to test it on as many different types of wound as possible.

Further work could also look at and ascertain the usefulness of the device in measuring the depth of wounds. There are currently no other devices that measure the depth of wounds against which the Clini-Rule can be compared.

CONCLUSION
The Clini-Rule can be used in the assessment of different types of wound and, because of its simplicity, it can be used in a variety of locations. It is minimally time-consuming, unlike wound tracings, and seems to cause less discomfort to patients.

Further work is under way to increase the number of participants to ensure the study is sufficiently powered before any final conclusions are reached.

Potential competing interest: Alison Metcalfe is a non-remunerated director of BHSD Ltd, which manufactures the Peri-Rule and Clini-Rule.