

A multi-site clinical evaluation trial of the Alfred/Medseed Wound Imaging System prototype

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Abstract

This paper describes a multi-site evaluation of the Alfred/Medseed Wound Imaging System (AMWIS). The evaluation comprised laboratory testing followed by trials at 34 clinical sites in five Australian states over a 12 month period. The aim was to determine its planimetric accuracy and clinical utility. AMWIS was developed to improve the precision of measurement and documentation of wounds through the use of digital still imaging and processing techniques. AMWIS allows the clinician to measure a wound and its component areas at the millimetre level as well as calculating wound volume, and document a range of wound characteristics and treatment.

A total of 79 patients had wound measurements performed and tracked on 100 wounds, generating data on 440 wound images. This enabled the determination of the system's accuracy and efficacy in wound surface area measurement and clinical utility. Results of laboratory planimetric testing produced a measurement error rate of +1.28 per cent in repeated measures of standard geometric two dimensional objects (n=360, p<0.01). Planimetric accuracy in clinical use was 94.9 per cent (n=440). Clinician evaluations indicated that AMWIS provided more accurate wound measurements, improved documentation, decreased the time required for wound assessment and increased the capability for conducting wound care research.

Primary Intention 2002; 10(3):120-125.

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Introduction

The ability to determine the efficacy of wound management techniques is dependent on the capacity to accurately measure and record the changes that occur in a wound as a function of a specific treatment. Wound assessment parameters are well understood, yet the ability to accurately measure the total size of a wound and its sub-components has presented clinicians and researchers with a practical challenge due to the irregular shape of many chronic wounds such as venous leg ulcers.

Chronic wounds of the lower extremity affect up to 1.3 per cent of the adult population and 3.6 per cent of individuals aged over 65 years^{1,2}. These wounds represent a significant financial burden on the Australian health care system, costing an average of \$27,493 per wound. This cost arises from the length of time that these wounds take to heal. Reported healing rates for chronic wounds indicate that 69 per cent heal in 12 weeks, 83 per cent heal in 24 weeks and 17 per cent remain unhealed at 52 weeks³.

Chronic wounds of the lower extremity also have important negative effects on the individual's quality of life due to pain, immobility, offensive smell, social stigma and social isolation⁴. Consequently there remains a need to develop precise measurement, documentation and research systems that can be easily used by clinicians to monitor the effectiveness of existing

and emerging wound management interventions. This paper describes the evaluation of one such system, the Alfred/Medseed Wound Imaging System (AMWIS)⁵.

Wound measurement

Wound assessment not only guides treatment, it is necessary to monitor the progress and effectiveness of treatment⁶. It has been suggested that wound measurement is one of the great mysteries of wound management and that there is no one way of measuring a wound that is accurate, consistent, cheap and easily used⁷.

Wound assessment tools have commonly been manual and wound measurement achieved through the use of rulers, grids and tracings⁸. Acetate tracing, perimeter measurements and simple rulers and grids can all be used to measure wounds but lack precision when dealing with complex and irregularly shaped chronic wounds. In addition, drawing a wound outline on acetate can be impeded by wound exudate, may cause the patient pain and represents a contamination hazard⁹. Counting 1cm squares on a such grids is popular but time consuming and, along with length by width calculations, lacks precision.

Digital imaging in wound measurement and assessment

Digital imaging and computerised recording and measurement systems are starting to replace manual methods of measurement and documentation^{5,10}. This could be seen as largely due to technological advances, including the ready availability of high quality digital cameras. An increasing interest in telemedicine services for rural and remote patients¹⁰⁻¹² together with a concerted drive to provide patient care in non-hospital settings¹³ has added further impetus to the development of computerised systems.

Richard *et al.*¹⁴ described a computerised counting method where the acetate tracing of a wound was placed on a computer screen and digitalised by outlining the perimeter with a mouse. One hundred and ninety two tracings were measured, also using 1cm squares as the grid, three times each, with no difference between repeated measures. However, the room for human error in tracing the wound itself and then tracing the tracing is doubled.

Similarly, others¹⁵ have imaged wounds with a scaling circle in place and loaded the data into a NIH image program. Three measurements were taken – the vertical diameter of the scaling circle, the ulcer area by hand tracing with a mouse and the area of the scaling circle on the limb. They concluded video imaging followed by image analysis was a clean, easy and precise way to measure venous ulcers and provide a permanent record.

Evaluation of digital images of various types of wounds have been demonstrated to be efficient and reliable for physicians to diagnose and make treatment decisions compared to 35mm

slides¹⁶. However, the need for colour images has been stressed¹⁷ because chronic wounds can have a mix of yellow slough, red granulation and black necrotic tissue and the proportions of each are important determinants of wound healing.

The Alfred/Medseed Wound Imaging System (AMWIS)

AMWIS is a software program that was developed to quantitatively determine wound size, wound characteristics and treatment interventions. Colour wound images are recorded with a digital still camera and then imported into the program for measurement, characterisation and documentation. The major primary design parameters for AMWIS were that it be accurate, provide consistently repeatable results, be easily used by wound care professionals and be relatively inexpensive. Secondary parameters included that it have the capability to securely transmit wound images and data via the internet and be able to download wound data to commonly used statistical analysis programs.

Methods

A multi-site evaluation trial was conducted between September 2000 to October 2001 at 34 sites in five Australian states. The study was undertaken in three phases:

- Laboratory testing of planimetric accuracy.
- Clinical testing of planimetric accuracy of operators of the system in the field.
- Clinical evaluation of utility, efficiency and effectiveness and the effects on quality improvement and research.

Signed consent was obtained from each trial site prior to data collection. Data comprised the complete, deidentified wound care file, associated images of each patient who had their wound assessed with AMWIS, and the clinician evaluation questionnaires.

Laboratory planimetric testing

Three two dimensional geometric objects of known size (square, circle and right angle triangle) were photographed using a Kodak DC3400 digital camera. Each image was recorded twice by the same experienced operator (NS) at a distance of 500mm from and perpendicular to the image plane. The digital images were then loaded into the AMWIS program, calibrated with a 10mm calibration target within the field of the digital image and measured using the standard AMWIS procedure.

The total surface area calculated in mm² by the program for each shape was recorded and compared to the known area for the standard objects. The difference between the actual surface area and the measured surface area constituted the error of measurement. The mean of this value was then expressed as a positive or negative measurement error percentage. A total of

360 (180x2) repeated measures were undertaken in this phase of testing and a correlation coefficient was calculated between the first and second measurement.

Clinical planimetric testing

Clinicians were instructed on the use of the AMWIS program and on the process of digital photography, including the use of standardised calibration procedures and the need for perpendicular photography of the wound surface. Where a wound was circumferential of a limb, as in the case of a burn or where the image was obviously recorded at an angle to the wound surface, the image was discarded to avoid the inclusion of images with parallax error.

Completed AMWIS patient files were collected from each of the trial sites. In each case the calibration target that was used in the original measurement was visible in the field of the digital photo and was used in the subsequent re-calibration and measurement. All suitable calibrated images were extracted and analysed by calculating the magnitude of measurement error in each image (Figure 1). The error rate was derived by dividing the sum of the sub-component wound areas by the total surface area of the wound.

In an error-free wound measurement, the sum of the wound sub-component areas would equal the total surface area of the wound. Thus, the difference between these two measurements constituted the error of measurement by the operator. The subsequent measurement error was expressed as a positive or negative percentage error rate.

Clinical evaluation

Each of the principal wound care practitioners using AMWIS at each site was asked to complete an evaluation questionnaire at the completion of the trial. The questionnaire required the respondent to rate the performance of AMWIS using a three point Likert scale for the following evaluation criteria:

- *Utility:* Accuracy, ease of use, relevance to patient casemix.
- *Effectiveness:* Healing rates, documentation, communication.
- *Efficiency:* Costs, care delivery processes.
- *Research:* Capacity to conduct research and research conducted.
- *Quality improvement:* Capacity to conduct QI and QI conducted.

Respondents were also able to make any comments that they felt relevant to the evaluation of the system or to elaborate on the items selected on the Likert scales.

Analytical procedures

All statistical procedures were carried out using SPSS V10.1¹⁸ computer program. Descriptive statistics were compiled for patient characteristics; Pearson's product moment correlation coefficients and measurement error rates were calculated for

test re-test measurements and clinical measurements. Clinicians' responses to the evaluation questionnaires were expressed as percentages. Additional comments made on the questionnaire were compiled for each evaluation area and major themes extracted.

Results

The total subject population comprised 79 patients (47 males and 17 female, 15 missing). The median age was 73 years (range 27-97). Table 1 presents the wound types that were imaged at the trial sites – the total number of images derived from the 100 wounds was 440.

Planimetric accuracy

Laboratory testing of measurement accuracy using standard two dimensional geometric shapes produced an accuracy rate of 98.72 per cent (measurement error = +1.28 per cent) between the actual surface area of the standard shapes and the AMWIS determination of surface area at the mm² level. Pearson's product moment correlation coefficient on test-retest measurements (n=360) produced a value of r=69.7 (p= <0.01). The accuracy of measurements of clinical wound images (n=440) from the evaluation sites was calculated to be 94.9 per cent (measurement error = -5.1 per cent).

Clinician evaluation

Table 2 presents the responses of clinicians regarding the clinical utility of AMWIS within their practice settings. Users were asked to rate the accuracy of AMWIS measurement compared to their existing techniques. Similarly, they were asked to rate the ease of use of the program and its relevance to casemix of wound care patients treated at the site.

AMWIS users were asked to rate the clinical effectiveness of the program (Table 3) in terms of its effects on wound healing rates and documentation and communication processes.

Figure 1. Part of the AMWIS wound assessment screen showing the calibrated wound image with demarcated wound areas and the associated measurements expressed in mm² and as percentages of the total wound surface area.

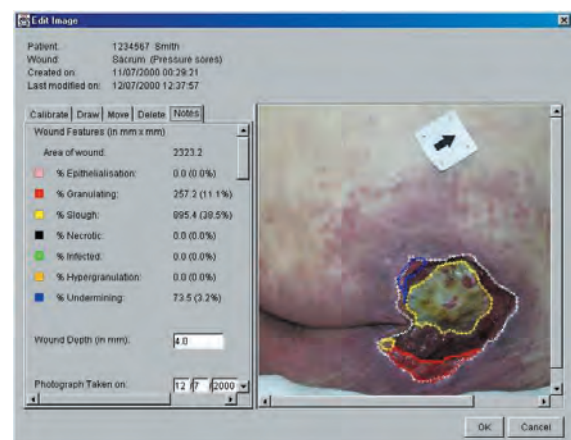


Table 4 reveals clinicians' judgement regarding the effects on efficiency of using AMWIS. Respondents noted that in 23.5 per cent of cases, costs were increased due to the increased time required to use the program. This was particularly noted in the outpatient clinic setting and was attributed to the attempts by clinicians to use existing work practices and add AMWIS to that process. We note that in many outpatient settings the use of AMWIS requires a change to work practices.

Clinicians reported that AMWIS increased their capacity to conduct wound care research and quality improvement activities (Table 5). It was pleasing to note that a number of trial sites had commenced to conduct wound research and quality improvement activities as a result of using AMWIS.

Discussion

The results of the AMWIS evaluation suggest the program provides wound care clinicians with a reliable and accurate measurement system that produces accuracy levels

approaching 95 per cent in clinical use and above 98 per cent in the laboratory setting. Clinicians note that their ability to accurately trace the wound margin and the perimeter of wound sub-components improves over time with experience in using the program. We believe that the clinical measurement accuracy reported in this study may improve as clinicians become familiar with the measurement process and their dexterity in tracing wound margins improves with practice. A further factor that impacts on the precision of wound measurement is the quality of the digital images that are being measured. We have noted that many novice AMWIS users require a period of familiarisation with the process of digital photography.

Clinician evaluations indicate that AMWIS provided improved accuracy, was easy to use and was relevant to the casemix of wound care patients at the trial sites. This was a pleasing result given the range of wound types that the system was used to measure and document. Similarly, positive outcomes were reported by users in the effective parameters of wound healing rates, documentation and communication. Clinicians noted that the system enabled them to make better wound care product choices based on the AMWIS reporting functions because the system enabled them to note either positive or negative changes in wound size and characteristics.

Table 1. Wound characteristics.

Type	n
• Abrasions	1
• Split skin graft	1
• Infection	1
• Malignant	2
• Traumatic	2
• Amputation stump	3
• Laceration	6
• Pressure ulcer	7
• Surgical incision	7
• Chronic leg ulcer	66
• Other	4
Total	100

Table 2. Clinician evaluation: utility (n=34).

How accurate was wound measurement using AMWIS compared to your current methods?			
	Worse	Same	Better
	0%	5.8%	94.2%
How easy was using AMWIS to measure wounds?			
	Hard	Neutral	Easy
	11.7%	5.8%	82.3%
How relevant was AMWIS to the casemix of wounds seen by your service?			
	None	Some	Very
Casemix	5.8%	11.7%	82.3%

Table 3. Clinician evaluation: effectiveness (n=34).

Do you believe that using AMWIS had an effect on the outcomes of wounds?			
	Negative	Neutral	Positive
	0%	35.3%	64.7%
Do you believe that using AMWIS had an effect on the quality of documentation of wounds and their progress?			
	Negative	Neutral	Positive
	0%	0%	100%
Do you believe that using AMWIS had an effect on the communication process about patients' wounds?			
	Negative	Neutral	Positive
	0%	23.5%	76.5%

Table 4. Clinician evaluation: efficiency (n=34).

Did using AMWIS have any impact on the cost of delivering your wound care service?			
	Increased	Neutral	Decreased
	23.5%	41.2%	11.8%
Did using AMWIS have any effect on how wound care was delivered at your agency?			
	Worse	Same	Better
	0%	58.8%	41.2%

The reporting functions of the system were also noted as having a positive effect on the ability of clinicians to produce better documentation for patients' clinical records. The ability to produce reports combining wound size changes over time as a function of treatment, combined with the relevant colour wound images, was noted as a particularly useful function.

The evaluation parameter of efficiency revealed that almost one quarter of respondents indicated that AMWIS resulted in increased costs. This result appeared due to a number of trial sites using AMWIS within existing work practices and processes and thereby increasing the time taken to assess individual patients. This was particularly noted in the outpatient or wound clinic setting.

We have also noted similar effects at our hospital when AMWIS was introduced into our vascular outpatient clinic but note that, following an initial period of adjustment to the new system, staff developed new processes that were considered to be more efficient to those previously in use.

AMWIS or any other new technology introduced into an existing clinical setting often causes work flow and/or practice change due to the nature of the technology. It was interesting to note that within this evaluation parameter more than 40 per cent of respondents felt that the care delivery system was improved by the use of AMWIS. This result suggests that the introduction of this technology produced practice change.

In the areas of research and quality improvement, all clinicians reported that they believed that AMWIS would increase their capacity to conduct these activities. It was pleasing to note that

Table 5. Clinician evaluation: research & quality improvement (n=34).

Do you believe that AMWIS could contribute to future wound care research at your service?	
Yes	No
100%	0%
Did using AMWIS contribute to you service's ability to conduct wound care research?	
Yes	No
23.5%	76.5%
Do you believe that AMWIS could contribute to future wound care quality improvement activities at your service?	
Yes	No
100%	0%
Did using AMWIS contribute to you service's ability to conduct wound care quality improvement activities?	
Yes	No
29.4%	70.6%

AMWIS was used in research activities in 23.5 per cent of sites and the 29 per cent of sites used the system to carry out quality improvement activities. The ability of AMWIS to download all wound data directly to a statistical program was noted by many clinicians as a valuable function because it eliminated the need to re-enter clinical data for research.

Limitations

The study was limited by the large variability in our understanding of wound care assessment and measurement at many clinical sites. There appears to be two principal methods of wound measurement used at the majority of the trial sites. Either the wound length and width is determined or the size is estimated by overlaying an acetate grid with 1cm squares and the number of squares over laying the wound is counted. Both methods have significant limitations when measuring irregular wounds. Therefore, when comparing existing methods to AMWIS, which provides surface area measurements at the mm level, it is not possible to determine the degree of improvement in wound measurement because AMWIS provides measurement that is much more precise than existing approaches.

Similarly, we do not have data on all current documentation, costing, research and quality activities at each trial site and are therefore dependent on the responding clinicians' assessment of the relative effect of using AMWIS on these factors. This point highlights the need for future research into these complex and often interrelated factors and their effects on wound care.

Conclusion

Precision in wound measurement and accurate documentation of wound characteristics are vital components of effective wound care. The results of this study suggest that AMWIS achieved these objectives in the clinical setting. Clinician evaluation of the system at 34 trial sites has been positive and specific suggestions for improvement of AMWIS have been incorporated into the final version of the system. On the basis of our results to date, we believe that AMWIS provides wound care clinicians with a potentially valuable wound management and research system.

Acknowledgments

The authors wish to express their thanks to the following individuals and organisations who assisted in this study.

Heather Byrne	Kerlyn Carville	Eric Dillon
Judith Donohue	Isabelle Ellis	Tal Ellis
Timothy Ellston	Judith Finn	Megan Laidlaw
Thelma Kemp	Julia Kittcha	Sunita McGowan
Pam Morey	Carlo Rizzi	Anna Sheppherd
Christina Steffan	Silver Chain	Smith + Nephew
Telehealth Development Unit, Health Department of WA		
Melissa Vernon		

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