A pilot study

A prospective, interventional study of the effectiveness of digital wound imaging, remote consultation and podiatry offloading devices on the healing rates of chronic lower extremity wounds in remote regions of Western Australia

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Abstract

Background: Lower leg ulceration is a significant health burden to the sufferer and the health service. The time to heal such wounds can take up to two to three years and some will lead to amputation and mortality, particularly for those who live in remote locations. Living in such areas makes accessing health care and health experts extremely difficult.

Methods: A pilot study utilising a three-month prospective interventional study was implemented into the Mid West and Murchison region of Western Australia (WA), investigating the effectiveness of digital imaging, remote consultation and podiatry offloading devices on the healing rates of chronic wounds of the lower limb. Wounds were photographed using digital imaging and assessed using the Alfred Medseed Wound Imaging System (AMWIS). Once assessed, the details were sent to a wound expert for advice on wound dressings and treatment protocol. The patient was referred to podiatry for design and implementation of appropriate offloading devices such as an in-shoe orthosis.

Thirteen subjects were recruited and eight used for data analysis with an average age of 70.3 years (42–87 years). Average ulcer duration prior to recruitment was 72 weeks and average size was 81 mm^2.

Results: An average weekly healing rate of 18.12% was calculated for the cohort. Three of the eight ulcers healed within the study period and the average decrease in size was from 81 mm^2 to 13 mm^2.

Conclusions: The results indicate there was a marked increase in the average weekly healing rates and this supports further investigation.

Background

Western Australia (WA) is a vast land mass with a low population density. Most of the land area is classified as remote. The populations within the remote regions have limited delivery of health services, particularly those of a specialised nature such as wound care. Delivery of health care to remote locations is time-consuming, expensive and at times impractical due to terrain, cost of transport and weather. Also many people including health professionals who reside in this region are transient in nature and, as such, this exposes many challenges in health delivery.

In response to this, health services deliver services on a part time or infrequent basis and rely upon agency staffing. One of the documented downfalls of this practice is the loss of treatment continuity due to high staff turnover[1]. Other factors that influence health care in these regions include poor local infrastructure making transport difficult and at times impossible, extremes in weather, a transient population, lack of advanced documentation and communication systems and the cost of acquiring specialised health practitioners.

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Remote areas of WA face many challenges in relation to health care not experienced by metropolitan populations. The recruitment of specialised health practitioners is a considerable test for health services and the direct result of this is a decrease in these services to the resident and visiting populations. This impact is most noticeable in treating chronic diseases such as diabetes.

Foot ulcers are a major cause of complication from diabetes mellitus[2]. The annual incidence of foot ulcers is between 1% and 4% in the general Australian population. Diabetic populations have a reported incidence of between 5% and 10%[3]. Of all lower limb amputations, 50% of the cases have a previous diagnosis of diabetes mellitus and 90% had a previous foot ulcer[4]. However, according to Wroe[5], 15% of diabetics will develop a foot ulcer and of all foot amputations, 85% will have an underlying diagnosis of diabetes.

Ulceration of the lower leg and foot is a significant burden to the sufferer by reducing quality of life, increased risk of complication and has the capacity to reduce life expectancy[6,7]. Diabetes is a major cause of lower limb ulceration, particularly within the Aboriginal population as a result of the high incidence of diabetes within this population group[8,9].

Australian Aboriginal populations have a much higher incidence of diabetes. The age-adjusted prevalence for Indigenous people was 11% in Australia. This represents an increase of almost four times above the incidence for the non-Indigenous population[10]. When this data is examined further, it is evident there is a distinct difference between remote and non-remote populations. Remote Indigenous populations have an incidence of 16% compared to 9% in non-remote areas for diabetes mellitus[11]. The author states this represents a real range between 20% and 30% when non-diagnosed cases are taken into account.

A lower extremity wound presents a significant financial cost to the Australian health care system, with the average cost of the lower extremity wound being A$27,493 per wound per year[12]. The treatment of diabetes and its complications cost US$116 billion in 2007 within the United States and 33% of this was related to foot ulceration[13].

One factor that impedes wound healing includes increased shearing forces to the area. This will create additional wound stress through friction and cause tissue damage and prevent repair. In the presence of peripheral neuropathy the protective reflex is absent and any un-noticed trauma may lead to ischemia, injury and tissue cell breakdown. Uraemia impairs healing by interfering with collagen deposition and decreases granulation within the wound. The elderly patient will display a decrease in collagen density, fewer fibroblasts and mast cells and fragmentation of elastin fibres[14].

Wound debridement is paramount in the promotion of healing for a diabetic foot wound. Debridement removes all devitalised tissue including callous, necrotic tissue and contaminated tissue. This leaves only viable, healthy tissue. Assessment of the wound is easier post-debridement as the excess tissue has been removed. Debridement may consist of sharp, autolytic and enzymatic techniques.

Removing stress forces from diabetic foot wounds is vital to establishing normal collagen deposition and reducing tissue microtrauma. Improper footwear is commonly associated with the incidence of plantar ulcers. The most effective way to treat and prevent neuropathic ulceration is removal of excessive plantar pressures[15,16]. Podiatric offloading modalities are used to remove shear stress from wounds and are a key aspect in management of diabetic plantar foot ulcers.

The introduction of teleconferencing, email and digital imaging has allowed for the delivery of health care through electronic media. Software such as the Alfred Medseed Wound Imaging System (AMWIS) permits accurate assessment and delivery of wound details to health professionals without the need for the patient or practitioner to travel. Wound care, particularly those of a diabetic nature, requires a team approach incorporating the general practitioner (GP), nursing staff, wound consultant and podiatrist.

Previous studies[1] have investigated the cost and clinical effectiveness of delivering diabetic foot ulcer treatment remotely; however, there have not been any published studies incorporating remote health delivery including podiatry. This pilot study investigates wound-healing rates by remote consultation, the use of AMWIS and podiatry to ascertain the need for further investigation. The development of a team approach, linked by this type of technology and its embrace by health services is paramount for the effective delivery of services for the treatment of lower leg ulceration.

Figure 1. AMWIS software with an ulcer image[1].

Methods

Aims of the research

The project is a pilot study incorporating the recruitment of 12–15 patients who have a diabetic foot ulcer. The research is investigating ulcer-healing rates when consulted off-site by wound consultants, AMWIS assessment and podiatry. Previous studies conducted[1] in the Kimberley region of WA showed this technique had a better healing rate and was A$190,000 less expensive than the control group; however, there was no podiatry service involved. Various authors have stated offloading of wounds and incorporating podiatry services is paramount in the treatment of diabetic foot ulceration[15,16]. The author concluded there is clear evidence for early intervention and cost-effectiveness for remote expert wound consultation using digital technology.

Design

A three-month, prospective, interventional study was conducted in the Mid West and Murchison region of WA. Geraldton is the major centre of this region. The study sample was drawn from residents of Geraldton and smaller remote communities lying within this region who were referred or presented to a mix of public and private podiatry clinics conducted by the author.

Study subjects were assessed by the podiatrist and the wound photographed using a digital camera. The ulcer was analysed with the AMWIS software utilising the documented methods[17]. The image was sent to a wound consultant at Fremantle Hospital Podiatry Department. The advice of the wound consultant was used to provide the appropriate wound dressings. The dressings were applied by the local nurse team or the podiatrist. Offloading devices were designed and implemented by the podiatrist, as was wound debridement.

This protocol was repeated every two weeks until the three-month study period ended or the ulcer resolved. A healing rate was determined by the percentage change in the ulcer size over the study period.

Subjects

Once subjects met the inclusion criteria and provided informed consent they were eligible for enrolment. Subjects were referred to the study from various sources. Principally these were community hospitals, community care nurses, private podiatry practice and GPs. The study received approval from the Human Research Ethics Committee of Curtin University.

Inclusion criteria

- Diagnosis of lower limb ulceration of one month or longer duration.
- Informed consent obtained.

Exclusion criteria

- Under 18 years of age.
- Inability to provide informed consent.
- Serious and unstable medical comorbidities.

Procedures

Principally the procedures of the study are incorporated into four parts: photographic catchment; wound assessment using

Figure 2. Plantar ulcer displaying 1-cm line adjacent to the wound.

AMWIS; specialised wound care and podiatry treatment including wound debridement; and administration of offloading devices.

Photographic catchment

During the initial examination a digital photo was taken of the ulcer with a 1-cm mark on a piece of paper adjacent to the wound included within the photo. This 1-cm line was orientated to the distal end of the foot. The line is used for calibration of the photo when using AMWIS.

After being photographed, the wound was assessed using AMWIS software. The software provides an accurate surface area measurement of the ulcer in millimetres^2. The ulcer was demarcated into different zones such as granulation tissue, necrotic tissue, erythema and so on. The surface area of the entire ulcer was recorded and compared to previous photographic recordings of the same ulcer. This provided a positive or negative healing rate. If the wound is smaller compared to the previous photos, it equates to a positive healing rate and vice versa. If the wound surface area is larger than the previous photo, then this equates to a negative healing rate.

Specialised wound care

Once the ulcer had been assessed the image was sent to a wound consultant with a description of the wound, subject history, wound history and current treatment modalities. This information was de-identified. The wound consultant then advised on treatment protocols by email. The advice was sent to the podiatrist who then passed on the information to the relevant site electronically for application by the nursing staff or podiatrist.

This was repeated each two weeks (preferable) or if longer than two weeks at each consultation and the wound consultant reviewed the ulcer progress from the AMWIS file. If any clarification was required the wound consultant was contacted by telephone.

Podiatry

The consulting podiatrist determined the required offloading techniques for the wound. These devices were specific for each ulcer and, once determined, the device was implemented at the earliest possible consultation. The devices used for the study sample included postoperative shoes, offloading in-shoe insoles, customised foot orthoses and padded ankle cuff. Once manufactured, these were sent directly to the patient and/or nursing staff with instructions. If required, a video-conferencing consultation was organised for review and fitting.

Callus debridement of the ulcer, if required, was performed by the podiatrist at each consultation. This was performed sharply with a scalpel prior to photographic catchment. This permitted a more accurate sizing of the ulcer as no parts of it were disguised from the overlying callus. It also formed part of the healing process in reducing pressure upon the wound margins.

Data management and analysis

The average rate of healing as a percentage, per week for each subject was calculated using the descriptive functions of SPSS. This data was recorded in SPSS and analysed using two sample T-test.

Results

Thirteen subjects were recruited over the three months. However, two were excluded due to an underlying

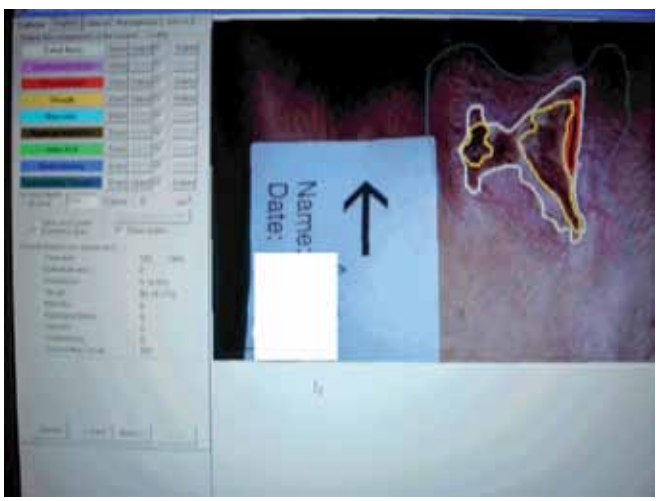

Figure 3. AMWIS software measuring ulcer size.

Table 1. Healing rate.
Descriptive statistics of age and healing rates.

	N	Minimum	Maximum	Mean	Std. deviation
Age	8	42	87	70.30	14.685
Healing rate (%)	8	4.20	50.00	18.1250	18.07972
Valid N (listwise)	8				

comorbidity of osteomyelitis. Three subjects were lost to the study with only one measurement recorded. Eleven patients had a diagnosis of diabetes mellitus and one patient without diabetes had a neuropathic ulcer from a lumbar spine compression injury.

The eight subjects used for data analysis averaged 70.3 years in age (42–87 years). There were four males and four females. Four subjects resided in Geraldton and accessed the health service regularly whilst the other four lived in remote locations and had a less accessible service. Of this group, one was of Aboriginal or Torres Strait Islander descent. Interestingly, the three subjects lost from the study were all of Aboriginal descent. These subjects were lost due to leaving the area.

The eight subjects all had one ulcer each; there were six foot ulcers and two lower leg ulcers. The average duration of the ulcers prior to commencement within the study was 72.1 weeks (16–192 weeks). Of the six foot ulcers, five were mixed neuropathic and ischaemic whilst the remaining foot ulcer was of a neuropathic aetiology. Both legs ulcers were of a pressure aetiology. The ulcer with the longest duration (192 weeks) was also the largest (189 mm^2) and was a medial ankle pressure ulcer of a hospital inpatient within a remote town.

The average size of the ulcers at time of recruitment was 81 mm^2 (8–192 mm^2) and at the end of the study period this had reduced to an average of 13 mm^2 (0–65 mm^2). Three ulcers healed during the study period and of the remaining five ulcers, all but two were under 10 mm^2.

The calculated average healing rate for the cohort was 18.12% per week (4.2–50%)

All patients with non-resolved ulcers went on to heal within two months of the study completion, apart from one patient, who passed away from unrelated complications.

All ulcers were smaller by the end of the study period, although three of the eight ulcers displayed periods of increase in size at least once during the study period. These were all foot ulcers and after changing the dressing protocol as advised by the wound consultant went on to decrease in size.

When the data was compared to each subject's location there was a noticeable difference, although not statistically significant. The group living within Geraldton healed on average 28.8% per week and those outside Geraldton at an average of 7.45%.

Discussion

This study demonstrated a positive healing rate for all patients with foot and leg ulcers using AMWIS, podiatry-offloading devices, in concert with remote wound care delivery using telehealth. Although there is a noticeable difference in healing rates when compared to similar studies without podiatry intervention, the small sample size of this study prevented statistical comparison. The sample did contain a variety of ulcers and included not just foot ulcers but lower leg pressure ulcers.

Although the results were not statistically significant, there is a distinct and measured increase in healing rates when compared to previous studies. Bearing in mind this is a pilot study and conclusions in respect of this comparison cannot be made, there is evidence further investigation is warranted.

Table 2. Group statistics.
Descriptive statistics between subject location.

	Location of Geraldton	N	Mean	Std. deviation	Std. error mean
Healing rate (%)	Outside Geraldton	4	7.4500	4.14769	2.07385
	Within Geraldton	4	28.8000	21.01492	10.50746
Valid N (listwise)	8				

Table 3. Ulcer types.

Ulcer aetiology	N
Mixed foot	5
Neuropathic foot	1
Pressure leg	2

Table 4. Average change in ulcer size in mm² over the study period.

Average ulcer size mm²	Week 1	Week 13
All ulcers	81mm²	13mm²

The healing rate of 18.12% per week is considerably higher than previously reported and is likely a product of the small sample size in conjunction with the incorporation of podiatry.

The increase in healing rate of this pilot study needs to be investigated further. There are a number of potential reasons for this. This study had a small sample size and there is the possibility of sample bias. In this study the podiatrists consulted the patients on a regular basis and there was no turnover of podiatric staff. This has an important effect of consistency of treatment protocol. However, in some of the more remote locations there was evidence of nursing staff turnover that did influence wound protocol and as such may have has an effect on healing rates. Santamaria *et al.*[1] found similar experiences within the Kimberley region and made the suggestion this can be overcome by employing wound care nurse practitioners to consult across entire health regions.

The proposal of a wound care nurse practitioner to consult over large geographical areas has merit. The available IT technology allows for fast and confidential transfer of patient information. In respect to the study, this technology was employed for transfer of digital images for AMWIS analysis. The use of AMWIS allowed for fast and accurate measurement of the wounds and consistency of treatment, which provided the nursing staff and patient with feedback on their wound healing.

When implementing the study in remote areas we found little resistance to change and in most cases the nursing staff expressed gratitude in having expert wound consultation to determine treatment plans. Expert wound consultation was passed on to the study team within two to three days of each AMWIS assessment. Therefore any change to the treatment protocol of the ulcer was obtainable very efficiently. One example of protocol from the wound consultant:

> *…There would appear to be some shear acting on the ulcer as shown by the subcutaneous bruising and the medial fistula. It may require some hydration. But this is problematic with, say, a hydrocolloid as it may create more maceration. Solutions could include: Foam, but not Lyofoam as it is too thin. Say Biatain or Hydrasorb.*
>
> *A small amount of gel may help: Intrasite in combination with a foam.*

The introduction of podiatry to this study allowed for the offloading of wounds to reduce shearing stress from weight-bearing. The improved healing rates in this study may be related to this and require further investigation.

Podiatry services within this study used a combination of padded ankle cuffs, footwear modifications, insoles, padding and custom foot orthoses to offload wounds. In all cases the patient consulted the podiatrist in person initially for assessment and design for the offloading modalities. Once a technique was devised and dispensed, it was followed through teleconference or direct follow-up.

Teleconferencing has many benefits for delivery of health services across remote areas. This study employed teleconferencing for podiatry follow-up appointments, assessment of wounds when on-site nursing staff were not available and for instruction on the application of dressings with the patient present. In many communities there is no full-time health service and teleconferencing is an ideal way to deliver support services.

One of the key benefits of this system of wound care was the evidence of wound size determining healing rates. On several occasions the wound characteristics changed and this was clearly evident from AMWIS. The exact sizing of the wound enabled early detection of wound change and consequently the wound protocol was adjusted to combat this. This early intervention enables a faster change in wound management, which helps to prevent wound degeneration. This has implications from a cost perspective, both for the patient and health service. It limits patient discomfort due to a positive healing rate being maintained and has the potential to prevent limb amputation.

The study has demonstrated this system of wound care for remote areas would benefit from further investigation. This is the first study to utilise expert wound consultation, AMWIS, digital technology and podiatry services to effectively treat lower leg wounds. A larger sample size and the incorporation of randomisation to a control and intervention group will help determine the effectiveness of this delivery modality.

Conclusions

The pilot study has demonstrated it is possible to incorporate remote expert wound consultation, digital technology, AMWIS and podiatry to treat lower leg wounds in a remote setting. The results display an increase in healing rates clinically when utilising this model, although this has not been statistically proven. It is proposed this form of health care delivery would be well served by further investigation to ascertain its effectiveness when dealing with a larger sample size. A major randomised clinical trial should be conducted to investigate the impact of this management protocol on ulcer healing rates and other relevant outcomes.

Competing interests

The author has no financial interest in AMWIS or its associated companies.

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