Doing better under pressure: An audit of post-surgical foot wounds in people with diabetes treated with negative pressure wound therapy (NPWT)

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ABSTRACT

Aim

Negative pressure wound therapy (NPWT)-related outcomes have not been systematically reported in Australia. We aimed to evaluate the clinical efficacy of NPWT on post-surgical foot wounds in a consecutive series of patients with diabetes.

Method

Data was extracted from the Diabetes Centre electronic database for all patients treated for post-surgical foot wounds between September 2006 and January 2011. Criteria were diabetes with peripheral neuropathy and an acute post-surgical wound to tendon or bone. A manual audit was conducted on identified cases to determine healing parameters, duration and cost of the NPWT. Adverse events and long-term outcomes were also determined.

Results

From a total of 155 post-surgical patients, 34, each with one wound receiving NPWT, were studied. Amongst the group, 19 were to tendon and 15 were to bone. More than half the wounds resulted from amputation. Complete wound healing was achieved in 79%, with a median healing time of 110 days. One treated ulcer required subsequent partial foot amputation.

Conclusion

NPWT used in diabetic post-surgical wounds was associated with a high rate of wound healing and a low amputation rate. These results accord well with reported international outcomes and support the increasing use of targeted NPWT.

Keywords: Negative pressure wound therapy, vacuum-assisted closure, diabetic foot ulcer, wound healing.

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INTRODUCTION

As the prevalence of diabetes rises, so does the number of foot complications, with diabetes remaining the most common cause of non-traumatic lower limb amputation[1-3]. In Australia, up to one in four people with diabetes will develop a foot ulcer, many requiring long-term treatment to avoid lower limb amputation. Treatment of diabetes-related foot ulcers (DRFU) can be very challenging, costly and often, despite best efforts, healing can be delayed and associated with complications[4]. In response to the increasing burden, attention over the last decade has been focused on the development of therapeutics and advanced wound care products[5]. While the evidence in this area continues to grow, negative pressure wound therapy (NPWT) is one such treatment that is being prescribed more

routinely for the healing of complex wounds[6]. It is a relatively non-invasive, readily available and accessible treatment modality that aims to improve the rate of granulation tissue formation by increasing local microvasculature and removing waste products and oedema[7].

NPWT use in the management of diabetes-related foot wounds continues to emerge in Australia, as many of these chronic ulcers fail to heal with standard care; which includes regular sharp debridement, treatment of infection, treatment of ischaemia, moist wound care and pressure offloading[4,8]. While traditional surgical management of DRFU often includes lower extremity amputation to preserve limb and life, our experience locally is that contemporary surgical intervention and management options are being offered to facilitate healing of wounds without the need for such major amputation. Furthermore, surgical debridements and minor amputations are being performed with the intention of utilising NPWT postoperatively to achieve wound closure. This has been reflected in data from our hospital that showed an increase in partial foot amputations and a decrease in major amputations[9,10]. This trend has also been identified in other Australian data recently published by Dillon *et al.*[11].

While many surgical wounds heal uneventfully by primary intention, complications including wound dehiscence are common in the diabetic neuropathic foot[12]. Post-surgical wounds left open to heal by secondary intention may also have healing delayed in this patient group. Whether NPWT can improve outcomes in this cohort is not clear. Therefore we conducted a retrospective audit to provide outcome data including rate and time to healing as well as duration of therapy and long-term outcomes on diabetic patients with post-surgical foot wounds treated with NPWT within our Diabetes Centre High Risk Foot Service (HRFS) at Royal Prince Alfred Hospital.

PATIENTS AND METHODS

We collected data from our purpose-built electronic database on all post-surgical wounds that were treated by our team, a multidisciplinary diabetes HRFS within a tertiary referral hospital, between September 2006 and January 2011. All patients included in the audit had diabetes and peripheral neuropathy and an acute post-surgical foot wound. Whilst we did not set out to search all surgical episodes of inpatient care, it is practice at our hospital that post-surgical wounds treated with NPWT in people with diabetes are referred to our HRFS by the treating surgical team. Acute post-surgical wounds were defined as those resulting from surgical debridement and/or partial foot amputation and were graded as University of Texas grade 2 (to tendon or joint capsule) and 3 (to bone). Wounds were excluded if there was severe peripheral arterial disease (defined as an ABI <0.6), if wounds were closed primarily with sutures or split skin grafts, or if they were located on the digits. The medical records of those who met the study criteria were manually audited to identify those who were treated with NPWT and to exclude those with missing data. This quality assurance audit on de-identified grouped data was supported by Sydney Local Health District and patients gave consent for data usage.

Using these audit methods, from September 2006 to January 2011 we managed 155 post-surgical foot wounds in 155 patients. Many (83%) of these were superficial wounds (University of Texas grade 1), with the remainder involving tendon and or bone (University of Texas grade 2 and 3). Of these, 37 were treated with NPWT. Three were superficial (University of Texas grade 1), 19 were grade 2 and 15 were grade 3. Most (34/37) were clinically infected at baseline (and the patients commenced on systemic antibiotic therapy); 13 were ischaemic in type. After excluding the superficial wounds (n=3), 34 patients (34 wounds) received NPWT between 2006 and 2011.

While we did not specifically set out to study the effectiveness of one topical NPWT device, all patients during this period were managed with the VAC® therapy system and were provided with standard clinical care according to our HRFS clinical guidelines that are based on best available evidence[4,15]. Wound area was determined by manual area measurement derived from the respective acetate tracing collected at the clinical service event.

In the wounds treated with NPWT, healing rates and times, adverse events and outcomes with a follow-up period of one year were then analysed and compared with other published data from two commonly cited large, multicentre randomised controlled trials (RCTs), including Armstrong *et al.*[13] and Blume *et al.*[14]. Our healing time results were reported as median to facilitate comparisons with those publications. Together, these results will facilitate an Australian benchmark on healing outcomes on complex diabetes-related foot ulcers treated with NPWT.

RESULTS

Patient and wound demographics

As described in the methods, there were 34 patients studied in the audit who received NPWT. The cohort comprised of 93% who had type 2 diabetes, 77% were males, and age was 58 ±11.3 years, with diabetes duration of 15 years (IQR 8.7–19.6). This is detailed in Table 1. Overall wounds had an average area of 18.5 cm^2, with 62% being the result of a partial foot amputation and 38% from an extensive surgical debridement and were mostly of the forefoot. The University of Texas stage and grade is also shown in Table 1, indicating that 12 were ischaemic and 31 were infected at the commencement of therapy.

Clinical outcomes

Results showed that 79% (27/34) of wounds healed in a median time of 110 (89–126) days or less. The median duration of NPWT was 31 days, with NPWT applied within a median of two days postoperatively. Figures 1 and 2 demonstrate the different types and characteristics of wounds included in the study. Figure 3 depicts a typical post-surgical wound from a partial foot amputation that was treated with NPWT with the development of more rapid granulation tissue after only two weeks of therapy and at wound closure. This is representative of the healing pathway seen in those treated with NPWT.

More than half the patients (68%) were discharged home with NPWT ongoing and were followed up on an outpatient basis. In most cases NPWT was ceased when the wound was superficial and clean rather than until complete closure. Complete healing was achieved in a median of 71 days following the cessation of NPWT.

Table 1: Patient demographics

		N=34
Age (yrs) ±SD		58.1±11.3
Gender (M:F %)		77%:23%
Diabetes (type 2: type 1 %)		93%:7%
Duration of diabetes (yrs) [IQR]		14.8 [8.7–19.6]
Univ. of Texas grade	2	19 (tendon)
	3	15 (bone)
Univ. of Texas stage	A	1 (not infected or ischaemic)
	B	21 (infected)
	C	2 (ischaemic)
	D	10 (infected & ischaemic)
Wound area (cm^2)		18.5
Type of surgical wound		
Partial foot amputation		21 (62%)
Surgical debridement		13 (38%)

Of the 27 wounds that healed, a third of patients (9/27) had an adverse event involving the index ulcer (study wound) before complete healing was achieved. These events are detailed in Figure 4. Of the seven that did not heal, two wounds were ongoing at the end of the study period, three patients were lost to follow-up, one required further amputation at the transmetatarsal level and one died before the wound was healed.

Within the one year follow-up period, 44% (n=15) of patients developed new ulcers at other sites, and amongst these, nine required minor amputation (mainly digits) and two had below-knee amputation (BKA). One required other foot surgery (tendo-achilles lengthening). In addition, two developed Charcot's arthropathy and four died.

DISCUSSION

NPWT has been used in Australia for more than a decade and is often utilised as an effective treatment in the healing of many challenging wounds. Healing is facilitated by the delivery of sub-atmospheric pressure to the wound, occurring through the application of specialised foam or gauze dressing to the wound bed, covered by an adhesive sealed drape that is connected to a pump and waste canister[16,17]. It is well supported in the literature for use on a wide range of wounds types, including split-skin grafts, leg ulcers and pressure injuries as an adjunctive treatment to reduce the complexity and size of wounds[6,18-21]. On the foot it is more traditionally used for complex wounds that are the result of partial amputations or wounds that have been surgically debrided[20]. These wounds are often large and deep and can take many months to years to heal with standard moist wound therapy and carry a high risk of infection, re-hospitalisation and the need for secondary amputation[6,21].

In our experience, the use of NPWT has increased and gained popularity within our hospital over the past 10 years, particularly with regard to diabetic foot wounds. What has not been quantified is the change in practice that has resulted from the confidence in this therapy. Patients with DRFU that may have previously resulted in a BKA are instead being offered extensive debridement or partial foot amputation with the intention of being managed with NPWT. This has been our experience and has provided the impetus to conducting this audit examining our healing outcomes reflecting on the direct impact of this therapy on our clinical practice. Figure 5 provides an example of this.

Figure 1 a) and Figure 1 b) provide examples of wounds commonly treated with NPWT that are that result of a surgical debridement.

Figure 2 provides an example of partial foot amputation that was treated with NPWT post operatively.

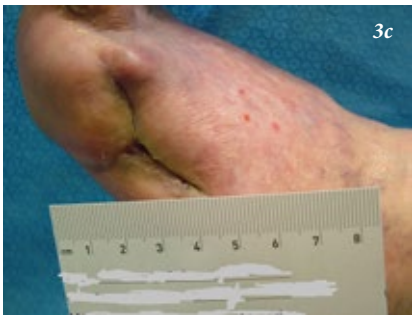

Figure 3(a,b,c) depicts a typical post-surgical wound from a partial foot amputation that was treated with NPWT with the development of more rapid granulation tissue after only 2 weeks of therapy and at wound closure. This is representative of the healing pathway seen in those treated with NPWT.

Table 2: Comparative data from two large multi-centre RCTs addressing the use of NPWT on partial foot amputations in patients with diabetes

Author	Cohort/study type	Wound characteristics	Outcomes
Armstrong DG *et al.*, 2005	n=77 RCT Diabetic partial foot amputation wounds	Univ. of Texas grades 2, 3 Area 22.3 cm^2 Duration 42 days (1.2 mths)	NPWT intervention group: 56% healed in 112 days Median time to healing 56 days 12% treatment-related adverse event Reduced rates of second amputation Reduced rates of major amputation
Blume PA *et al.*, 2008	n=169 RCT Diabetic foot ulcers; surgical and non-surgical wounds	Wagner grade 2,3 29.6% infected area 13±18.2 cm^2 Duration 198±323 days	NPWT intervention group: 43.2% healed in 112 days Estimated median time to healing 96 days NPWT duration 63±36 days 90% occurred in home care Fewer secondary amputations

This observational audit involves a relatively small but specific cohort and it provides us with data on which we can compare clinical outcomes over time and presents an opportunity for comparison to other like services. We have identified two other published series using similar patients[13,14]. Both of these studies (Table 2) are large RCTs, the first by Armstrong *et al.*[13] and the latter by Blume *et al.*[14]. Both studies compared healing rates and time to healing of NPWT with standard wound therapy on diabetic foot wounds with a higher proportion achieving healing and at more rapid rates in the NPWT intervention groups. Our patient cohort was similar to these two studies with regard to age, gender, diabetes duration as well as wound grading and size, noting particularly that the majority of wounds were large and deep with either tendon or bone exposed. We could not compare our results with a historic in-house control group as most post-surgical wounds of this size and complexity were previously managed by the surgical teams in an inpatient setting.

In the Armstrong *et al.* study, 56% of wounds healed within 112 days compared with Blume *et al.*, which reported 43% healing within the same time point. Our results compare well with the intervention group in the RCTs with the majority (79%) of wounds in our series healing in less than 16 weeks. Our higher rate of healing could possibly be attributed to the wound duration prior to the application of NPWT. In our audit all wounds were considered acute following surgical intervention, with NPWT commenced in a median time of two days postoperatively, compared to the longer duration and more chronic nature of the wounds in the RCTs. The number of adverse events and long-term outcomes were similar with no major adverse events, fewer secondary amputations and fewer major amputations[13,14].

Whilst we have not looked directly at cost-effectiveness and resource utilisation for NPWT versus standard wound care, there have been a number of studies supporting lower overall costs and a greater proportion of wounds healing in the NPWT groups[22,23]. The average cost of treatment for each patient in our group was just over $3000, for rental of the device and the dressing consumables based on our median use of 31 days. A clinician's clinical time spent performing dressing changes can be variable, based on individual experience and the wound's location (owing to the difficulty in obtaining a closed seal on the foot) as may the frequency of dressing changes that are required each week, which typically occur every 48–72 hours. The need for tightly coordinated care between services, service providers and the patients themselves is paramount. This is foremost when treatment is to continue in the home care setting. In our district, this is facilitated by standardised forms for clinical handover that are used across services such as the inpatient, HRFS and community nursing services.

CONCLUSION

NPWT is often used in our service for the management of complex, post-surgical wounds. Our results are encouraging, with close to 80% achieving complete wound closure in less than 16 weeks and with a low rate of secondary intervention and major amputation. While many factors may influence this result, the increasing use of NPWT is supported in this setting. To our knowledge, this is the largest Australian audit addressing NPWT in people with diabetes, and publication of this data will help to facilitate an Australian benchmark on the healing outcomes of complex, post-surgical, diabetes-related foot wounds treated with NPWT.

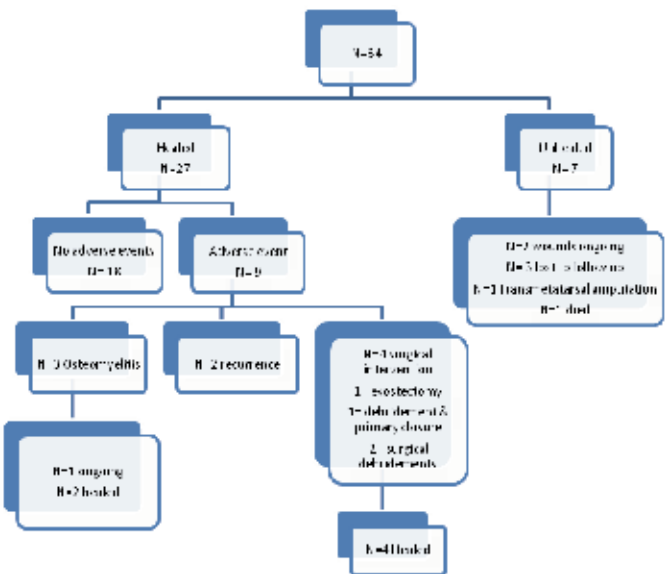

Figure 4: Results of the study

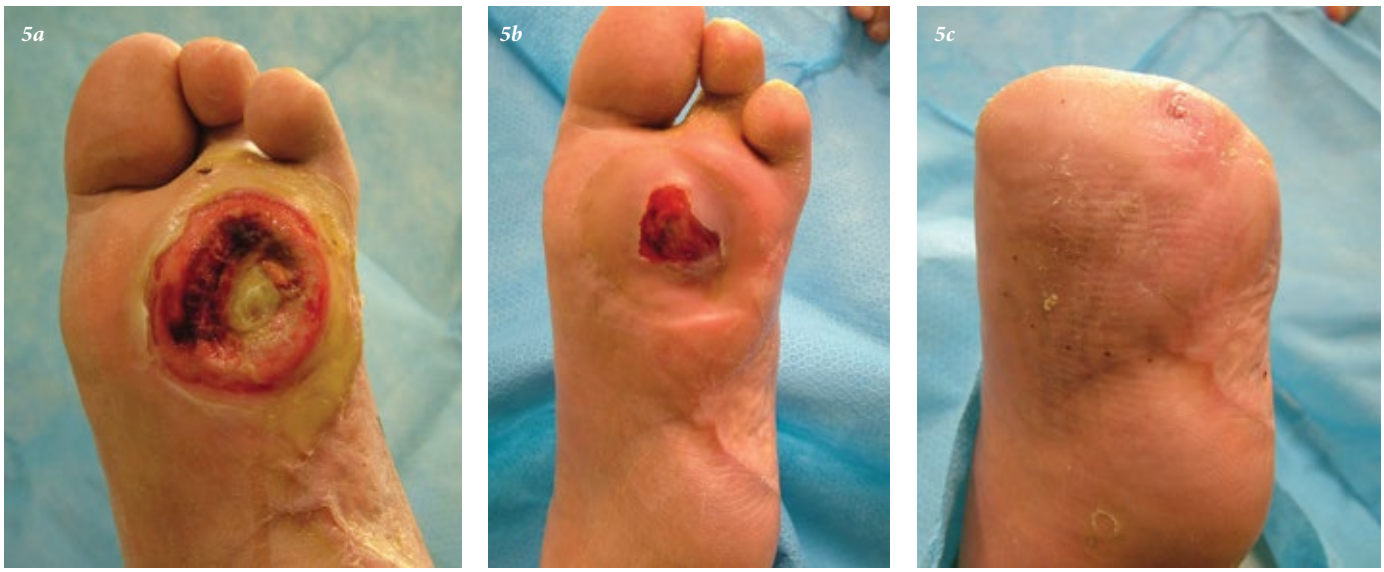

Figure 5 (a,b,c) Illustrates a post-surgical wound in a patient included in the audit, whose ulcer was surgically debrided with the intention of utilising NPWT to achieve wound closure, before proceeding with a planned and considered transmetatarsal amputation (TMA) that could be closed primarily. This staged approach aims to reduce surgical complications and future ulcer risk.

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