Use of NPWT with and without Soft Port technology in infected foot wounds undergoing partial diabetic foot amputation

• **Objective:** Negative pressure wound therapy (NPWT) has previously been shown to be effective in closing diabetic foot wounds that have undergone amputation over a 16-week period. For patients with plantar foot wounds, NPWT is a key therapy. An alternative NPWT with and without a novel soft, flexible port system needs to be evaluated for its comparable efficacy. Our objective was to show the non-inferiority of an alternative negative pressure system, and in a small subset, a novel foam dressing system.
• **Method:** We performed a single centre prospective study of patients with diabetes undergoing open bone resection in the foot for acutely infected wounds. Wounds were treated with NPWT/soft port technology (SPT), for 112 days or until primary closure or the wound was deemed ready for delayed primary closure. Rate of closure and quality of life were analysed. A previously published cohort was used as a control.
• **Results:** Of the 30 patients initially recruited, 29 met eligibility requirements and had NPWT applied a median of 2 days postoperatively. There were seven patients (24%) who had delayed primary closure (mean=58 days) and 52% had sufficient progress to change in treatment (15/29; mean=62 days). Only one patient reached the 112-day mark without sufficient progress to be closed. The primary method of delayed primary closure was split-thickness skin graft. There was a reduction in wound area 56.3% (initial mean area=17.4cm^2 to final mean area=7.6 cm^2; p=0.001) at the end of treatment (mean=58.7 days) reduced to 4.3cm^2 a 67.2% reduction (p=0.004) at the end of study (112 days).
• **Conclusion:** The alternative NPWT and the soft port technology was well tolerated and effective in the population in aggregate. There was no inferiority between the two technologies. The aggregate closure or progression to be ready for closure rate of 75% at 69 days compares very favourably with previously published data for NPWT in this population of 56% at 56 days (range: 26–92 days). Both cohorts did significantly better than previously published standard of care closure rates of 39% at 77 days.

• **Declaration of interest:** J.C. Lantis is a paid consultant for Smith & Nephew, Acelity, Macrocure and Manukamed. This trial as supported by an institutional grant to St Luke's and Roosevelt Hospital sponsored by Smith & Nephew. The outcome of the trial had no bearing on the condition of the grant. No investigator holds an equity position in Smith & Nephew. C. Gendics is a paid consultant of Acelity.

negative pressure wound therapy; chronic wounds; pressure ulcers; diabetic foot ulcers; amputation

J.A. Schwartz,[1] MD, Tissue Healing and Wound Repair Fellow; **A. Fuller**,[1,2] Clinical Research Assistant; **E. Avdagic**,[1,2] Clinical Research Assistant; **C. Gendics**,[2] RN, CCRC Senior Clinical Research Coordinator; **J.C. Lantis**,[1] MD, Vice Chairman Department of Surgery, Chief of Vascular/Endovascular Surgery

Continued page S6

In the last decades, many studies have demonstrated the efficacy of negative pressure wound therapy (NPWT) in the management of challenging lower extremity wounds. In particular, Armstrong and Lavery carried out a randomised controlled trial (RCT) to investigate the effects of NPWT compared with the standard of care on complex partial foot amputation wounds in patients with diabetes. While not well defined in the paper, most of these patients must be thought to have had an infection. There were 162 patients enrolled in the 16-week study, with 77 patients in the NPWT treatment group[1]. Those receiving NPWT demonstrated increased complete closure versus patients receiving standard wound care (SWC) (43 (56%) versus 33 (39%), respectively p=0.04). In addition, the NPWT group was superior to SWC in time to achieve complete closure, with median time to closure being 56 days (range: 26–92) versus 77 days (range: 40–112; p=0.005), and the rate of formation of granulation tissue, (42 days (range: 40–56) versus 84 days (range: 57–112; p=0.002). The frequency and severity of adverse events were similar in both treatment groups, although the number of patients who underwent a secondary amputation was higher in the control group.[1]

McCallon et al. compared the use of NPWT with saline-soaked gauze to facilitate wound closure in a small pilot study of 10 postoperative diabetic foot wounds. The endpoint was time taken to achieve

Table 1. Comorbidities of enrolled patients (n=29)

Medical condition	Current (%)	Prior (%)	None (%)
Anaemia	9 (31.0)	1 (3.4)	19 (65.5)
Stroke (cerebral vascular accident)	0	2 (6.9)	27 (93.1)
Hypertension	25 (86.2)	0	4 (13.8)
Peripheral vascular disease	21 (72.4)	0	8 (27.6)
Congestive heart failure	3 (10.3)	0	26 (89.7)
Rheumatoid arthritis	0	0	29 (100)
Osteoathritis	0	0	29 (100)
Others	9 (31.0)	1 (3.4)	19 (65.5)

1. St. Luke's-Roosevelt Hospital Center, New York, US
2 Mount Sinai, St Luke's New York, NY 10025

Email: jlantis@chpnet.org

complete wound resolution, defined as closure by secondary intention or by delayed primary closure. Satisfactory healing in the NPWT group was achieved in 22.8 (standard deviation (SD) 17.4) days compared to 42.8 (SD 32.5) days in the control group. The NPWT group demonstrated an average decrease of 28.4% (SD 24.3) in wound size compared to an average increase of 9.5% (SD 16.9) in the control group.[2]

As the use of NPWT has widened, novel devices aimed at improving the acceptability or delivery of this therapy have been produced. To provide clinicians with scientific evidence to use these newer devices, we believe it is important to demonstrate their efficacy compared with existing NPWT systems. While some systems look very like the traditional set-up and others are self-powered, they should all be tested against the standard of care.

The aim of this study was to determine the clinical efficacy of an alternative NPWT system in post-surgical open diabetic foot amputation wounds. In addition a new, softer and more flexible connection for the tubing which exits the wound was incorporated in a portion of the evaluation. To have an adequate comparator, this study specifically mimics the inclusion and exclusion criteria and endpoints of the Armstrong and Lavery partial foot amputation paper.[1]

Materials and methods

A prospective evaluation of a new NPWT device was undertaken, with the Armstrong and Lavery cohort used as a control group.[1] Even though it was 10 years ago, the SWC arm has not significantly changed compared with the SWC as practised now. A 112-day prospective, non-randomised clinical evaluation was performed to determine the clinical efficacy and cost-effectiveness of a newer NPWT system (Renasys Go, Smith & Nephew, Largo FL, US) in reducing the surface area of a diabetic foot ulcer immediately following operative resection of soft tissue and bone.

The patients were recruited at a single tertiary care wound care program. After the first 20 patients the subsequent 9 patients were treated with the Renasys system using a Soft Port connection between the wound and the canister (Smith & Nephew, Largo, FL, USA). The Soft Port technology fundamentally works as a bridge type of dressing, taking any hard port structures off the foot. This allows for better use of accommodative footwear as well as potentially better flexibility down the leg. Initial pressure settings were at −120mmHg and continuous.

The quality of life (QoL) analysis was performed using a short-form health survey (SF-36), keeping track of the patients' health and wellbeing at the initial screening assessment and at the 112-day follow-up. The SF-36 health survey includes eight sections of questions, with a total score of 1–100, and includes analysis of physical functioning, role limitations due to physical health, role limitations due to emotional problems, energy and fatigue assessment, emotional wellbeing, social functioning, pain, and general health evaluation. A score of 100 represents the highest possible level of functioning.

All patients underwent an informed consent process as outlined in the declaration of Helsinki. The protocol and informed consent process was reviewed and approved by the local institutional review board.

Eligibility criteria

Inclusion criteria were: ≥18 years of age, must not be pregnant or lactating if female and of childbearing potential, the presence of an acute diabetic foot amputation wound (≤8 days old) distal to the transmetatarsal level of the foot, and evidence of adequate perfusion in the affected extremity (defined as ankle-brachial pressure indices (ABPI) ≥0.7 and ≤1.2 and/or ankle Doppler velocity wave form analysis having normal, triphasic, or biphasic waveform pattern). Moreover, we only included patients with an HbA_{1c} ≤12% within 90 days of screening visit and adequate nutrition (defined as pre-albumin level of ≥16mg/dl or an albumin level of ≥3g/dl within seven days of screening) to allow for adequate wound healing.

Study design

All patients underwent surgical debridement and resection of the affected part of their foot and application of NPWT occurred within eight days of bone resection. NPWT was started a mean of 2.5 days (median: 2 days, range: 0–5 days) after surgical resection. There was no difference in the time to application between port types. The NPWT was changed three times per week as per the manufacturer's guidelines and in accordance with the investigators' clinical judgement. The number and frequency of postoperative dressing changes were recorded. There were a were a minimum of nine study visits between the first treatment visit and the day 112 of therapy.

Confirmation of wound closure was made by an independent blinded physician who reviewed images of the patients' wounds. Wound area and depth were

measured using tracing sheets and a depth probe. Wound volume was estimated as reference wound area x reference wound depth.

Objectives and wound evaluation

The primary outcome was measured as the time taken (days) to achieve complete wound closure, with closure defined as '100% re epithelialisation without drainage or dressing requirements.' This endpoint is aligned with previous trials, allowing us to compare our cohort with others.

Secondary but perhaps more practical surrogate endpoints were assessed, including:

- The number of NPWT therapy days required to achieve sufficient progress to allow for delayed primary closure or to warrant a change in treatment
- The number of patients achieving complete wound closure
- The number of patients undergoing delayed primary wound closure (defined as 'wound closure by split-thickness skin graft, myocutaneous flap, or suture closure by surgeon').

Statistical methods:

Statistical analysis was performed with version 9.1.3 SP4 of the SAS software package (SAS Institute, Cary, NC). A Kaplan–Meier estimate was used to separately calculate the median time to achieve complete wound closure and the median time to achieve primary wound closure, warrant a change in treatment or achieve complete wound closure by secondary intention. The corresponding 95% confidence interval (CI) is also presented in each case.

The marginal homogeneity test, stratified by patient, was used separately to test for reductions in exudate level between baseline, treatment discontinuation and end of study. The Wilcoxon signed-rank test was used separately to test for a difference in reference wound dimensions, including area, depth and volume, between baseline, treatment discontinuation and end of study. The Wilcoxon signed-rank test was used to test for a difference in the percentage of granulation tissue and healthy tissue between baseline and, treatment discontinuation and end of study. All data was summarised using frequency distributions and summary statistics, and 95% CIs were generated where appropriate. All significance tests were two-sided. The Soft Port sub group was compared across all parameters to the traditional subgroup.

Results

Patient and wound demographics

A total of 29 patients, 23 (79.3%) males and 6 (20.7%) females, were enrolled from 27 July 2010, with the final patient completing the trial on 7 June 2013. The original port was used with 20 patients and 9 were treated with the soft flexible port system The mean patient age was 59.3 years (range: 36–84 years).

Table 2. Location of partial amputation (n=29)

	Number (%)
1st metatarsal	9 (31.0%)
2nd metatarsal	2 (6.9%)
4th metatarsal	1 (3.4%)
5th metatarsal	7 (24.1%)
Transmetatarsal	3 (10.3%)
2 rays	1 (3.4%)
Other	6 (20.7%)

The mean patient body mass index (BMI) was 29.3kg/m^2 (range: 20.0–48.1kg/m^2). Of the patients recruited, four (13.8%) patients were active smokers, nine (31.0%) were previous smokers, and 16 (55.2%) had never smoked; 24 patients (82.8%) had type 2 diabetes, while five (17.2%) had type 1 diabetes. Previous amputation of the contralateral foot had taken place in 19 (65.5%) patients, while the remaining 10 (34.5%) patients had no history of amputation (Table 1).

The reference wound type and surgical procedure required for all patients can be seen in Table 2. The median duration from amputation to placement of the NPWT device was 2 days (range: 0–5 days). The median reference wound area was 17.4cm^2 (mean: 22.8cm^2, range: 3.3–67.7cm^2). The median reference wound depth was 14.5mm (mean: 15.6mm, range 3.3–33.3mm) and the median reference volume was 23.1cm^3 (mean: 31.2cm^3, range: 5.0–108.3cm^3). The levels of exudate among patients varied; no exudate

Table 3. Clinical signs of infection

	All patients (n=29)
Any sign of infection	**28 (96.6%)**
Wound static or deteriorating	18 (62.1%)
Increased exudate/secretion levels	7 (24.1%)
Increased pain	10 (34.5%)
Increased temperature around the wound	1 (3.4%)
Discolouration of granulation tissue	8 (27.6%)
Friable granulation	3 (10.3%)
Tissue necrosis	6 (20.7%)
Local erythema	23 (79.3%)
Oedema	25 (86.2%)
Purulent drainage	1 (3.4%)
Dehiscence	0
Odour	2 (6.9%)
Other	2 (6.9%)
Reference wound clinically infected	26 (89.7%)

Table 4. Final wound closure method

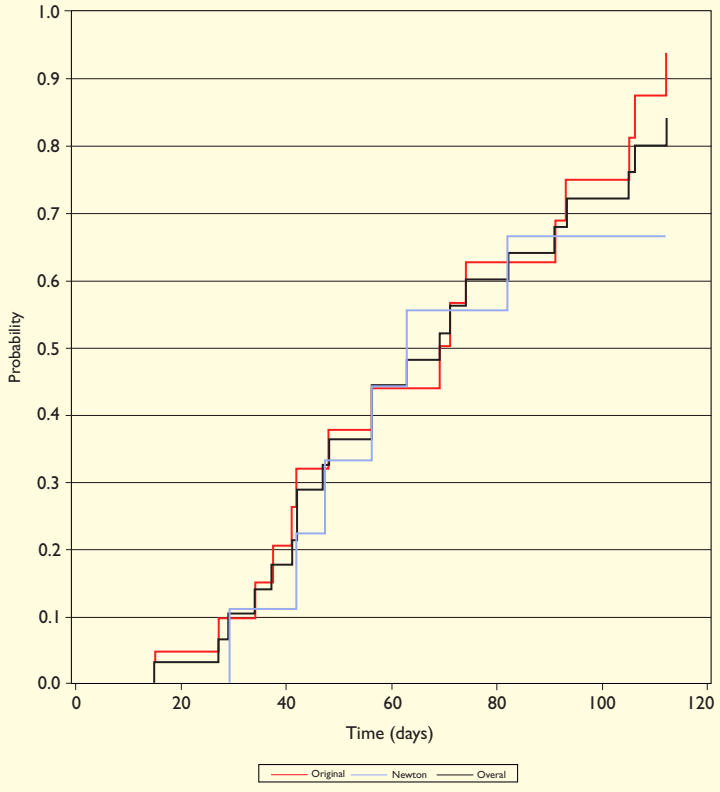
Wound closure status	All patients (n=29)
Wound closed (see wound closure method)	7 (24.1%)
Sufficient progress to warrant a change in treatment (see planned treatment until closure)	15 (51.7%)
Wound not closed	7 (24.1%)
Wound closure method	
Split-thickness skin graft	6 (20.7%)
Primary intention	1 (3.4%)
Planned treatment until closure	
Hydrogel	2 (6.9%)
Enzymatic debridement agent	1 (3.4%)
Santyl Collagenese	2 (6.9%)
Dakins wet to dry	1 (3.4%)
Other	4 (13.7%)

was seen in two (6.9%) patients, light exudate in 14 (48.3%) patients, and moderate exudate in 13 (44.8%) patients.

Baseline reference wound pain was measured on a scale of 0–9 (0 being no pain) and the median level of pain recorded on the scale was 5 (mean: 4.0, range: 0–9). Initial assessment occurred in the hospital in 26 (89.7%) patients, while the remaining three (10.3%) patients were treated in the outpatient setting. Debridement was required at the initial assessment before NPWT application in 13 (44.8%) patients. The median percentage of granulation tissue at the initial assessment was 80% (mean: 76.9%, range: 0–100%). The median percentage of non-viable tissue at initial assessment was 10% (mean: 13.3%, range: 0–50%). The median percentage of healthy tissue (red granulation and pink epithelial tissue) recorded at initial assessment was 15% (mean: 30.7, range: 0–100%).

Clinical signs of infection noted at the initial assessment can be seen in Table 3, where 28 (96.6%) patients had one or more clinical signs of infection and 26 (89.7%) patients had a clinically infected reference wound. All 29 were treated with systemic antibiotics.

Fig 1. Kerier Myer plot of time to facilitate primary wound closure, warrant a change in treatment or achieve closure by secondary intention



Primary endpoint analysis

Delayed primary closure occurred in seven patients (24%) (mean: 58 days; median: 47 days; range: 34–112 days). At a mean of 62 days (median 56; range: 15–106 days), there were 15 patients (52%) who had sufficiently progressed to lead to a change in treatment from NPWT to another advanced wound dressings or therapy. Only one patient (3.4%) reached the 112-day mark without sufficient progress to be closed and six patients (20.7%) had early discontinuation of treatment in the study at an average of 51 days (median: 53; range: 28–78 days). The reasons for early discontinuation were non-adherence to the therapy (one patient), insufficient progress (one patient) and exposed bone that went to surgery (one patient). The true median estimate of the time needed to achieve complete closure could not be calculated due to the small number of patients (n=7, 24.1%) who achieved complete wound closure during the study period. This was not surprising given the fact that primary wound closure is not the main purpose of NPWT.

Table 4 demonstrates details regarding wound closure at treatment discontinuation. The methods used to achieve wound closure following discontinuation of NPWT were as follows: split-thickness skin graft (n=6, 20.7%) and primary intention (n=1, 3.4%). Reasons for failure of wound closure included: failed graft (n=1, 4%), wound dehiscence (n=1, 4%), and wound infection (n=3, 12%). The remaining 15 patients (60%) had either failed wound closure due to only partial take of a skin graft or they were in the process of progressing towards wound closure. However, in all cases there was significant decrease in the size of the wound. Given that all wounds started as infected, this appears to be an appropriate surrogate clinical endpoint. For wounds with a skin graft that were not completely closed (n=4) at the 112-day fol-

low-up, the median percentage graft was 85% (mean 77.5%, range 50–90%). These results must be evaluated in the setting of wounds that came to the hospital necessitating immediate surgery, and at least 14 days of postoperative antibiotics.

Secondary endpoint analysis

The length of time it took for primary wound closure was 69 days (Kaplan-Meier estimate). The corresponding 95% CIs for the median estimate were 47–91 days. There were 22 (76%) patients who achieved a combined assessment of either primary wound closure, wound bed preparation warranting a change in treatment or complete wound closure by secondary intention by the end of the study (Fig 1). Similar estimates were observed between both original and the soft flexible port system.

Change in wound area

At initial assessment, the median area of the reference wound was 17.4cm^2 (mean: 22.8cm^2, range: 3.3–66.7cm^2), while at treatment discontinuation it was 7.6cm^2 (mean: 15.9cm^2, range: 1.7–66.1cm^2). The resulting median percentage reduction in area was 39.5% (mean: 12.9%, range: −593.9–90.5%; p=0.001). This result signifies a median percentage area reduction per week of 6.0% (mean −1.1%, range: −148.5–14.2%). At the end of the study, the median area of the reference wound was 4.3cm^2 (mean: 11.3cm^2, range: 0–66.1cm^2). The resulting median percentage reduction in area between initial assessment and study discontinuation was 67.2% (mean: 5.0%, range: −752.4–100%; p=0.004).

Change in wound depth

The median depth of the reference wound at the initial assessment was 14.5mm (mean: 15.6mm, range: 3–33.3mm) while at treatment discontinuation it was 4mm (mean: 6.1mm, range: 0–22.3mm). The resulting median % depth reduction between initial assessment and treatment discontinuation was 64.0% (mean: 56.7%, range: −133.3–100%; p<0.001). This resulted signifies a median % depth reduction per week of 8.4% (mean: 9.4%, range: −22.2– 28.7%). At the end of the study, the median wound depth was 3.5mm (mean: 5.5mm, range: 0–22.3mm). The resulting median % depth reduction between initial assessment and study discontinuation was 78.2% (mean: 58.4%, range −133.3–100%; p<0.001).

Change in wound volume

The median volume of the reference wound at initial assessment was 23.1cm^3 (mean: 31.2cm^3; range: 5.0 – 108.3cm^3), while at treatment discontinuation it was 2.8cm^3 (median: 9.8cm^3; range: 0–61.7cm^3). The resulting median percentage volume reduction between initial assessment and treatment discontinuation was 91.2% (mean 54.5%, range: −364.9–100%). This result signifies a median percentage volume reduction per week of 10.8% (mean: 7.3%; range: −91.2–33.3%; p<0.001). There was evidence of a significant reduction in reference wound volume between the initial assessment and treatment discontinuation (median: 79.8%; CI 61.3–92.4). At the end of the study, the mean volume of the reference wound was 1.1cm^3 (mean: 9.7cm^3; range: 0–61.7cm^3). The resulting mean percentage volume reduction between initial assessment and study discontinuation was 94.7% (mean: 24.9; range: −965.5–100). There was evidence of a significant reduction in wound volume between the baseline assessment and study discontinuation (median: 91.0%; CI 73.1–96.0; p= 0.005).

Change in tissue type in the wound bed

In our study, an insufficient number of patients fit criteria to allow for a median analysis of the above parameter. However, we did observe an increase in the percentage of healthy tissue (pink epithelial tissue and red granulation tissue) between initial assessment (median: 15%; mean: 30.7%; range: 0–100%) and treatment discontinuation (median: 57.1%; mean: 70%; range: 0–100%); this increase was significant (median 30%, 95% CI 7.5–57.5%; p=0.016). This was a relatively subjective analysis, as there is not a reproducible granulation score, and the score was based on visual assessment of the non-blinded evaluator. However it should be noted that none of the patients started out with any granulation tissue and therefore any change was clinically noticeable.

Incidence of foot salvage

Foot salvage was defined as the ability to retain the amputation level at a minor level (a trans-metatarsal amputation or more distal amputation). Of the 20 patients with wounds not completely closed at assessment day 112 of follow-up, 17 (89.5%) patients had no complications or re-amputations, two (6.8%) patients underwent re-amputation or minor amputation and one patient had a left first ray amputation; this patient discontinued treatment on day 14 due to sufficient progress allowing for a change in treatment modality. After discontinuing treatment on day 42, because of sufficient progress to change the treatment modality, one (3.4%) patient underwent transmetatarsal amputation with skin flap closure. Finally, one (3.4%) patient had severe osteomyelitis which resulted in a right below knee amputation. The incidence of limb salvage was 96.6% in this high-risk cohort.

Complications

Complications assessed included wound-related hospital readmission, wound-related delayed hospital discharge, wound-related surgical procedure, and wound-related infection.

- **Wound-related hospital admission** There were five hospital admissions in the entire 32 patients evaluat-

ed for enrolment. Three were related to the study wound and two were unrelated to the study wound for pneumonia and respiratory failure that led to death. The three wound-related admissions were for: worsening ipsilateral peripheral artery disease (which made the patient acutely ineligible for NPWT), acute injury to the non-study foot resulting in partial amputation, and osteomyelitis related to the wound resulting in below-knee amputation. These three patients were not analysed in the intent to treat analysis as their peripheral arterial disease was too severe for inclusion.

• **Wound-related infection** Clinical diagnosis of wound infection, at the initial assessment (application of NPWT) or at a minimum of one follow-up assessment, was observed in 24 (82.8%) patients. Only two (6.9%) patients were given a clinical diagnosis of infection after having an initial assessment where they were considered non-infected. The minority of patients, 8 (27.6%), had no clinical signs of infection at initial assessment or at end of treatment, while the majority, 21 (72.4%), were clinically infected at baseline. In the latter group, all eventually resolved and there were no infections at the end of treatment. All patients underwent resection of infected tissue—with positive culture data and suppurative foot infections being the reason for resection.

Change in the patient's quality of life

The changes observed in each of the eight categories, between the initial assessment and the end of the study, are shown in Table 5. The categories shaded in turquoise demonstrate an increase in patient wellbeing, while those highlighted in cream remained constant. Although there were a number of categories where an increase was observed, the only category where the patient's health had improved by a noteworthy amount was in the 'pain' category. The remainder of the categories demonstrated either an improvement by a negligible amount or no change. On average, no patients' health deteriorated in any of the categories.

Discussion

The fundamental goal of this research was to replicate the study performed by Armstrong and Lavery,[1] analysing the use of a similar NPWT device with a novel soft and flexible connection, with acutely infected wounds as this is typical of the patients referred to our unit. We opted to use a smaller non-comparative patient cohort to allow for easier accrual, more detailed wound assessments and better QoL assessments than in previous NPWT papers.

The primary endpoint in their study was complete wound closure, while secondary endpoints included foot salvage and treatment-related complications. By comparison, their study would be clinically extrapolated to include wounds that started with acute infection as well. However, their endpoints were different and the size of the study precluded detailed analysis.[1] Therefore, we include more detail in regards to method of closure, rate of closure and QoL.

In the Armstrong and Lavery trial, the percentage of patients that had wound closure at the end of the 112-day treatment period was 56% versus 39% for control.[1] We saw a total of 7 (24.1%) patients achieved primary wound closure at time of discontinuation of NPWT; although this is perhaps unsurprising given their wound infection status at recruitment. Most providers of care for patients with diabetic foot complications do not use NPWT to achieve complete wound closure, and we would argue that complete wound closure is not the correct endpoint for a NPWT trial. In the 'real-world' clinical setting, the primary use of NPWT is for wound-bed preparation before another treatment strategy for wound closure. With this real-world application in mind, in our study an additional 15 (52%) patients had sufficient progress leading to a change in treatment and were closed by a variety of other strategies including; skin grafting, topical growth factor application and placement of biologic skin equivalents. Therefore, at the end of the study period we had a total closure rate of 76%. It is interesting to note that, when NPWT was applied within 2 days of resection for diabetic foot infection and followed later by application of advanced closure

Table 5. Change in quality of life (QoL) category score

QoL category	Mean	Median	Min	Max	n
Physical functioning	1.5	0	-47.8	90	26
Role limitations due to physical health	15	0	-100	100	25
Role limitations due to emotional problems	24	0	-100	100	25
Energy/fatigue	7.1	5	-35	50	25
Emotional wellbeing	8.6	4	-28	56	25
Social functioning	-1.9	-6.3	-75	62.5	26
Pain	17.3	12.5	-42.5	77.5	26

techniques, as deemed appropriate, there was a higher closure rate and a shorter duration of NPWT use than in previously published papers (69 days versus 112 days, 75% versus 56% closure rate, both of which are better than moist wound care alone which showed a 39% closure rate).[1]

The Armstrong and Lavery trial was notable for two other points. First, patients who were treated with NPWT did not undergo any major amputations. Second, there was a higher than expected infection-related complication rate. Interestingly, the moist wound therapy group when compared with the NPWT group had a significantly higher number of secondary minor amputations, 3% in NPWT and 11% in the control group (p=0.06). In addition, the NPWT group when compared with the control group had a significantly lower rate of major (defined as above the ankle) amputations (0% in NPWT versus 6% in control; p=0.06).

On the other hand, because nearly all of our patients started the trial with a clinically infected diabetic foot wound (82.8%), only 6.9% of patients who were not initially infected at baseline, became clinically infected. In our study, the majority of patients had resolved their infections by the end of NPWT use. Armstrong and Lavery a showed a higher percentage of patients (17%) developing lower extremity related infections in the NPWT group than in the control group (6%). As there is unlikely to be any substantial differences between different NPWT units based on published evaluations[3], it suggests that our practice might be to stop NPWT at an earlier point when wound-bed preparation is complete and move to alternative means of closure. It may be that prolonged NPWT invites subsequent infection.

The physiologic response of the wound to NPWT and the % rate of closure has only been documented in one study.[4] The study focused on the fact that the majority of the wound volume reduction, quoted as 66%, seen with NPWT is derived from wound depth reduction. We believe that our study is also useful in documenting the rate at which wound closure can be expected when using NPWT. Specifically, we showed that during a median wear time of 69 days, the wounds decreased in area by a median of 39.1% (6% per week) and the wound depth decreased by a median of 64.8% (8.4% per week). Therefore, NPWT had the greatest impact on total wound volume with a 79.8% total reduction or a reduction in wound volume of 10.8% per week. We believe that knowing these statistics are helpful to answer patient's questions and addressing their expectations as to the anticipated time of wound closure, inquiries often asked of treating physicians.

It was somewhat surprising to us that the patients' QoL did not change significantly as their wounds improved. On the other hand, suffering with anatomic deformity and gait abnormalities, as well as recognising their advanced diabetes status and need for long-term accommodative footwear, may have played a role in their dissatisfaction and disappointment. Improvements of pain level, were recognised and appreciated. Of note, the soft and flexible port technology, which was a portion of this study, did not have a positive or negative clinical impact on the patients' outcomes when compared across parameters to the traditional system, but it was deemed more accommodative to footwear and more desirable by the patients and clinicians on subjective criteria.

Limitations

This study certainly has limitations in regards to its size which is certainly not pivotal, but large enough to generate non-inferiority data. In addition, it uses a known control cohort that is historic in nature, and it could be argued too historic in nature. On the other hand, it does collect all data prospectively and in general is more detailed than a larger study. It is also potentially skewed as it took place in a very ethnically diverse urban setting, which may not translate to other populations. It is also subject to the biases associated with single centre studies.

Conclusion

It appears that a different NPWT system, with or without a soft and flexible patient connection applied to surgically resected diabetic foot wounds showing clinical signs of infection, demonstrated equivalent results to a previously published trial.[1] It appears that evaluating progression of tissue type within the wound bed, especially progression to healthy granulation tissue that allows for a change in therapy, is the most effective way of using NPWT, rather than maintaining negative pressure with a goal of second intention closure. ■

References

1 Armstrong, D.G.,Lavery, L.A. for the Diabetic Foot Consortium. Negative pressure wound therapy after partial diabetic foot amputation: a multicentre, randomised controlled trial. The Lancet 2005; 366: 9498, 1704–1710.

2 McCallon, S.K., Knight, C.A., Valiulus, J.P. et al. Vacuum-assisted closure versus saline-moistened gauze in the healing of postoperative diabetic foot wounds. Ostomy Wound Management 2000; 46: 8, 28–32, 34.

3 Rahmanian-Schwarz, A., Willkomm, L-M., Gonser, P. et al. A novel option in negative pressure wound therapy (NPWT) for chronic and acute wound care. Burns 2012; 38: 4, 573–577.

4 Joseph, E., Hamori, C.A., Bergman, S. et al. A prospective randomized trial of vacuum-assisted closure versus standard therapy of chronic nonhealing wounds. Wounds 2000;12: 3, 60–67.