Use of the Prevena™ Vacuum Assisted Closure (VAC) for non-traumatic lower-extremity amputations — a pilot study

Wound infection rates for major lower-extremity amputations (LEA) for end-stage peripheral vascular disease can be as high as 30%. Negative pressure wound therapy (NPWT) has been used to assist wound healing of open wounds and is well known to improve healing rates and prevent infective complications. The PREVENA™ Incision Management System (KCI Medical, Singapore) protects the incision from external contamination, helps hold incision edges together, removes fluid and infection materials and delivers continuous negative pressure at approximately -125mmHg for up to seven days. The authors believe it is feasible to apply NPWT directly to closed incisions of major LEA sites in order to prevent or minimise surgical site infections (SSI). This 20 patient pilot study aims to see if this device can reduce our SSI rate following major LEA.







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Wound infection rates for major lower-extremity amputations (LEA) for end-stage peripheral vascular disease can be as high as 30% (Wu et al, 2010). This constitutes a major burden of morbidity and potential mortality because vascular surgical patients are often frail and elderly and have significant comorbidities such as chronic renal failure and diabetes. These factors contribute to poor wound healing and subsequent surgical site infections (SSIs) (Kalish et al 2014; Turtiainen et al, 2014). This is especially pertinent for major lower-limb amputations, which often require long incisions on patients who may have poor nutritional status and are operated on as emergency cases. Negative pressure wound therapy (NPWT) has been used to assist wound healing of open wounds and is well known to improve healing rates and prevent infective complications (Tanaka and Hakala, 2014). Postulated mechanisms for this include increased wound blood flow, increased granulation tissue formation, decreased bacterial counts, and stimulation of wound healing pathways through shear stress mechanisms (Thompson and Marks, 2007). NPWT involves a piece of foam applied over the incision, an adhesive drape, and an electric-powered device that places negative pressure on the wound. The PREVENA™ Incision Management System (KCI Medical, Singapore) protects the incision from external contamination, helps hold incision edges together, removes fluid and infection materials and delivers continuous negative pressure at approximately -125mmHg for up to seven days (KCI, 2016). Previously, such NPWT systems have been successfully used in cardiothoracic surgery to prevent sternal wound infections (Colli, 2011) as well as in incision management in colorectal surgical procedures (Chadi et al, 2015). Other studies have demonstrated the beneficial effects of using NPWT in vascular surgical procedures, including bypass incisions and femoral vascular access (Sabat et al, 2016; Strugala and Martin, 2017).

The authors believe it is feasible to apply negative pressure wound therapy directly to closed incisions of major lower limb amputation sites in order to prevent or minimise SSIs. Factors that have been associated with LEA revision include poor stump formation (37.5%), infection (25%), recurrent ulceration (18.8%), stitch abscess (6.3%), neuroma (6.3%) and pressure

necrosis (6.3%) (Kumar et al, 2015). Beaulieu et al (2015) noted that the main reasons for re-admissions included infection (49%), ischemia (29%), non-healing wound (19%) and indeterminate wounds (4%)

QI PROTOCOL

The authors are currently carrying out a single-centre pilot prospective single-arm QI project at the Department of Vascular Surgery at Singapore General Hospital. The authors' institution is a tertiary referral centre and the oldest restructured government hospital located in the centre of Singapore. Its Department of Vascular Surgery carries out over 900 lower limb revascularization procedures for critical limb ischaemia and around 200 LEAs, which include below-knee amputations (BKAs) and above-knee amputations (AKAs). Recent local audit data suggested that the SSI rate for LEAs is around 20%, which the authors considered too high. The authors' aim is to reduce this by 50% within the next year. Therefore, the authors have initiated this quality improvement (QI) project, which was approved by their hospital governance committee.

For the QI project, the authors intend to apply the VAC Prevena™ closed incision system to all patients who meet the inclusion criteria from November 2018 onwards. Twenty patients will be recruited for this pilot project as part of an initial feasibility study.

Inclusion criteria:

- Must be at least 21 years or older
- Closed incision of a non-traumatic BKA or Above Knee Amputation (AKA)
- Able to comply with VAC procedures and schedule.

Exclusion criteria:

- Traumatic amputations
- Surgical incision that is not completely closed or partially closed
- Patient has a contraindication to incisional negative pressure wound therapy such as poor skin condition or macerated wound edges.

PLANNED SURGICAL PROCEDURE

The surgeons are using Prolene 3/0 interrupted mattress sutures to close the incision tension-free. Immediately afterwards, while still in the operation theatre itself, -125mmHg negative pressure is applied on the closed skin incision *[Figure 1]*. To make sure that there is no leakage, the edges of the VAC dressing will be reinforced as necessary. Wound inspection of BKA and AKA incisions takes place on Day 5 post-operatively *[Figure 2–4]*. Drain removal (if needed) also takes place at Day 5 post-op unless there is a compelling indication to keep the drain in situ. The duration of antibiotic therapy is standardised to 7 days, unless the clinician

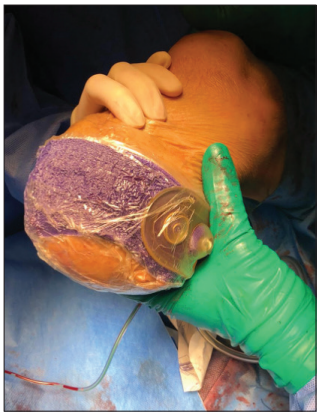

Figure 1. Application of VAC Prevena™ at after skin closure in the theatre on a BKA stump

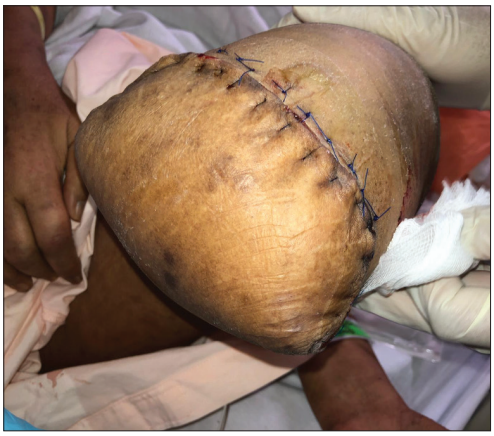

Figure 2. Patient A on first wound inspection on Day 5 following BKA and VAC Prevena™

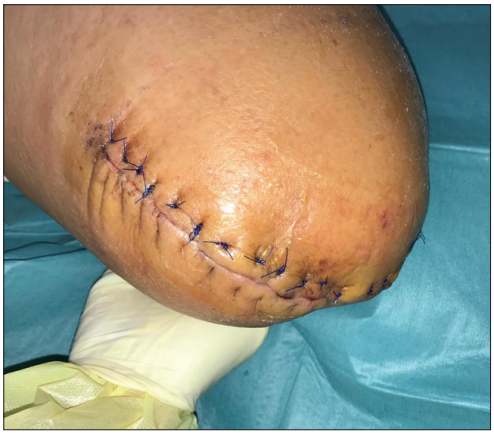

Figure 3. Patient B on first wound inspection on Day 5 following AKA and VAC Prevena™

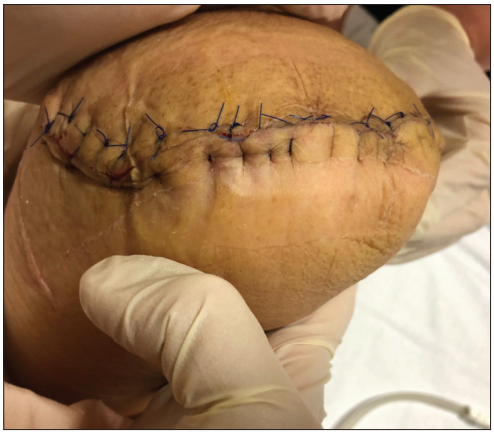

Figure 4. Patient C on first wound inspection on Day 5 following BKA and VAC Prevena™

in charge recommends that the patient may benefit from a prolonged course of antibiotics. The choice of antibiotics is determined by bacterial culture tests and the prescription of analgesia is left to the clinician's discretion. Suture removal for the incisions will be at 3 weeks after surgery, unless there is obvious dehiscence. Subsequent data collection will be done by the medical and podiatric teams using a standardised data collection form.

The following outcome measures will be measured:

Primary outcome measures:

- Reduction of the percentage of post-operative SSIs after major lower limb amputations, according to CDC classification of the Health Protection Surveillance Centre (2008).

Secondary outcome measures:

- Number of surgically-related wound re-admissions: the number of times patients are re-admitted to the hospital for their surgical wound infections post-discharge for a period of 90 days
- Percentage of incisions that remain closed at 30 days post-operatively
- Percentage of incisions that remain closed at 90 days post-operatively
- Percentage of individuals needing revision amputation at a higher level.

The outcome data will be collected by interviewer-based questionnaire.

PRELIMINARY DATA

To date, we have applied the VAC PrevenaTM System on eight patients who had major LEAs: four patients with a BKA and four patients with AKA as a result of peripheral vascular disease (PVD) and diabetic foot infection. Sadly, one of the patients succumbed to a non-ST segment elevation myocardial infarction at post-op Day 35. Of the seven remaining patients, one patient developed a SSI (Clavein Dindo classification 3) and required repeated wound debridement and washout. At a mean of 57.7 days follow up (range 30 to 90 days), the remaining six patients' wounds healed well and there were no hospital re-admissions for wound-related interventions. All eight patients noted a reduction in pain during the first week and seven patients were very satisfied with the dressing. One patient found it troublesome to sleep.

Generally, the authors noted there was minimal maceration and bruising of the surrounding skin after removal at Day 5 post-op.

CONCLUSION

While the initial results appear promising, the authors are awaiting the results of their QI project. As a future project, the authors hope to look at the cost-effectiveness of using the Prevena™ wound management system in the Asian population. WAS

References

Beaulieu RJ, Grimm JC, Lyu H et al (2015) Rates and predictors of readmission after minor lower extremity amputations. Journal of Vascular Surgery, 62(1): 101–5

Chadi SA, Vogt KN, Knowles S et al (2015) Negative pressure wound therapy use to decrease surgical nosocomial events in colorectal resections (NEPTUNE): Study protocol for a randomized controlled trial. *Trials* 16(1): 322

Colli A (2011) First experience with a new negative pressure incision management system on surgical incisions after cardiac surgery in high risk patients. *Journal of Cardiothoracic Surgery* 6: 160

Health Protection Surveillance Centre (2008) *CDC Definitions for Surgical Site Infection Surveillance.* Available at: https://www.hpsc.ie/az/microbiologyantimicrobialresistance/infectioncontrolandhai/surveillance/surgicalsiteinfectionsurveillance/casedefinitions/File,3058,en.pd (accessed 11.12.2018)

Kalish J, Farber A, Homa K et al (2014) Factors associated with surgical site infection after lower extremity bypass in the Society for Vascular Surgery (SVS) Vascular Quality Initiative (VQI) *J Vasc Surg* 60(5): 1238–46

KCI (2016) *The First Disposable Powered Negative Pressure System Designed Specifically for the Management of Closed Surgical Incisions.* Available at: https://www.acelity.com/products/prevena-incision-management-system (accessed 11.12.2018)

Kumar D, Singh S, Shantanu K et al (2015) Need of revision of lower limb amputations in a North Indian tertiary care centre. *Journal of Clinical and Diagnostic Research* 9(12): RC01-RC03.

Sabat J, Tyagi S, Srouji A, Pechman D, Gupta AM, Lucido D, Grossi R, Bernik T (2016) Prophylactic negative pressure therapy for femoral incision in vascular surgery: preliminary results of a prospective randomized trial. *J Vasc Surg* 63(6): 94S–95S

Strugala V, Martin R (2017) Meta-analysis of comparative trials evaluating a prophylactic single-use negative pressure wound therapy system for the prevention of surgical site complications. *Surg Infect (Larchmt)* 18(7): 810–9

Tanaka T, Panthee N, Itoda Y, Yamauchi N, Fukayama M, Ono M (2016) Negative pressure wound therapy induces early wound healing by increased and accelerated expression of vascular endothelial growth factor receptors. *European Journal of Plastic Surgery* 39(4): 247–56

Thompson JT, Marks MW (2007) Negative pressure wound therapy. *Clinics in Plastic Surgery* 34(4): 673–84

Turtiainen J, Hakala T (2014) Surgical wound infections after peripheral vascular surgery. *Scandinavian Journal of Surgery* 103(4): 226–31

Wu J, Chan T, Bowring G (2010) Functional outcomes of major lower limb amputation 1994–2006: a modern series. *Journal of Prosthetics and Orthotics* 22(3): 152–56