Use of the PREVENA™ Incision Management System in a very high-risk patient


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Initial studies using incisional negative pressure wound therapy demonstrated improved surgical site infection rates and led to the development of the PREVENA™ Incision Management System (Acelity, USA), which encloses the wound, preventing microbial contamination, an reduces tension around the closed incision reducing the chances of dehiscence. In this case study, PREVENA was successfully used to prevent surgical site infection following the excision of an abdominal wall fistula and abdominoplasty in a high-risk patient.

Aseptic surgical techniques and protocols are specifically employed to minimise the risk of surgical site infections (SSIs) (Berríos-Torres et al, 2017). A surgical incision creates a communication point between soft tissue and open viscera. When a SSI occurs it is typically the result of flora that occur naturally on the surrounding skin (Wiley and Ha'eri, 1979). The increased probability of complications at the surgical incision site are especially noted in high-risk patients, such as the morbidly or moderately obese, metastatic breast cancer patients undergoing chemotherapy, and those with advanced Alzheimer's disease (Riou et al, 1992).

Good clinical practice aims to minimise variables and improve SSI rates (World Health Organization, 2016). Optimal skin preparation, draping and gowning; clean closure of surgical incisions; controlling the patient's temperature; and a sound prophylactic antibiotic protocol are all key features of good clinical practice (Jolivet and Lucet, 2018). However, complications are still an unavoidable outcome for some patients (Anderson et al, 2008).

In recent years, surgeons have employed incisional negative pressure wound therapy (NPWT) as a tool for stabilising and maintaining the integrity of closed incisions and creating an optimal environment for healing (Stannard et al, 2006). The closed NPWT system creates a controlled environment around the surgical incision, minimising oedema at the incision site, and decreased the rate of SSIs and surgical dehiscence (Ingargiola et al, 2013).

History of incisional negative pressure wound therapy

Incisional NPWT was first introduced to provide a clean, dry wound environment in the immediate postoperative period (Gomoll et al, 2006). The V.A.C.® Therapy System (KCI, USA) was used to deliver continuous negative pressure to primarily closed incisions in areas with high rates of wound complications in 35 patients. GranuFoam™ (KCI, USA) dressing was applied intra-operatively to the closed incision in combination with Adaptic Touch™ dressing (Acelity, USA), which was applied as a non-adherent interface and was left *in situ* for 3–5 days. Gomoll and colleagues (2006) concluded that the practical and theoretical advantages of incisional V.A.C. Therapy would lead to better clinical outcomes.

A retrospective study in which patients were treated with incisional NPWT (n=235) or a conventional dressing protocol (n=66) found a significant reduction in the number of infections in patients treated with NPWT (Reddix et al, 2009). Dehiscence was only reported in the conventional dressing cohort (P=0.0414). A review of incisional NPWT and a case study series found that NPWT reduced surgical incision post-surgical complications and accelerated wound healing (Stannard et al, 2006). Results such as these led to the development of the PREVENA™ Incision Management System (Acelity, USA).

It must be noted that the incorrect application of foam dressings, the absence of a non-adherent interface layer and varied clinical experience in NPWT applications can result in unfavourable complications, such as bleeding, skin irritation, infection and delayed wound healing (Fagerdahl et al, 2012; Li and Yu, 2014). The development

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Box 1. Risk factors that may compromise wound healing (Riou et al, 1992).

- Age >65 years
- Wound infection
- Pulmonary disease
- Vascular disease
- Haemodynamic instability
- Ostomies
- Hypoalbuminemia
- Systemic infection
- Obesity
- Uraemia
- Hyperalimentation
- Ascites
- Hypertension
- Length and depth of incision
- Foreign body in the wound
- Anaemia
- Jaundice
- Diabetes (poor control)
- Active smoker
- Type of injury
- Radiation therapy
- Steroid use
- Malignancy

Figure 1. Mrs X underwent abdominoplasty to remove 11.5 kg of excess tissue.

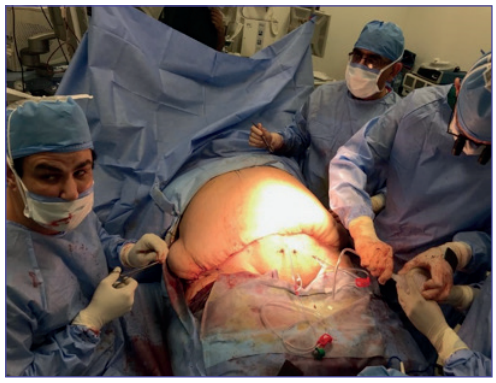

Figure 2. A 90 cm incision was made and drains placed distal to the incision.

of an application-specific incisional NPWT management system is, therefore, highly attractive.

Overview of the problem

An SSI is a bacterial infection that has occurred after surgery at the site of the incision (Horan et al, 1992). In the United Kingdom, SSIs are the third most common healthcare-acquired infection (National Institute for Health and Care Excellence, 2013). Across the European Union, SSIs equate to 19.6% of all healthcare-associated infections and cost an estimated EUR19bn per year (European Centre for Disease Prevention and Control, 2013).

Risk factors that may compromise healing are listed in *[Box 1]*. Typical incision management systems utilise multi-layer gauze bandaging as passive therapy; however, a preclinical study demonstrated that bacteria can migrate through 64 layers of gauze bandaging (Lawrence, 1994), which suggests a multi-layered gauze system may not be suitable. PREVENA addresses this issue by utilising a customisable dressing stabilised with a semi-occlusive drape that has passed the international standard bacteriophage penetration test (ASTM 1671-07). The exterior drape can act as a barrier to viral (as small as 27 nm) and bacterial sources of contamination, effectively creating a closed system around the wound (Lytle et al, 1990).

The application of -125 mmHg of negative pressure at the incision site with PREVENA reduces lateral tension around the suture line by approximately 50% (Wilkes et al, 2012). A sutured full-thickness wound simulated before and after PREVENA application demonstrated a reduction in lateral force about the suture line. Importantly, force vectors were realigned to those typically observed in uninjured tissue. PREVENA Therapy, therefore, effectively provides a bolstering effect that increases the force required to dehisce the edges of the incision compared conventional methods.

Studies using a porcine model have demonstrated that haematoma/seroma formation was significantly decreased (P=0.002) after 4 days of PREVENA Therapy (Kilpadi et al, 2011). The same study found an increased accumulation of colloids in selected lymph nodes following PREVENA Therapy compared to control sites treated with a semipermeable standard dressing, suggesting PREVENA may help improve lymph flow and long-term impact of therapy.

Overall, the results of preclinical studies suggest that PREVNA Therapy has excellent potential for use in incision wound healing and reduction of SSI rates.

Patient case

Mrs X, a 42-year-old woman, was admitted for the excision of an abdominal wall fistula and hernioplasty. The patient had diabetes mellitus, for which she was taking Glucophage, insulin and Dostinex. She was a smoker with a body mass index of >70.

Mrs X presented with a history of abdominal wall infection caused by a prosthetic mesh that

Figure 3. PREVENA customisable dressing was applied directly after skin closure.

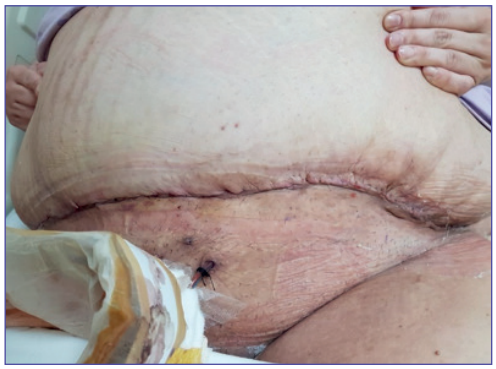

Figure 4. There was no swelling or erythema on day 4 when the dressing was removed.

had been implanted 18 months earlier and, subsequently, had to be removed. Since then, she had suffered from abdominal pain caused by a complex abdominal fistula and thick exudating infection around the fistula site.

On the day of surgery, Mrs X was classified as extremely high-risk. The fistula on the abdominal wall was removed and mini-abdominoplasty was performed, during which 11.5 kg of excess skin and fat were removed *[Figure 1]*.

Excision of the umbilicus was performed, leaving the patient with a 90 cm horizontal incision line with two drains on the lower part *[Figure 2]*. PREVENA CUSTOMIZABLE™ (Acelity, USA) dressing was applied directly after skin closure, and -125 mmHg continuous pressure applied *[Figure 3]*. Four days later, the PREVENA dressing was removed to reveal a clean, closed incision, free from haematoma, swelling or erythema *[Figure 4]*.

Mrs X was assessed 3 weeks postoperatively. The incision site appeared to be clean, dry and well-epithelialised *[Figure 5]*.

Conclusion

PREVENA Incision Management System demonstrates great capabilities in managing high-risk patients requiring surgical intervention (Javed et al, 2018). Studies have shown it to reduce postoperative SSI after median sternotomy in a comprehensive patient population (Grauhan et al, 2013; 2014), minimise postoperative complications and reduce seroma in orthopaedic surgery cases (Pachowsky, et al, 2012). Strong clinical evidence established by many surgical specialties has led to the addition of incisional NWPT in recent global guidelines on the prevention of SSIs (World Health Organization, 2016). In the current case study involving a patient at very high risk for SSI, the use of PREVENA led to successful healing by 3 weeks post surgery. WME

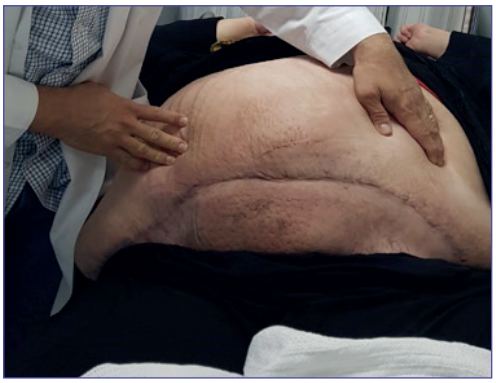

Figure 5. Three weeks after surgery the site was clean, dry and well-epithelialised.

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