Avance® negative pressure wound therapy system: a clinical focus

Many factors combine to make hard-to-heal wounds challenging to clinicians. Several different methods have been used to intervene and encourage these wounds to heal, as delay in their healing leaves them open to further complications. Negative pressure wound therapy (NPWT) is an effective treatment to improve the healing rates and closure of many different types of wounds. This article presents data from clinical case reports in which the Mölnlycke Avance® NPWT system was used. The ability of the system to manage exudate, minimise pain at dressing removal and encourage mobility (due to its portability) had a positive effect on patient quality of life.

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KEY WORDS
Negative pressure wound therapy (NPWT)
Dehisced surgical wounds
Post-amputation wounds
Diabetic foot ulcers

Negative pressure wound therapy (NPWT), also referred to as topical negative pressure (TNP), negative pressure therapy (NPT), vacuum-assisted closure (VAC), sub-atmospheric pressure wound therapy, and sealed surface wound suction (Banwell and Teot, 2003), has rapidly gained acceptance by clinicians for use in the management of acute, traumatic, infected and chronic wounds (Moues et al, 2005). NPWT has been reported to exert a number of biological effects that can have a positive effect on the healing of wounds (*Table 1*).

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NPWT systems have been documented as being suitable for the treatment of a variety of different wound types, including acute and traumatic wounds, chronic wounds (pressure ulcers, diabetic foot ulcers, post-amputation wounds, venous leg ulcers), partial-thickness burns, flaps and grafts, and sternotomy wounds. Split-thickness skin graft healing also appears to be improved with NPWT (Argenta et al, 2002).

From the perspective of the patient, sleep disturbance from noisy pumps (and alarms) and reduced mobility due to the size and weight of some systems are important factors that need to be considered by clinicians when NPWT is indicated.

Two types of NPWT systems are widely reported in the medical literature, which differ in terms of the type of dressing used to transfer negative pressure to the wound surface. Much of the literature focuses on the use of open-cell polyurethane foam with a negative pressure setting of -125mmHg (Argenta et al, 1997). An alternative dressing interface (moistened gauze) and a negative pressure setting of -80mmHg has also been described. Referred to as the Chariker-Jeter technique, this gauze-based approach was first evaluated for the management of soft-tissue injury, before delayed primary or secondary closure, in paediatric orthopaedic trauma patients (Chariker et al, 1989). Since then, a number of studies have confirmed that the Chariker-Jeter technique can be used to treat various wound types in both adults and children (Campbell, 2006; McCord et al, 2007; Campbell et al, 2008; Chariker et al, 2009).

While clinical complications associated with NPWT are infrequent and usually associated with low morbidity, a number of issues are encountered with this therapeutic intervention, e.g. difficulties in maintaining airtight seals, inappropriate dressing changes, insufficient protection between vital structures and dressings, pain (especially at dressing removal), macerated tissue, and pressure damage from tubing placement (Mandal, 2007). From the perspective of the patient, sleep disturbance from noisy pumps (and alarms) and reduced mobility due to the size and weight of some systems are important factors that need to be considered by clinicians when NPWT is indicated.

Avance® NPWT system (Mölnlycke Health Care) has been developed as a flexible and easy to use system to help promote wound healing, including drainage and removal of infectious material or other fluids, under the influence of continuous and/or intermittent negative pressure. The Avance pump (*Figure 1*) is lightweight and portable; it incorporates a rechargeable battery in the docking station so that it can be operated independently off the mains, thereby encouraging patient mobility during treatment. Acoustic and optical signals are triggered for variances from the set values as well as for any alerts or alarms.

The availability of a choice of two sizes of canister (800ml and 300ml on the same pump) for collecting wound fluid and a range of different dressing kits gives flexibility for the clinician (*Table 2*). Avance™ Dressing Kits include a wound filler (either foam- or gauze-based), a transparent film dressing (Avance® Transparent Film) and a flat surgical drain (*Figure 2*). The choice of either foam (Avance® Foam)- or gauze (Avance® Gauze)-based dressing kits allows for variation of treatment depending on the clinical requirements and the patient's needs. Differences in the performance of gauze- and foam-based wound fillers suggest the use of the latter for faster formation of granulation tissue where scarring is less of a problem, with the former being used for cosmetic reasons when scarring needs to be minimised and in skin graft preparation (Malmsjo and Ingemansson 2010). With the Avance NPWT system, clinicians also have the option of utilising dressing kits which include an atraumatic soft silicone wound contact layer (Mepitel® with Safetac®, Mölnlycke Health Care) that can be used between the wound bed and the wound filler to minimise pain at dressing changes and prevent in-growth of tissue into the wound filler (Banwell, 1999; Terrazas, 2006).

The Avance NPWT system is appropriate for use on:

- Traumatic wounds
- Surgical (sternal/abdominal/extremity) wounds
- Amputation wounds
- Chronic wounds, including pressure ulcers, diabetic foot ulcers and venous leg ulcers
- Partial-thickness burns
- Dehisced wounds
- Flaps and grafts.

The Avance pump was developed by Medela AG (Baar, Switzerland), a company with over 50 years of experience in vacuum technology. The same system is marketed as a whole by Medela in the United States of America under the Invia® Wound Therapy system brand, the trade name for the gauze dressing kits and pump systems as a whole. The following sections of this article summarise

Table 1
Biological effects of negative pressure wound therapy

- Creates suction force that enables drainage of excessive fluid and debris (Argenta et al, 1997)
- Induces mechanical deformation of the wound edge tissue (Morykwas et al, 1997; Morykwas et al, 2006)
- Promotes a moist wound healing environment (Banwell, 1999)
- Reduces bacterial colony counts (Morykwas et al, 1997)
- Increases granulation tissue formation (Morykwas et al, 1997)
- Removes oedema (Lu et al, 2003)
- Stimulates cell-mediated immune response (Chen et al, 2005)
- Decreases blood vessel permeability (Chen et al, 2005)
- Stimulates angiogenesis and blood flow to the wound margins (Evans and Land, 2001; Greene et al, 2006)

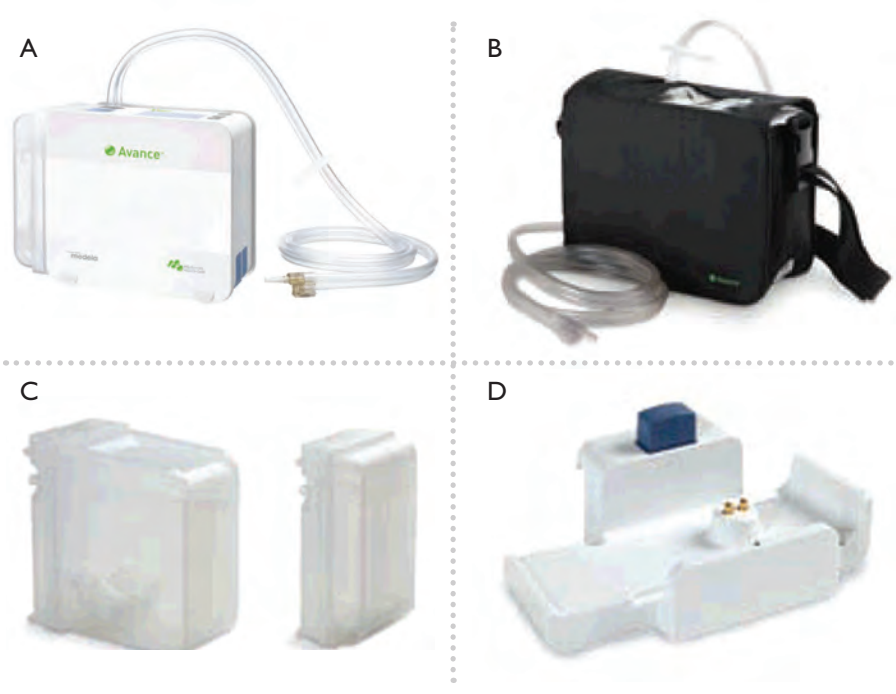

Figure 1. Avance pump (A), carrying case (B), canisters (300 and 800ml sizes) (C) and docking station (D).

Table 2
Features of Avance NPWT system

Convenience	▸▸ One system for all wound types ▸▸ Flexible choice of dressings, i.e. foam- or gauze-based wound filler, with or without soft silicone wound contact layer (Mepitel with Safetac)
Patient comfort	▸▸ Lightweight and portable pump ▸▸ Quiet operation of pump ▸▸ Dressing-related pain minimised when used in conjunction with soft silicone wound contact layer
Ease of use	▸▸ Simple settings and operation ▸▸ Recharging docking station allows user to stay mobile ▸▸ Green colour of Avance foam facilitates monitoring of wound status, bleeding and exudate

the results of pre-clinical and clinical evaluations of Avance/Invia NPWT system undertaken to date.

Pre-clinical studies have demonstrated that the foam and gauze dressings supplied with Avance NPWT system are equivalent in function to those of other commercially available dressings for use with NPWT (Malmsjo and Ingemansson, 2010). Studies have also shown that experimental wounds treated with the system develop healthy regenerated tissue (Paglinawan et al, 2008; 2009).

The system has also been evaluated in the clinical setting. For example, three patients with chronic wounds (two sacral pressure ulcers and a leg ulcer that required a skin graft) were treated with a gauze filler and continuous negative pressure at a setting of -80mmHg (Wyndham-White et al, 2010). After 21 days of treatment, one of the sacral pressure ulcers showed great improvement. Similarly, a stage III pressure ulcer had diminished in volume after 10 days of therapy. After 49 days of treatment, granulation tissue formation had reached the level of the skin and NPWT was discontinued. The ulcer that required a skin graft underwent treatment with the NPWT system before and after grafting, resulting in good wound bed perfusion and improved graft uptake. The nursing and medical teams found the NPWT system lightweight and easy to use. They also observed that its use was associated with a decrease in nursing time required for dressing changes.

Clinical studies have also demonstrated that this NPWT system can remove infectious materials from wounds as a consequence of constantly draining away fluid and that, in the case of severe infections, can be used in conjunction with antimicrobial products (Marquardt et al, 2008; Marquardt et al, 2010a; 2010b). Several surgical laparotomy wounds that had postoperative subcutaneous wound infections showed a clean surface without slough and could be closed after two to eight days of treatment with the NPWT system. The cosmetic results were good. Three open abdominal wounds that could not be managed with standard dressings were treated with the NPWT system (antimicrobial-impregnated gauze used as the filler). All wounds showed clean granulation tissue and secondary healing. Once NPWT had been discontinued, the wounds were successfully managed with conventional dressings. The portability of the NPWT system allowed patients to be mobile during treatment and they rated the system as being comfortable.

More recently, a prospective clinical study was conducted to evaluate Avance NPWT system in the treatment of foot ulcers (n=1) and post-amputation wounds (n=14) in patients with diabetes in both acute and home care settings. Maximum treatment (continuous negative pressure setting of -120mmHg) was set at four weeks and dressing changes (Avance Foam Dressing Kits used exclusively) were undertaken three times per week. The wounds showed a general trend in reduced area from baseline (median 22.9 cm^2; range 0.5–55 cm^2) to final visit (median 15.3 cm^2; range 2.4–63.5 cm^2); this equates to a median change (calculated from the percentage change in wound area for each patient individually) of -41% (range -82% to +15%). The wounds were also associated with a reduction in depth from baseline (median 17.0mm; range 0–35mm) to final visit (median 5mm; range 0–35 mm).

The device effectively managed wound exudate and most patients reported low levels of pain during therapy. Ease of use of the system was

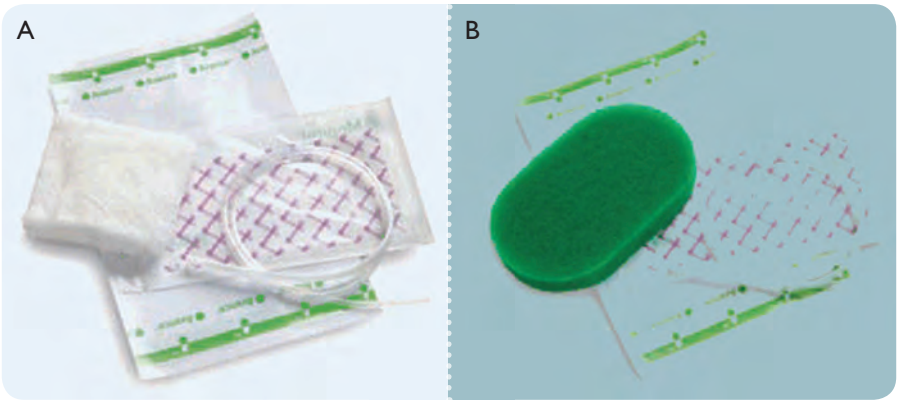

Figure 2. Avance dressing kits: Avance gauze (A) and Avance foam (B).

rated highly by both investigators and patients (Stansby et al, 2010).

In the remainder of this article, a number of case reports involving the use of the Avance NPWT system on a variety of clinically challenging wounds (all associated with more than one factor known to delay healing) are presented. In each case, Avance NPWT system was used to ascertain if it could promote a good healing response and to gauge its performance from the perspective of both the clinician and patient.

The first case presented involves a patient with a diabetes-related post-amputation wound. Patients with diabetes are at a high risk of lower extremity amputations (Singh et al, 2005). Interventions aimed at improving the healing response are vital, as the clinical prognosis of patients that have undergone diabetic lower extremity amputation is poor (Schofield et al, 2006).

The subject of the second case is surgical wound dehiscence. Two common complications occur with surgical wounds, infection and dehiscence where the wound fails to close (Baxter, 2003). These are both more likely to occur in patients with underlying medical problems and increase in likelihood with age. When a wound fails to close by normal means, appropriate treatments need to be considered.

The third case relates to a sacral pressure ulcer. Pressure ulcers are often painful, associated with high levels of exudate and prone to infection, making them ideal candidates for treatment with NPWT.

The fourth and final case involves a patient with a partial-thickness burn. A significant burn can damage the skin's protective function. The resulting inflammatory response and induction of immune dysfunction increases the likelihood of infection (Schwacha, 2003). Burns are often painful and the more rapidly they heal the less likelihood there is of further complications (Pruitt, 1990). As with other wounds, burns will heal more slowly when other factors are involved, such as infection or medical pathophysiology. When intervention is required to aid the healing response, it is important to use an appropriate method that will minimise scarring upon healing and decrease pain during treatment (Richardson and Mustard, 2009).

Case report 1: diabetes-related post-amputation wound

This case report relates to an 87-year-old male inpatient with a number of ongoing medical conditions: hypertension (diagnosed 18/06/2001); type II diabetes and bifasicular heart block (diagnosed 29/08/2009); hypertrophic cardiomyopathy (diagnosed 22/09/2009); and orthostatic hypotension (date of diagnosis not known). Previous medical history included: breast cancer with mastectomy (1991), basal cell carcinoma (date not known), venous ulceration (2003) and deep vein thromboses (1992–2003).

The patient presented with a two-day-old wound resulting from left halux and head of first metatarsal amputation. Before treatment with the Avance NPWT system, the surface area of the wound was 14.6cm^2, the depth of the wound was 15mm and the ratio of non-viable to viable tissue was 0:100 (*Figure 3*). Treatment with Avance NPWT system (continuous pressure setting of -120mmHg) in conjunction with Avance Foam Dressing Kits was started (*Figures 4* and *5*). After 11 days of NPWT (a total of five dressing changes), the surface area of the wound had decreased to 9.2cm^2 (i.e. a 37% reduction from baseline). Furthermore, the depth of the wound had reduced from 15mm to 0mm (i.e. a 100% reduction from baseline), enabling the patient to be converted to advanced wound dressings (*Figure 6*). Throughout the duration of NPWT, there was no sloughy or necrotic tissue in the wound bed. Both the clinicians and the patient found Avance NPWT system easy to use and no adverse events

Figure 3. Case report 1, treatment day one.

Figure 4. Case report 1, treatment day five.

Figure 5. Case report 1, treatment day five, with Avance Foam *in situ*.

Figure 6. Case report 1, treatment day eleven.

were reported. Moreover, the patient did not find the noise level of the pump disturbing.

Case report 2: surgical wound dehiscence

This case relates to a 35-year-old male inpatient with immune deficiency. The patient presented with a three-day-old dehisced surgical wound following laparotomy and appendicectomy. Before treatment with the Avance NPWT system, the wound measured 13.5cm (length) by 2.5cm (width) and 3.5cm (depth) (*Figure 7*). It was associated with moderate levels of exudation and minimal bleeding. The periwound skin was healthy/intact. The patient was extremely anxious and afraid that his wound would open more if he moved. His anxiety impacted on his pain levels and his immobility increased his risk of thromboembolic complications.

Treatment with Avance NPWT system (continuous pressure setting of -120mmHg) in conjunction with Avance Foam Dressing Kits was started. Mepitel with Safetac was used as an interpositional layer between the wound bed and the foam-based wound filler. Dressing changes were undertaken every two to three days (*Figure 8*).

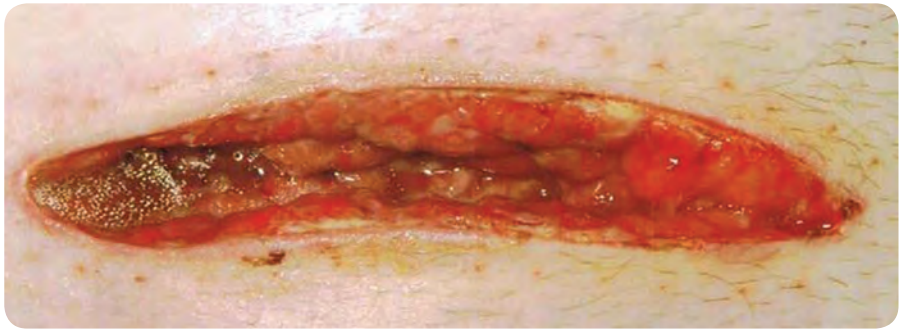

Figure 7. Case report 2, treatment day one.

Figure 8. Case report 2, treatment day three.

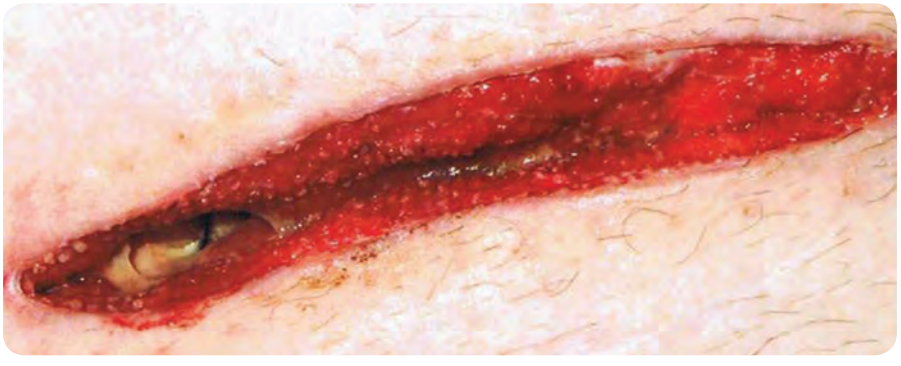

Figure 9. Case report 2, treatment day five.

After five days of NPWT (a total of three dressing changes), the wound had decreased in size to 12cm (length) by 1.5cm (width) by 1.5cm (depth), and was associated with low exudation but no bleeding (*Figure 9*). No trauma to the tissue was observed at dressing change.

At the end of the treatment period, the clinician was surveyed with respect to the equipment and dressings used. The clinician was asked to rate a number of different parameters pertaining to the therapy as either 'very poor', 'poor', 'good' or 'very good'. The clinician rated the ease of set-up, use, and portability of Avance NPWT system as 'good' to 'very good'. The Avance Foam Dressing Kits were also rated as 'good' to 'very good' in terms of:

- Ease of dressing application
- Ability of dressings to stay in place during wear
- Exudate management
- Ease of dressing removal
- Ability of dressings to prevent trauma on removal
- Ability of dressings to minimise pain on removal.

Once treatment with Avance NPWT system had started, the patient felt that his wound was 'supported' and he was no longer afraid to mobilise. His psychological well-being improved considerably. The patient

experienced a high degree of comfort during use of Avance NPWT system. Using a validated pain assessment tool (Harms-Ringdahl et al, 1986) with a scale of zero ('no pain at all') to 10 ('worst pain imaginable'), pain levels (when negative pressure was activated/deactivated, and during dressing removal) were rated by the patient as being one or zero. The portability of the system meant that he was able to mobilise without any restrictions.

During his period of treatment with the Avance NPWT system, the patient developed a common bond with another patient who was receiving NPWT with a different system. They compared the different colours (i.e. black and green) of the wound fillers they were being treated with and the ease of mobility of the two systems. The other patient had to push his pump around on a drip stand and thus wanted to be switched to treatment with the Avance NPWT system.

Case report 3: sacral pressure ulcer

This case relates to a 68-year-old male patient with a sacral pressure ulcer. The patient was admitted to a district general hospital on 26th March, 2010 after suffering a cerebral vascular accident (CVA). He was initially transferred to the local neurological hospital for assessment and care and then transferred back to the district general hospital stroke unit for rehabilitation.

He is a diet-controlled diabetic and the CVA left him with bilateral weakness (the patient had a CVA back in 2004 but, unlike the most recent one, this did not result in any limb weakness).

On 29th March 2010, he was referred to a tissue viability department with a necrotic, blackened heel and necrotic areas to his left foot. The dry necrotic area on his heel was left dry and eventually peeled away to reveal new intact tissue. The two ulcers that developed on the dorsal region of his left foot were treated with hydrogel and hydrocolloids and subsequently healed. On 24th May, the patient was again referred to the tissue viability department, this time with a grade/category 3 sacral pressure ulcer. The wound initially required debridement, which was successfully achieved. At this point, the sacral wound was slow to respond to treatment and dressings were being renewed quite frequently, sometimes on a daily basis, owing to faecal incontinence. The patient's family was concerned about the impact that the wound was having on the patient. He was spending the majority of the time in bed but the family wanted to take him out in the wheelchair and were keen for him to be discharged home. Taking all this into consideration, NPWT was considered to be the best option to accelerate healing, manage exudate levels and reduce the frequency of dressing changes.

Treatment with Avance NPWT system (continuous pressure setting of -80mmHg), in conjunction with Avance Gauze Dressing Kits, was associated with accelerated healing (*Figures 10–12*), effective management of exudate levels, and reduced frequency of dressing changes. Despite the patient being faecally incontinent, the staff found that the dressings were less contaminated than the conventional dressings used before starting NPWT.

The patient's family started to believe that the wound would heal and the patient would be discharged home. The patient's wife was allowed to be present at the dressing changes to witness for herself how the wound was progressing. This gave her a positive outlook for the future and she constantly reinforced this to her husband. Eventually, the patient became more positive about the prospects of his wound healing. During treatment with Avance NPWT system, the patient's wife was able to take her husband out in his wheelchair.

After approximately nine weeks, treatment with Avance NPWT system was stopped because exudate levels had become minimal and the wound had reached the stage where it could be managed with conventional dressings until complete healing was achieved.

Figure 10: Case report 3, treatment day one.

Figure 11. Case report 3, treatment day 27.

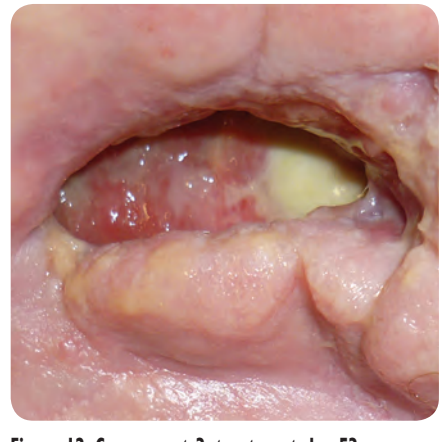

Figure 12. Case report 3, treatment day 53.

In summary, the use of Avance NPWT system was associated with positive clinical (i.e. good healing response, exudate control and reduced frequency of dressing changes) and patient-centred (i.e. quality of life) outcomes.

Case report 4: burn injury

This case report relates to a 58-year-old male who presented with a full-thickness burn to his left foot. The burn had been sustained following an explosion of a molten aluminium container. The molten aluminium landed on the patient's foot and went into his boot, the boot was immediately removed using a quick release mechanism. The 2.5% full-thickness burn affected the dorsum, instep and sole of the left foot. The patient had no significant underlying medical conditions.

Figure 13. Case report 4, pre-debridement.

Figure 14. Case report 4, application of split skin graft.

On admission the blisters were de-roofed and the wound dressed with Bactigras. Subsequent dressing changes occurred and silver dressings were applied (*Figure 13*). On day 3 post burn the patient went to theatre for an excision of the burn to the dorsum aspect of his foot, split skin grafting (donor site right thigh) and application of Avance NPWT system (*Figure 14*). Following excision, the wound measured 15x9cm; a contact layer (Mepitel® One with Safetac) was applied, followed by Avance Gauze Dressing Kit. The Avance NPWT system was set to continuous therapy with a pressure setting of -80mmHg, and a good seal was achieved. A wound contact layer was favoured to further protect the split skin graft.

The Avance NPWT remained *in situ* at the aforementioned pressure settings for five days. The treatment was not interrupted and the NPWT was easy to care for by the nursing team, the patient was also able to mobilise with the assistance of walking aids.

On day 5 post split skin graft, the Avance NPWT was removed, with the gauze requiring soaking to aid removal. On inspection there was 99% graft take (*Figure 15*).

Figure 15. Case report 4, day five post split skin graft.

Conclusion

The data generated from laboratory and clinical evaluations of the Mölnlycke Avance NPWT system indicate that it is clinically effective (i.e. it is a single system that can be applied to a wide range of wound types in both hospital and home settings) and is easy to use (i.e. it is lightweight and portable). With a choice of foam- or gauze-based wound fillers and the added option of an atraumatic wound contact layer (i.e. Mepitel with Safetac), Avance NPWT system offers flexibility to the clinician and, for the patient, comfort and minimal inconvenience. Larger studies are currently ongoing to elucidate fully the true clinical benefits of the Mölnlycke Avance NPWT system. WUK

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Key points

- Negative pressure therapy improves healing rates and closure of many different wound types.
- Patient quality of life needs to be considered when negative pressure wound therapy is indicated.
- Avance Negative Pressure Wound Therapy (NPWT) system has been designed as a flexible and easy to use means of delivering therapeutic negative pressure to wounds.
- Studies have shown that Avance NPWT system is associated with patient comfort.
- The lightweight and portable Avance pump minimises inconvenience and encourages patient mobility.