Single use negative pressure wound therapy (suNPWT) system with controlled fluid management technology — an evaluation of performance

In this article, the results from simulated clinical use tests evaluating the performance of a single use negative pressure wound therapy (suNPWT) system (Avance® Solo NPWT System, Mölnlycke Health Care AB) are presented. This suNPWT system is designed with a negative pressure pump, a distal canister and an absorptive multilayer dressing, and introduces Controlled Fluid Management (CFM) Technology™. The performance was compared to those of two canister-less suNPWT systems, designed around absorptive multilayer dressings and solely relying on the capacity of the dressings to manage fluid through absorption and moisture vapour transmission (evaporation). **Method:** The technical performances of the suNPWT systems were evaluated with respect to fluid management and delivery of the intended negative pressure using a wound model simulating clinical use on a moderate exudating wound and a 3-day dressing change regimen. **Results:** With the canister-less suNPWT systems, a loss of performance of the intended negative pressure was observed as saturation of the dressing occurred during the 72-hour test time. In comparison, the canister-based suNPWT system continuously delivered the intended negative pressure to the simulated wound throughout the 72-hour testing time, without any saturation of the dressing observed. **Conclusion:** The results could be explained by the design of the canister-less suNPWT systems, managing fluid in the dressing only, and that dressing saturation impedes the delivery of the intended negative pressure. In comparison, the canister-based suNPWT system has the capacity to transport excess exudate and infectious material from the dressing to the canister, thereby reducing the risk of dressing saturation.

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Negative pressure wound therapy (NPWT), also referred to as topical negative pressure (TNP), vacuum-assisted closure (VAC), sub-atmospheric pressure wound therapy and sealed surface wound suction (Banwell and Téot, 2003), has gained widespread acceptance by clinicians for use in the management of closed surgical incisions, as well as acute and chronic wounds (Apelqvist et al, 2017a). NPWT has been reported to have a number of positive biological effects on the healing of wounds *[Box 1]*, and to improve patients' quality of life and reduce health costs (Dowsett et al, 2012; Wounds UK, 2013). However, to achieve optimal clinical outcomes, it is a prerequisite that the NPWT system provides effective exudate removal and delivers the intended negative pressure continuously throughout the duration of therapy.

Reusable and single use NPWT systems

Historically, NPWT systems were reusable

Box 1. Potential biological effects of NPWT on wound healing.

- Wound contraction, bringing the edges of the wound together (Apelqvist et al, 2017b; Torbrand et al, 2018)
- Wound oedema reduction (Chen et al, 2005)
- Impact of strain on cell function (Glass et al, 2014; McNulty et al, 2017)
- Increased cell proliferation (McNulty et al, 2017; Borys et al, 2019)
- Modulation of cytokines (Glass et al, 2014; Borys et al, 2019)
- Reduction in matrix metalloproteinases (MMPs) (Moues et al, 2008; Glass et al, 2014; Borys et al, 2019)
- Modification of reactive oxygen species (Bellot et al, 2019)
- Changes in capillary morphology (Chen et al, 2005; Erba et al, 2011; Glass et al, 2014)
- Impact on blood and lymph flow (Chen et al, 2005)
- Reduction of bacterial load (Moues et al, 2008 ; Ngo et al, 2012)
- Promotion of granulation tissue growth (Glass et al, 2014).

and designed with a negative pressure pump equipped with a canister for collection of fluid from the wound. The negative pressure pumps were generally large and heavy, and often powered by a mains electricity source, all features that had a tendency to restrict patients' mobility (Apelqvist et al, 2017b). As a consequence, reusable NPWT systems have been, and continue to be, mostly utilised for inpatient care, although they can be adapted for use in the home (Moffatt, 2011).

One of the advances in the delivery of NPWT has been the development and commercialisation of single use (su)NPWT systems, which are generally lightweight and operated either mechanically or by battery. These characteristics allow patients to be mobile while receiving NPWT.

Available suNPWT systems, such as e.g. PICO™ (Smith + Nephew), Avelle™ NPWT System (ConvaTec) and the NANOVA™ Therapy System (3M), are designed with an absorptive multilayer dressing connected to a negative pressure pump, but with no canister to collect excess fluid drawn from the wound. This means that the dressing manages all exudate by absorption and moisture vapour transmission (evaporation), without any mechanisms by which wound exudate and infectious material can be continuously cleared from the dressing.

Challenges of saturated dressings

The key benefits of NPWT, e.g. optimising blood flow in the wound bed, reducing oedema and bacterial colonisation (Ranaweera, 2013), are very much dependent on the intended negative pressure from the pump being continuously delivered to the wound during therapy time, thus ensuring the removal of excess fluid from the wound bed and periwound skin.

In canister-less suNPWT systems designed with an absorptive dressing, the capacity of the systems to deliver continuous negative pressure may be impaired as the dressing becomes saturated during the course of therapy. Loss of negative pressure leading to retention of exudate in the dressing would increase the risk of compromising healing, due to periwound skin damage (e.g. maceration) and associated complications, such as leakage and soiling, malodour, increased risk of infection, protein loss, fluid and electrolyte imbalance, wound expansion, increased frequency of dressing changes, patient discomfort and pain, and psychosocial effects (World Union of Wound Healing Societies [WUWHS], 2007; Dowsett, 2012; WUWHS, 2019).

Increasing the frequency of dressing changes would be one option to mitigate these risks, however, according to the principle of undisturbed wound healing (Morgan-Jones et al, 2019), dressing changes should be as infrequent as possible to reduce risk for contamination and damage to the periwound skin. To comply with this, a NPWT system that manages and removes exudate from the wound bed effectively and consistently is a prerequisite (WUWHS, 2019).

Avance® Solo NPWT System

Avance Solo NPWT System (Mölnlycke Health Care AB) is a suNPWT system based on Controlled Fluid Management (CFM) Technology™ which combines the characteristics of larger, reusable NPWT systems while being lightweight and portable, allowing the patient to be mobile. With this system, exudate and infectious material are managed by a combination of absorption and evaporation in the multilayer dressing, and transport of excess fluid to the canister, thus reducing the risk of the dressing becoming saturated and interrupting the delivery of NPWT (Data on file 2020a, 2020b) *[Figure 1]*.

Avance Solo NPWT System is intended to deliver nominal 125 mmHg for up to 14 days (Data on file, 2020a), and is indicated for the removal of low-to-moderate exudate in a variety

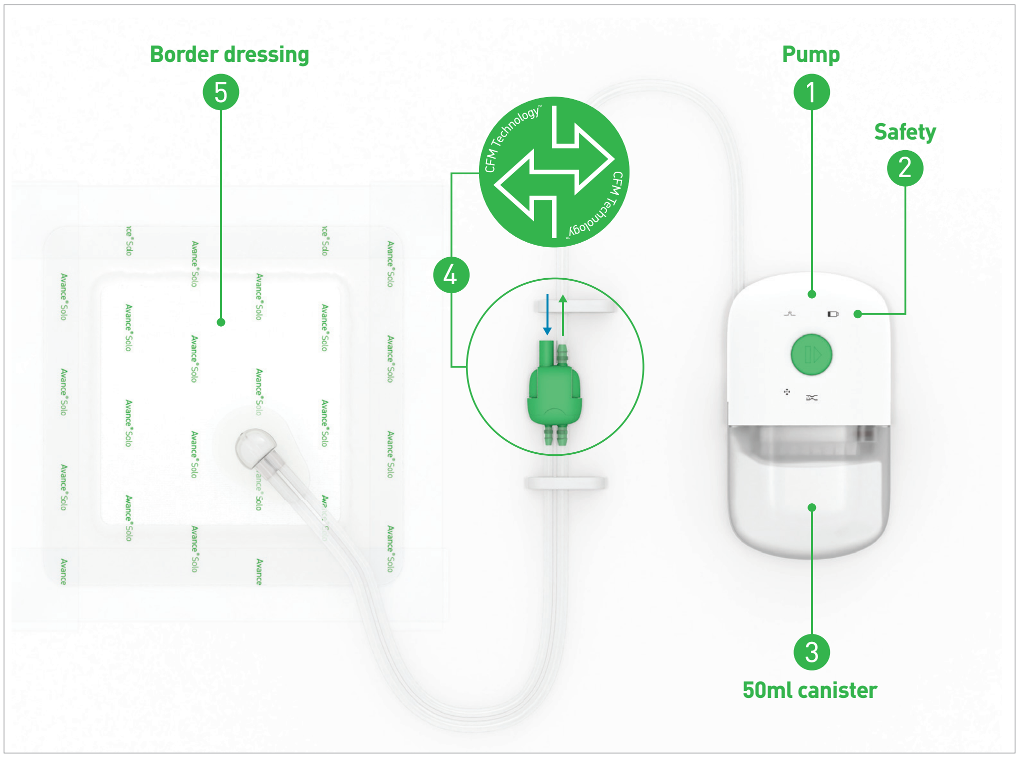

Figure 1. Avance® Solo NPWT System comprising: (1) pump (delivers a regulated pressure of -125 mmHg to the wound for up to 14 days) with (2) audible and visible notifications and alarms triggered when at risk for loss of therapy, fitted with (3) 50 ml canister, (4) quick connector featuring Controlled Fluid Management (CFM) Technology™ (5) border dressing. A foam wound filler is also available. The CFM Technology provides a controlled inflow of air (blue arrow) which allows transport of excess fluid from the dressing to the canister (green arrow).

Box 2. Indications for the Avance Solo NPWT system.

The Avance Solo NPWT system is indicated for the removal of low-to-moderate volumes of exudate in a range of wound types:
- Chronic, acute, traumatic, subacute and dehisced wounds
- Ulcers (such as diabetic, venous or pressure)
- Surgically closed incisions
- Flaps, grafts

of wound types *[Box 2]*. It is suitable for use in both hospital and home care settings.

The hypothesis for this study was that the canister-based design and CFM Technology differentiates Avance Solo NPWT System from canister-less suNPWT systems. Under conditions of simulated clinical use, the performance of Avance Solo NPWT System was compared with those of two commercially available canister-less suNPWT systems.

Materials and methods

suNPWT systems for investigation

Avance Solo NPWT System is designed with a negative pressure pump, a canister, and a breathable, multilayer dressing designed with an absorptive core, a pressure distribution layer, and a protective wound contact layer. The system delivers negative pressure nominally at 125 mmHg and manages exudate through its CFM Technology, i.e. excess fluid is transported from the dressing for collection in the canister. The multilayer absorptive dressing can be left in situ for up to 7 days. More frequent dressing changes may be required when the system is used on moderately exuding wounds.

The canister-less suNPWT systems included in this evaluation are both designed with a negative pressure pump and breathable, multilayer wound dressings with an absorptive core, a pressure distribution layer, and a protective wound contact layer. The systems are indicated to deliver NPWT at a nominal negative pressure of 80 mmHg, and to manage exudate via the dressing through a combination of absorption and evaporation of moisture through its outer film. According to the intended use of these systems, the dressing should typically be changed every 3-4 days but may be left in place for up to 7 days.

Ability of suNPWT systems to deliver negative pressure

To evaluate the performance of the canister-based suNPWT with the canister-less suNPWT designs in terms of their fluid management capacity and delivery of the intended negative pressure to the wound bed, the suNPWT systems were applied to a wound model simulating a moderately exuding wound and a 3-day (72 hours) dressing change regimen. The dressings were applied to the simulated wounds and connected to the respective negative pressure pumps. The suNPWT systems were then subjected to horse serum (to mimic wound exudate with respect to viscosity, osmolarity and pH) delivered from underneath the dressing by a peristaltic pump with a controlled fluid outlet. The flow speed was set at 1.1 g/cm^2/24 hours to simulate a moderately exuding wound (Malmsjö et al, 2014) and the wound area was, in alignment with intended use of the suNPWT systems subjected to evaluation, defined as 25% of the wound pad area.

Delivery of the intended negative pressure from the suNPWT pump and its distribution to the simulated wound was measured at multiple positions using differential pressure transmitter sensors (model KIMO CP214-BNs, Kimo Instrument Sverige AB, Gothenburg, Sweden, operating between –500 and 500 mbar) and sampled every 60 seconds throughout the test time (NI-DAQmx control unit and a custom-made LabVIEW software code, National Instruments, Austin TX, USA).

Impact of increasing saturation of dressing on the ability to deliver intended negative pressure

To investigate the impact of dressing saturation on the continuous delivery of the intended negative pressure to the simulated wound, a more detailed evaluation was undertaken to measure negative pressure as output from the pump to the simulated wound at a range of saturation levels of the dressing. The saturation levels subjected to the dressing corresponded to 20%, 40%, 60% and 80% of fluid volumes expected from a moderately exuding wound (1.1 ml/cm²/24 hours) treated with NPWT and mimicking a 3-day dressing change regimen. The same wound model as described in the previous section was used and the measurements of delivery of negative pressure were sampled every 60 seconds over a 24-hour period for each simulated use and saturation level. The sampled data were subjected to statistical analysis (two-sample T-test and 95% Confidence Interval [CI]).

All tests were performed with five replicates (*n*=5) for each of Avance Solo NPWT System and the two canister-less suNPWT systems.

Results

Ability of suNPWT systems to deliver intended negative pressure

In the canister-less suNPWT systems, the negative pressure from the pump remained at the intended nominal 80 mmHg; however, the negative pressure delivered to the simulated wound reduced over the duration of the test time *[Figure 2]*. For the Avance Solo NPWT system, the negative pressure measured in the simulated wound was maintained at the intended negative pressure of 125 mmHg throughout the simulated therapy time *[Figure 2]*.

Impact of increasing saturation of dressing on the ability to deliver negative pressure

A decline in negative pressure delivered to the wound bed as a function of increasing dressing saturation was observed with both of the canister-less NPWT systems *[Figure 3]*.

When the canister-less NPWT systems were subjected to a fluid volume corresponding to 60% of the expected exudate level from a moderate exudating wound with a 3-day dressing change regimen, the negative

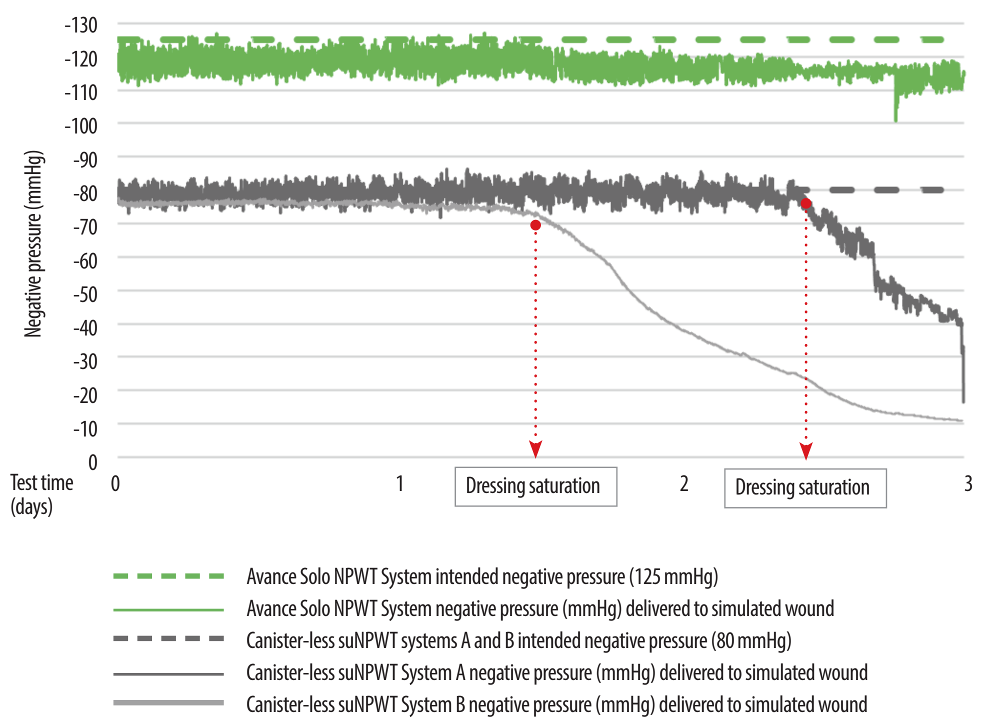

Figure 2. The performance of suNPWT systems to deliver intended negative pressure during simulated clinical use on a wound model mimicking a moderately exudating wound with a 3-day (72 hours) dressing change regimen. The graph illustrates the intended negative pressure (dotted line) versus the actual negative pressure delivered to the simulated wound for the canister-based (green) and two canister-less suNPWT (dark and light gray) systems. With both of the canister-less suNPWT systems, loss of performance of the intended negative pressure (80±20 mmHg) was observed as a function of increased saturation of the dressing. In comparison, the canister-based suNPWT system continuously delivered the intended negative pressure to the simulated wound throughout the test time, independently of increased fluid volume and without any saturation of the dressing observed.

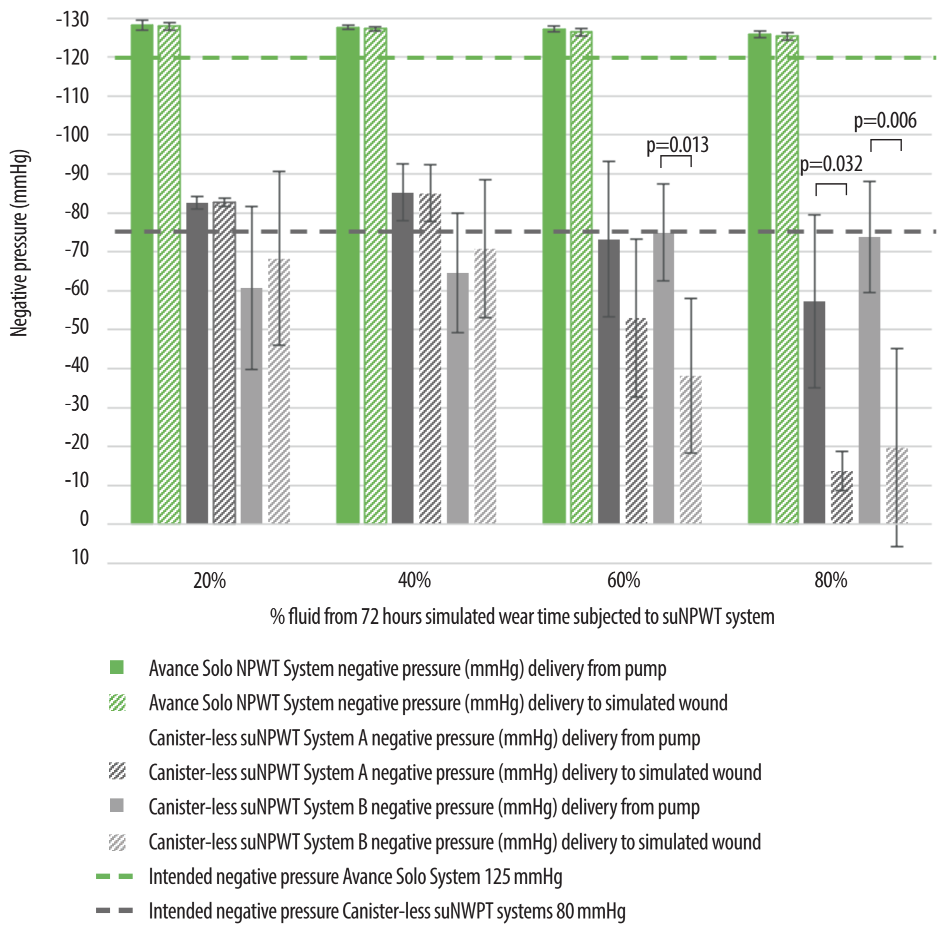

Figure 3. suNPWT systems performance on delivery of intended negative pressure as output from the pump and delivery to the simulated wound. The performance was measured when dressings were subjected to a range of saturation levels corresponding to 20%, 40%, 60% and 80% of the fluid volume expected from a moderately exudating wound with a 3-day dressing change regimen. For the Avance Solo NPWT System, the negative pressure delivered from the pump to the simulated wound (green bars) was 100% of the intended negative pressure 125 mmHg. However, for the canister-less suNPWT systems (A and B), delivery of negative pressure deviated from the intended negative pressure of 80 mmHg as saturation of the dressing occurred (dark and light grey, respectively).

pressure delivered to the simulated wound dropped to 66% (system A) and 48% (system B), respectively, of the intended negative pressure of 80 mmHg. For canister-less suNPWT system B, there was a statistically significant difference between the negative pressure output from the pump and the negative pressure delivered to the simulated wound.

At fluid volumes corresponding to 80% of exudate levels expected from a moderate exudating wound with a 3-day dressing change regimen, the negative pressure delivered to the simulated wound bed was only 14% (system A) and 25% (system B) of the intended negative pressure of 80 mmHg, respectively. For both canister-less suNPWT systems, the difference between negative pressure measured as output from the pump and delivery to the simulated wound was statistically significant.

In comparison, for the Avance Solo NPWT System, the negative pressure delivered to the simulated wound bed was maintained at the intended 125 mmHg throughout the 72-hour test time (no statistical significant difference) as fluid was removed through the dressing to the canister.

Discussion

NPWT has been shown to promote wound healing by removing excess wound fluid and infectious material from the wound, and by achieving benefits of application of negative pressure to a wound such as increased perfusion, reduction of oedema and bacterial colonisation (Ranaweera, 2013). Removal of excess exudate and infectious material from the wound also supports undisturbed wound healing by allowing reduced frequency of dressing changes, an important factor to reduce the risk of contamination of the wound, periwound skin damage and maceration (Morgan-Jones et al, 2019) - important factors that can impact negatively on the barrier function of the skin and its capacity to re-epithelialise (Wounds UK, 2013). These reported benefits of NPWT do not only promote wound healing but also improve patients' quality of life and reduce health costs (Dowsett et al, 2012; Wounds UK, 2013). NPWT has been shown to lower the incidence of dehiscence and infection in post-surgical wounds (Stannard et al, 2012; Wounds UK, 2013), and it is often used in the management of complex wounds where wound healing is particularly challenging.

To achieve the benefits of negative pressure wound therapy and support undisturbed wound healing, the NPWT system applied should remove exudate from the wound and deliver the intended negative pressure consistently to the wound throughout the intended therapy time. In this study, the fluid management characteristics and delivery of intended negative pressure of one canister-based suNPWT System (Avance Solo NPWT System) was evaluated alongside to two canister-less suNPWT systems. The hypothesis evaluated was if a canister-based NPWT system designed with CFM Technology would provide more effective fluid management and thus a greater ability to continuous deliver the intended negative pressure as compared to two suNPWT systems with canister-less design. In canister-less suNPWT systems, where fluid management relies on dressing absorption and moisture vapour transmission (evaporation) only, there is a risk that delivery of intended negative pressure could be impacted as saturation of the dressing occurs during the therapy, calling for more frequent dressing changes. For the evaluation, a wound model simulating clinical use on a moderate exudating wound with a 3-day dressing change regimen was used, measuring delivery of intended negative pressure from the negative pressure pump of the suNPWT system to the simulated wound bed.

The results show that for the canister-less suNPWT systems designed around an absorptive dressing, there was a decline in negative pressure delivered to the simulated wound as a function of increasing dressing saturation. This performance could be rationalised by excess wound fluid absorbed in the dressing leading to gel-blocking impacting adversely both on capacity of fluid management and delivery of intended negative pressure (Wack et al, 2007). The canister-based Avance Solo NPWT System performed with continuous delivery of negative pressure and the removal of excess fluid from the dressing for collection in the canister, with no saturation of dressing observed for any volume subjected to the dressing. With this canister-based system, the risk for loss of therapy as a function of saturation of the absorptive dressing is substantially reduced.

Limitations

Efficient wound healing relies on a variety of complex and interdependent biological and social factors. Although the present laboratory simulation was designed to mimic real-world conditions for wound exudate management and the application of negative pressure, the suNPWT systems might produce different results in clinical practice. For example, in the clinical reality the efficiency of evaporative loss of wound exudate depends on a variety of factors, including ambient temperature and humidity, composition and volume of exudation, and dressing size and wear time (Malmsjö et al, 2014).

Conclusions

In recent years, there have been substantial developments in NPWT. There are now numerous products available offering alternative delivery systems to the original re-usable systems, which allow clinicians to select the best system to meet the needs and expectations of their patients.

The evolution of NPWT has led to the availability of systems that incorporate some of the benefits of the earlier NPWT systems but are considerably smaller and more portable. A canister-based suNPWT system, such as the Avance Solo NPWT System, offers effective delivery of negative pressure to the wound through a portable system with a multilayer dressing and utilising CFM Technology. Such deliverables can lengthen dressing wear time and facilitate undisturbed wound healing, thereby reducing the risk of wound contamination and damage to periwound skin. Fewer dressing changes also reduce the risk of pain and discomfort to the patient.

The research data presented in this article show that the Avance Solo NPWT System offered effective fluid management and consistent delivery of intended negative pressure as compared to the two canister-less suNPWT systems when evaluated in a simulated wound model. The results of this simulation merit further investigation to determine whether they could be replicated in real-world clinical practice, and whether they could lead to improvements in wound healing outcomes and patient quality of life. WINT

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Declaration

This article is supported by Mölnlycke Health Care.