CLOSED INCISION NEGATIVE PRESSURE WOUND THERAPY:

A literature review and an introduction to Avance® Solo

Wounds International

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FOREWORD

Wounds that result from surgical interventions should, in theory, present less of a clinical challenge than other types of wounds as they are generally 'clean' and formed by pre-determined incidents. However, despite many advances in the technologies and techniques used in the pre-, intra- and post-operative phases of patient care, surgical site complications continue to be a major cause of delayed healing, morbidity and mortality, all of which contribute to a significant economic burden on health care providers (Sandy-Hodgetts et al, 2020).

Post-operative dressings are integral to the management of closed surgical incisions and, in order to ensure a continuum of care throughout the healing phase, ideally should provide the following: flexibility, good adhesion and 'stay-on-ability', high absorption capacity, protection of the surrounding skin, good seal/barrier, elimination of dead space between itself and the wound (thus avoiding the pooling of exudate), comfort during wear, atraumatic removal, and ease of use (Morgan-Jones et al, 2022). However, in certain circumstances (e.g. if high exudation/leakage is present or the patient is considered to be at high-risk for surgical wound complications), more specialised interventions are generally required. One such intervention is the application of negative pressure over the incision site, i.e. closed incision negative pressure wound therapy (ciNPWT).

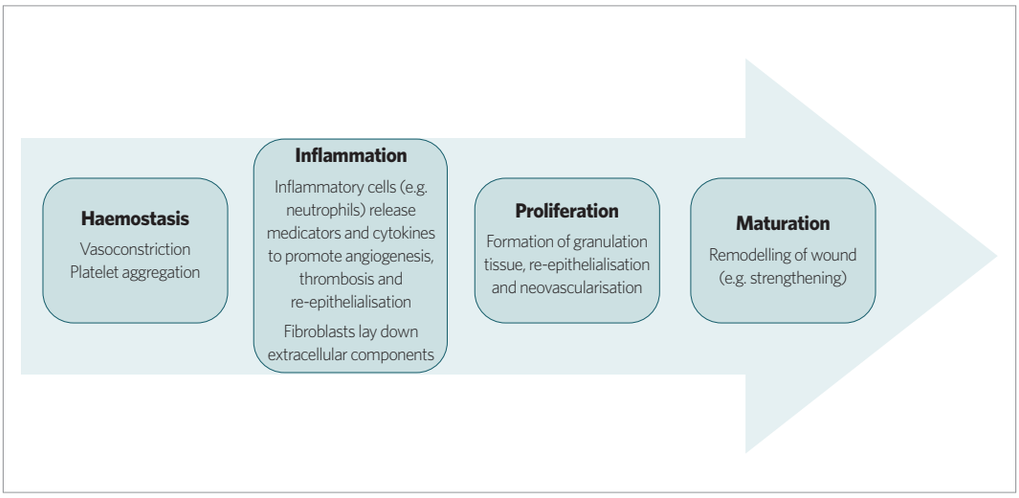
The first part of this supplement provides a detailed review of the published data generated from research undertaken in both laboratory and clinical settings to elucidate the mechanisms of action of ciNPWT and investigate its efficacy and safety, particularly in relation to the prevention of surgical wound complications.

The second part of this supplement introduces the Avance® Solo Negative Pressure Wound Therapy (NPWT) System, focusing on the findings of recent research that has been carried out to evaluate its performance. Also featured are a number of case studies that relate to the use of the Avance Solo NPWT System on closed surgical incisions and highlight the importance of taking into consideration the impact of interventions on patients.

SURGICAL INCISION MANAGEMENT

Acute wounds, such as those resulting from surgical procedures, typically heal in an orderly and timely manner and, in doing so, progress through four distinct, but overlapping phases (Figure 1; Wallace et al, 2022).

Figure 1 Phases of wound healing (Wallace et al, 2022)



There are two main approaches to wound healing (closure): primary and secondary (Table 1), with the majority of surgical wounds undergoing primary closure (Yao et al, 2013).

Table 1. Methods of wound closure (Yao et al, 2013)

Primary closure	Secondary closure
For wounds where tissue loss is minimal and wound edges can be satisfactorily approximated	For wounds that are intentionally left open (e.g. due to infection or inability to approximate wound edges)
Typically associated with faster re-epithelialisation and less scarring	Typically associated with slower re-epithelialisation and more scarring

Box 1. Materials used to hold incision edges together (WUWHS, 2016)

- Clips
- Skin adhesives
- Skin closure devices
- Staples
- Sutures
- Tapes.

A surgical incision made through the skin and underlying tissues, in which the edges of the incision have been brought together (closed) to facilitate healing by primary intention, is referred to as a closed surgical incision (World Union of Wound Healing Societies [WUWHS], 2016). A variety of materials are commonly used to hold the edges of closed surgical incisions together (Box 1).

Closed surgical incisions are associated with a variety of post-operative complications; these include infection (surgical site infection [SSI]), dehiscence, blistering, seroma, haematoma, local skin ischaemia and necrosis, and poor quality/abnormal scarring (Table 2; WUWHS, 2016; Beele et al, 2020). According to the World Health Organisation, major complications (i.e. those that are potentially life-threatening and require hospitalisation and intervention) affect up to and over 25% of patients undergoing surgical procedures carried out in industrialised countries (Willy et al, 2017).

Table 2. Surgical site complications (Vaughan-Shaw et al, 2013; WUWHS, 2016; Centers for Disease Control and Prevention [CDC], 2021)	
Description	**Definition**
Surgical site infection (SSI)	*Superficial incisional SSI* Infection occurs within 30 days after any operative procedure, involves only skin and sub-cutaneous tissue of the incision and the patient has at least one of the following: • Purulent drainage from superficial incision • Organism(s) identified from a specimen obtained aseptically from the superficial incision or sub-cutaneous tissue by a culture or non-culture based microbiologic testing method which is performed for purposes of clinical diagnosis or treatment • Superficial incision that is deliberately opened by a surgeon, attending physician or other designee and culture or non-culture-based testing is not performed AND at least one of the following signs or symptoms: • Pain or tenderness; localised swelling; erythema or heat • Diagnosis of a superficial incisional SSI by the surgeon or attending physician or another designee *Deep incisional SSI* Infection occurs within 30 or 90 days after the operative procedure, involves deep soft tissues of the incision (e.g. fascial and muscle layers) and the patient has at least one of the following: • Purulent drainage from the deep incision • A deep incision that spontaneously dehisces, or is deliberately opened or aspirated by a surgeon, physician or physician designee and organism(s) identified from the deep soft tissue of the incision by a culture or non-culture based microbiologic testing method which is performed for purposes of clinical diagnosis or treatment, or culture or non-culture based microbiologic testing method is not performed AND at least one of the following signs or symptoms: • Fever (>38°C); localised pain or tenderness • An abscess or other evidence of infection involving the deep incision that is detected on gross anatomical or histopathological examination, or imaging test *Organ/space SSI* Infection occurs within 30 or 90 days after the operative procedure, involves any part of the body deeper than the fascial/muscle layers that is opened or manipulated during the operative procedure and the patient has at least one of the following: • Purulent drainage from a drain that is placed into the organ/space (e.g. closed suction drainage system, open drain, T-tube drain, CT-guided drainage) • Organism(s) identified from fluid or tissue in the organ/space by a culture or non-culture based microbiologic testing method which is performed for purposes of clinical diagnosis or treatment • An abscess or other evidence of infection involving the organ/space that is detected on gross anatomical or histopathologic examination, or imaging test suggestive of infection AND meets at least one criterion for a specific organ/space infection site* **as defined in the Surveillance Definitions for Specific Types of Infection (CDC, 2021)*
Dehiscence	The splitting apart or rupturing of the margins of a previously closed wound along some or all of its length. Dehiscence may be superficial (separation at the skin level only) or deep (separation of tissue below the skin; may or may not include skin separation)
Seroma	A collection of serous fluid that forms in a cavity or potential space (e.g. under a skin flap) and is distinct from an abscess. Lymphatic fluid/leak from tissue disruption may contribute to the fluid collection. A seroma generally contains few red blood cells

Table 2 (continued). Surgical site complications (Vaughan-Shaw et al, 2013; WUWHS, 2016; Centers for Disease Control and Prevention [CDC], 2021)	
Description	**Definition**
Haematoma	A collection of blood that may be found in an organ (e.g. liver or kidney), in muscle or beneath the skin. A haematoma may form beneath the skin in a closed surgical incision. Ecchymosis (bruising) should be distinguished from a haematoma, and may occur separately or in conjunction with a haematoma
Oedema	An excessive accumulation of serous fluid in the intercellular spaces of tissue. Post-operative oedema occurs in part as a result of the cytokine response to surgical injury, which increases the permeability of the capillary membranes to proteins (e.g. albumin) and results in a redistribution of plasma proteins and fluid from the intravascular to the interstitial space

For the provider, these complications can extend patients' length of stay in hospital, lead to an increase in unplanned hospital re-admissions, and delay other planned interventions (e.g. chemotherapy, radiotherapy), all of which can result in increased healthcare costs. From the perspective of patients and carers, these complications can have a negative impact on quality of life, increase morbidity (e.g. systemic complications, long-term sequelae, pain, anxiety), and increase the risk of mortality (WUWHS, 2016). Hence, appropriate measures should be taken to prevent these, often avoidable, complications from occurring (Figure 2).

Figure 2 Expected benefits from avoiding unnecessary closed surgical incision complications (WUWHS, 2016)

Measures taken to prevent surgical incision-related complications begin in the pre-operative period (e.g. with the use of antimicrobial sealants), before continuing into the intra-operative period (e.g. with the use of antimicrobial-impregnated sponges), and then into the post-operative period (Scalise et al, 2016). A variety of interventions are used in the post-operative period, including the use of simple dressings (e.g. sterile gauze), debriding agents, topical antimicrobial agents, and more advanced dressings (e.g. foams and hydrocolloids), as well as the topical administration of autologous blood products, growth factors, cultured skin and NPWT (Scalise et al, 2016; Beele et al, 2020; Norman et al, 2020).

CLOSED INCISION NEGATIVE PRESSURE WOUND THERAPY (CiNPWT)

NPWT can be described in simple terms as a closed, sealed system that applies negative pressure typically ranging from -50 mmHg to -125 mmHg to the wound. To achieve this, the wound is covered or filled (depending on its depth) with a dressing (usually foam or gauze) and sealed (by means of an adhesive dressing or occlusive drape) before negative pressure is applied by connecting tubes from the dressing to a pump and fluid collector (canister; Norman et al, 2020).

Since NPWT systems became commercially available in the late 20th Century, the therapy has become widely accepted as a key intervention in the management of a diverse range of acute and chronic wounds (Grant-Freemantle et al, 2020, Chen et al, 2021; Jiang et al, 2021; Song et al, 2021). More recently, supported by the results of numerous clinical studies, including randomised controlled trials (RCTs; see Appendix), NPWT is increasingly being used in the management of closed surgical incisions (ciNPWT; Sahebally et al, 2018; Shiroky et al, 2020; Ailaney et al, 2021; Boland et al, 2021).

Compared to conventional dressings, ciNPWT appears to be more efficacious in reducing the occurrence of closed surgical incision complications (DiMuzio et al, 2017; Giannini et al, 2018; Newman et al, 2019; Higuera-Rueda et al 2021), thereby delivering better economic outcomes by reducing the need for costly treatment of these avoidable clinical problems (Kwon et al, 2018; Nherera et al, 2018; Wikkeling et al, 2021).

With respect to the clinical studies described above, one of two levels of negative pressure were generally applied to the closed surgical incisions, i.e. -80 mmHg (Galiano et al, 2018; Hasselmann et al, 2020; Holford, 2020; Bueno-Lledro et al, 2021) or -125 mmHg (Pachowsky et al, 2012; Pleger et al, 2018; Newman et al, 2019; Higuera-Rueda et al 2021).

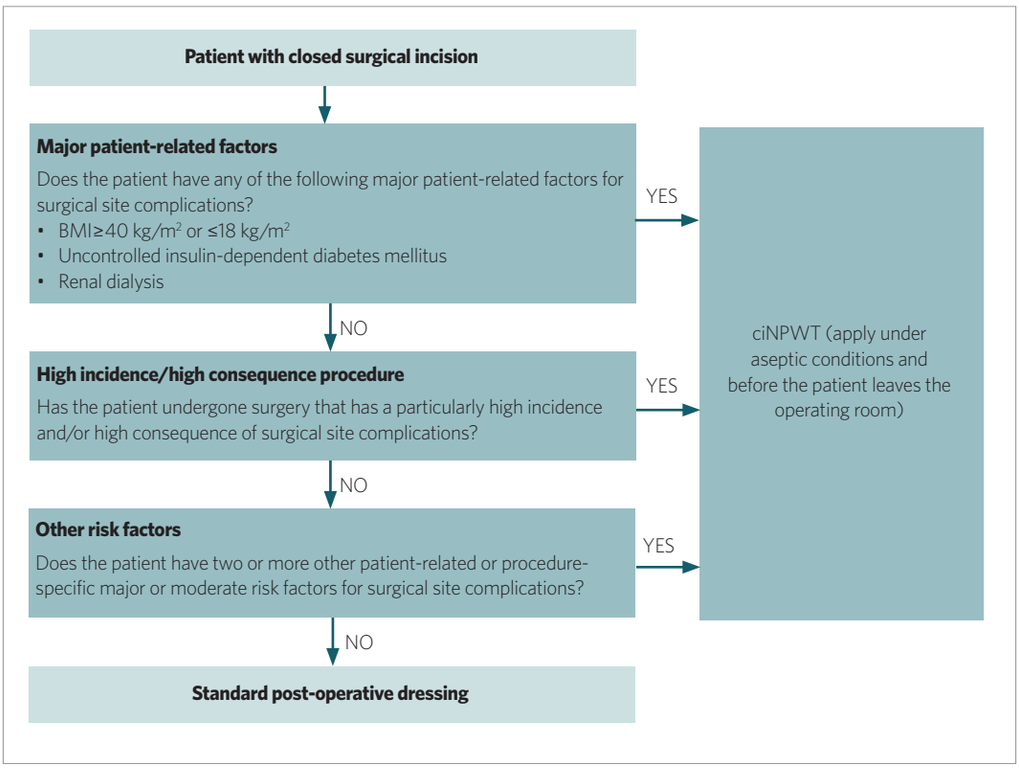
In an attempt to compare the reported clinical outcomes with the two different negative pressure levels and conventional dressings, a meta-analysis of the data generated from six RCTs involving 611 patients with closed surgical incisions resulting from total hip and knee arthroplasties was undertaken. The analysis indicated that patients receiving -125 mmHg ciNPWT displayed significantly fewer overall complications (p=0.00001) and persistent wound drainage (p=0.002) in comparison to subjects receiving -80 mmHg ciNPWT and conventional dressings. The findings led the research team to recommend the use of -125 mmHg ciNPWT for patients undergoing total joint arthroplasties (Elhage et al, 2021; Table 3).

Table 3. Featured study (Elhage et al, 2021)

Description	Definition
Aims	To investigate whether ciNPWT at -125 mmHg or -80 mmHg or conventional dressing reduces incidence of surgical site complications in total hip and knee arthroplasty
Methods	Non-stratified and stratified meta-analyses of prospective RCTs
Results	• Data from 6 RCTs involving 611 patients (51.7% hip and 48.2% knee arthroplasties) included • ciNPWT applied to 296 patients (63.1% -125 mmHg; 36.8% -80 mmHg) and conventional dressing applied to 315 patients *Non-stratified analysis:* • ciNPWT associated with lower risk of persistent wound drainage than conventional dressing (OR=0.28; p=0.002) • No significant difference between ciNPWT and conventional dressing with regard to haematoma, blistering, seroma and dehiscence *Stratified analysis:* • ciNPWT at -125 mmHg associated with fewer overall complications (p=0.0001) and persistent wound drainage (p=0.002) than ciNPWT at -80 mmHg • ciNPWT associated with shorter hospital stay than conventional dressing (p=0.005)
Conclusions	When compared to conventional dressing and -80 mmHg ciNPWT, the use of -125 mmHg ciNPWT is recommended in patients undergoing total joint arthroplasty

An international expert working group proposed that ciNPWT is used on patients who have intrinsic risk factors for surgical incision complications or who have had surgical procedures associated with particularly high incidence and/or high consequence of incision site complications (WUWHS, 2016; Figure 3).

Figure 3 Proposed rationale for ciNPWT (WUWHS, 2016)



MECHANISMS OF ACTION OF CINPWT

When negative pressure is applied to a closed incision, the dressing through which the pressure is administered collapses vertically and contracts laterally. This helps to close the gap in the incision and to eliminate the vertical compression in the sides of the incision (Wilkes et al, 2012).

A number of different mechanisms of action of ciNPWT are described in the published literature. In addition to the provision of a physical barrier to external contamination, these include: the reduction in lateral tension across the wound; the improvement in lymphatic drainage (i.e. reduction of oedema), the reduction in size of seromas and haematomas, and the improvement in perfusion (WUWHS, 2016; Nam et al, 2018). These are described in more detail in the section below.

REDUCTION IN LATERAL TENSION ACROSS THE WOUND

In clinical studies reported in the literature, lower rates of dehiscence of surgical incisions have been observed in subjects receiving ciNPWT, compared to those receiving conventional dressings (Stannard et al, 2012; Conde-Green et al, 2013; Muller-Sloof et al, 2018; Di Re et al, 2021). One of the risk factors for dehiscence of closed surgical incisions (sutured or stapled) is the presence of lateral tension across the wound (WUWHS, 2016). The results of a number of *in silico* (finite element modelling; Wilkes et al, 2012; Table 4; Loveluck et al, 2016; Table 5), *in vivo* (porcine model; Suh et al, 2016) and *in vitro* (skin model; Wilkes et al, 2012; Table 4; Loveluck et al, 2016; Table 5) studies have identified that ciNPWT

exerts a compressive force that reduces the tension in sutures and staples, thereby increasing the 'breaking strengths' of the closed surgical incisions. In one study, the force required to 'separate' a closed incision was approximately 10% greater when -120 mmHg pressure was applied compared to when -80 mmHg pressure was applied (Loveluck et al, 2016; Table 5).

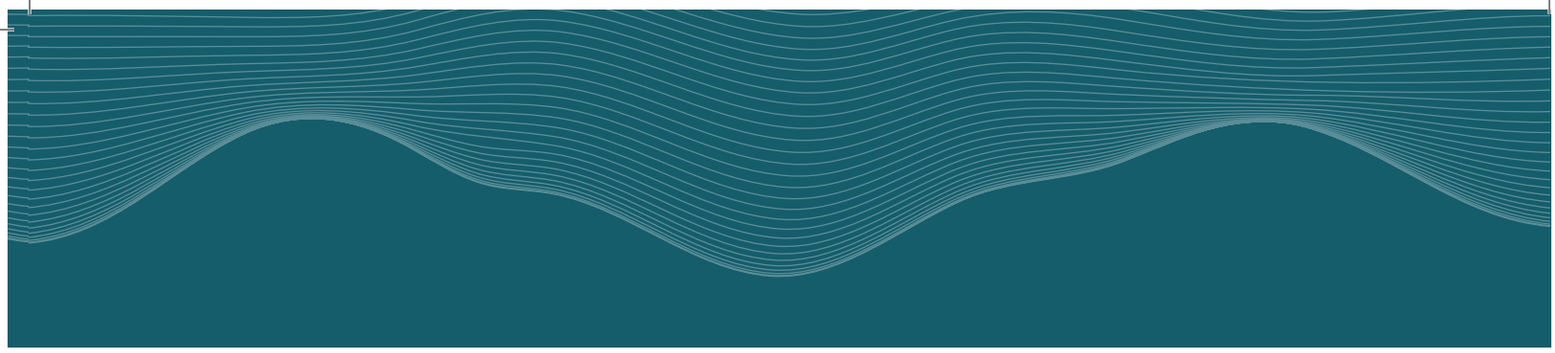
Computational modelling indicates that a continuous delivery of negative pressure at -125 mmHg is advantageous over the application of pressure at -80 mmHg with respect to reducing stress concentration levels around sutures (Orlov and Gefen, 2021). This research is discussed in detail in a later section of this supplement.

Table 4. Featured study (Wilkes et al, 2012)	
Laboratory-based simulated clinical use testing	
Aims	To investigate the effect of ciNPWT (-125 mmHg) on stresses around closed incisions (simulated model)
Methods	Determination of the force required to disrupt simulated incisions (closed with sutures or staples) with or without ciNPWT
Results	• 51% greater force required to extend sutured incision edges approximately 10mm with ciNPWT (92.9±2.6 N) than without ciNPWT (61.7±0.3 N; $p<0.05$) • 43% greater force required to extend stapled incision edges approximately 10mm with ciNPWT (98.8±0.0 N) than without ciNPWT (69.3±0.4 N; $p<0.05$)
Conclusions	ciNPWT was demonstrated to reduce and normalise tissue stresses and bolster appositional forces at the incision. The results are consistent with the findings of *in silico* studies undertaken by the same research group (see below)
Computational modelling	
Aims	To investigate the effect of ciNPWT (-125 mmHg) on stresses around two finite element analysis (FEA) models
Methods	Determination of the lateral stresses on two models representing closed incision wounds with or without ciNPWT • Model 1: Closed incision with sub-cutaneous void (sutured throughout depth) • Model 2: Closed incision with sliding fascial separation (sutured at epidermal and sub-dermal level only)
Results	• Model 1: Approximate 50% reduction (2.2–2.5 kPa to 0.9–1.2 kPa) along incision after application of ciNPWT • Model 2: Approximate 45% reduction (27.8 kPa to 15.4 kPa) at superficial layers and approximate 50% reduction (8.4 kPa to 4.2 kPa) at deep layers after application of ciNPWT
Conclusions	ciNPWT was demonstrated to reduce and normalise tissue stresses and bolster appositional forces at the incision. The results are consistent with the findings of an *in vitro* study undertaken by the same research group (see above)

Table 5. Featured study (Loveluck et al, 2016)	
Aims	To investigate the effect of ciNPWT on lateral tension across the wound
Methods	• Finite element analysis computational modelling • Biomechanical testing using synthetic skin • Canister-less ciNPWT system

Results	*Computational modelling:*
	• Reduction in force on individual suture from baseline (without negative pressure) to after the application of ciNPWT (reduction increased with amount of negative pressure applied):
	  • -40 mmHg: 1.31 to 0.56 N (reduced to 43%)
	  • -80 mmHg: 1.31 to 0.40 N (reduced to 31%)
	Biomechanical testing:
	• Force required to generate 8mm separation of the top edges of the incision in the skin model (required force increased with amount of negative pressure applied):
	  • -40 mmHg: 30.5 N
	  • -80 mmHg: 33.0 N
	  • -120 mmHg: 35.0 N

Conclusions	The results indicate that a canister-less ciNPWT system is able to reduce lateral tension across closed surgical incisions, which may explain observed reductions in surgical site complications with ciNPWT



By bolstering the appositional forces at the closed surgical incision through the reduction of lateral tension, ciNPWT has the potential to improve scar outcomes (Apelqvist et al, 2017). The results of a study involving a porcine wound model indicate that the application of ciNPWT may have a greater effect on wound strength in the early stages of healing and therefore better scar biomechanics, compared to the application of standard dry dressings (Glaser et al, 2012; Table 6). In a RCT involving patients who had undergone breast reduction mammoplasty, better scar outcomes were obtained with the application of ciNPWT to wounds healing by primary intention, compared to those that had been covered by conventional dressings (Holford, 2020).

Table 6. Featured study (Glaser et al 2012)	
Aims	To investigate the effect of ciNPWT on spinal incisions in an *in vivo* model
Methods	• Porcine wound model (subjects n=8) • Two end-to-end midline spine incisions were closed in a standard fashion • ciNPWT was applied to one incision while standard dry dressings were used on the other (control) • After 3 or 5 days, all incisions underwent biomechanical (failure load, failure energy and stress) and scar scale evaluation
Results	• ANOVAs compared the groups (3-day versus 5-day, ciNPWT versus control, p<0.05) • Significantly improved scar height grade with ciNPWT than with the control • Failure load (4.9±4.0 vs 16.5±14.6 N), energy absorbed (8.0±9.0 vs 26.9±23.0 mJ) and ultimate stress (62±52 vs 204±118 N/mm^2) were lower in the control group • No differences between groups with respect to incision scar width (histological analysis)
Conclusions	Application of ciNPWT presented a trend toward improved early healing strength and significantly improved incision appearance. Clinically, ciNPWT may improve incision integrity, minimising the risk of dehiscence and subsequent infection

IMPROVEMENT IN LYMPHATIC DRAINAGE

Oedema imparts increased pressure on the wound which compromises the microvascular blood flow, thereby reducing the inflow of oxygen and nutrients. In turn, this can reduce resistance to infection (Kamolz et al, 2004; Apelqvist et al, 2017). By far the greatest proportion of the research into the effects of negative pressure on reducing oedema has focused on open wounds (Kamolz et al, 2004; Young et al, 2013); however, there are research data which indicate that ciNPWT can also enhance lymphatic drainage.

In a retrospective comparative review of patients who underwent inguinal lymph node dissections as treatment for penile or urethral cancer, lower extremity lymphoedema was observed in subjects receiving ciNPWT, compared to those receiving conventional dressings (0% versus 46%, respectively; p=0.032; Tauber et al, 2013). These findings are consistent with observations from an earlier study in which stable isotope-labelled nanospheres were used to demonstrate enhanced lymph clearance with the application of ciNPWT (Kilpadi and Cunningham, 2011; Table 7).

Table 7. Featured study (Kilpadi and Cunningham, 2011)	
Aims	To investigate the effect of ciNPWT on haematoma/seroma formation, fluid removal into the canister of the ciNPWT system, and involvement of the lymphatic system
Methods	• Porcine wound model (subjects *n*=8) • Two sets of contralateral subcutaneous dead spaces with overlying sutured incisions were created • Stable isotope-labelled nanospheres were introduced into each dead space • Each contralateral incision was assigned to continuous negative pressure (-125 mmHg) and film dressing (control) • After 4 days of ciNPWT, the weight of haematoma/seroma and fluid volume in canisters was determined; pre-identified lymph nodes (*n*=5) were harvested and key organs (*n*=5) biopsied
Results	• 25±8 g (standard error, SE; 63%) less haematoma/seroma in ciNPWT sites, compared to control sites (p=0.002), without any fluid collection in the canister* • Approximately 60 µg (50%) more 30- and 50-nm nanospheres from ciNPWT sites than from control sites (p=0.04, p=0.05, respectively) • Greater nanosphere incidence from ciNPWT sites than from control sites in lungs, liver and spleen (p<0.05); no nanospheres detected in kidney biopsies **the lack of fluid collected in the canister suggests that the sutured closure of the incision sites provided an adequate barrier to direct communication of negative pressure to the sub-cutaneous dead space (i.e. fluid was believed to have been cleared by endogenous mechanisms)*
Conclusions	Application of ciNPWT significantly decreased haematoma/seroma levels without fluid collection in the canister, which may be explained by increased lymph clearance

REDUCTION IN SIZE OF SEROMAS AND HAEMATOMAS

Collections of serum and blood in the tissues around closed surgical incisions create nutrient-rich dead spaces that provide favourable conditions for microbial growth (Nordmeyer et al, 2016; Apelqvist et al, 2017).

In addition to the previously reported in vivo study which observed significantly decreased haematoma and seroma levels when ciNPWT, as opposed to film dressings, was applied to porcine wounds (Kilpadi and Cunningham, 2011; Table 7), a number of clinical studies have been undertaken to determine the effect of ciNPWT on seromas and haematomas at the incision site. For example, in a clinical study involving 100 vascular surgery patients, groin incisions were randomly assigned to the application of ciNPWT (-125 mmHg; *n*=58) or a conventional adhesive dressing (control; *n*=71). Compared to the control group, the incisions that received ciNPWT were associated with significantly fewer complications, as assessed after 5–7 days (p<0.0005) and 30 days (p=0.023) and in revision surgeries (p=0.022). Of the reported complications, haematoma was the second most commonly reported in the control group (*n*=8; 14%), compared to zero cases in the ciNPWT group (p=0.02; Pleger et al, 2018). In another clinical study, closed surgical incisions 'sealed' more rapidly after the application of negative pressure over haematomas, compared to the use of conventional dressings (Stannard et al, 2006; Table 8).

Table 8. Featured study (Stannard et al, 2006)	
Aims	To investigate the effect of ciNPWT on surgical incisions and in the evacuation of draining haematomas
Methods	• Patients with surgical incisions which drained a minimum of 5 days after surgery for traumatic injury • Randomised to either ciNPWT (*n*=13) or pressure dressing (*n*=31) • Key outcome measures: time of drainage; need for return to operating room; infection
Results	• Mean (range) haematoma drainage time significantly shorter in ciNPWT group: 1.6 (0.5) days in ciNPWT group vs 3.1 (0–11) days in dressing group (p=0.03) • Number of patients who developed an infected haematoma requiring surgical evacuation: 1 (8%) in ciNPWT group vs 5 (16%) in dressing group (no statistical analysis reported)
Conclusions	The findings suggest that surgical incisions seal more rapidly after the application of negative pressure over haematomas

As well as demonstrating an effect of ciNPWT on haematomas, clinical studies have shown that, compared to the use of conventional dressings, ciNPWT can lower the volume of seromas during post-operative care (Pachowski et al, 2012; Table 9; Nordmeyer et al, 2016).

Table 9. Featured study (Pachowski et al, 2006)	
Aims	To investigate the effect of ciNPWT on the healing of surgical incisions and on the development of seromas
Methods	• Patients with surgical incisions resulting from total hip arthroplasty • Randomised to either ciNPWT (*n*=9) or conventional dressing (*n*=10) • Ultrasound assessment of seromas on days 5 and 10 post-operatively
Results	• Mean seroma volumes significantly lower in ciNPWT group at day 10: 1.97±3.21 ml in ciNPWT group vs 5.08±5.11 ml in control group (*p*=0.021) • Incidence of seroma lower in ciNPWT group: 4/9 (44%) in ciNPWT group vs 9/10 (90%) in control group (no statistical analysis reported) • Period of antibiotic use was shorter in ciNPWT group: mean 8.44±2.24 days in ciNPWT group vs 11.8±2.82 days in control group (*p*=0.005)
Conclusions	The application of ciNPWT was associated with decreased development of post-operative seromas in the wound

PROVISION OF PHYSICAL BARRIER TO EXTERNAL CONTAMINATION

In addition to reducing the size of seromas and haematomas that would otherwise provide favourable conditions for microbial growth, a ciNPWT system plays an important role in helping to prevent the entry of microorganisms from the external environment to the incision site (Manoharan et al, 2016; Ailaney et al, 2021).

Lower rates of SSI have been observed in subjects receiving ciNPWT, compared to those receiving conventional dressings, in clinical studies involving patients who have undergone a variety of different surgeries, including:

- Abdominal surgery — laparotomy (O'Leary et al, 2017); inguinal hernia repair (Bueno-Lledro et al, 2021)
- Cardiothoracic surgery — sternotomy (Grauhan et al, 2013; Witt-Majchrzak et al, 2015)
- Orthopaedic surgery — total hip/knee arthroplasties (primary and revision; Elhage et al, 2021)
- Trauma surgery — fractures (Reddix et al, 2010; Stannard et al, 2012)
- Vascular surgery — groin incisions (Matatov et al, 2013; Gombert et al, 2018; Hasselmann et al, 2020).

From the outcome of a recently undertaken systematic review and meta-analysis of data generated from 44 RCTs, it was concluded that there is moderate certainty that ciNPWT reduces the risk of SSIs across all surgical procedures (Shiroky et al, 2020; Table 10).

Table 10. Featured study (Shiroky et al, 2020)	
Aims	To investigate whether ciNPWT reduces the risk of SSIs and other surgical incision complications when compared with conventional dressings
Methods	• Systematic review of RCTs that compared a ciNPWT system to any non-NPWT dressing in surgical wounds intended to heal by primary intention • Primary outcome: SSI • Secondary outcomes: dehiscence, pain, seroma, healing time, length of stay (LOS), device-related complications, cost-effectiveness, quality of life • Data synthesised using random effects meta-analyses • Quality of the evidence appraised by using the Grading of Recommendations, Assessment, Development, and Evaluations (GRADE) framework
Results	• Data from 44 RCTs involving 5,693 patients included in analyses • Patients receiving ciNPWT experienced nearly a 40% reduction in the risk of SSI, relative to those with conventional dressings (statistically significant: pooled risk ratio 0.61, 95% confidence interval 0.49–0.74, I^2 = 26%) • Statistically significant reduction in dehiscence and seroma incidence was observed • Effect remained consistent across surgical specialties and brands of NPWT devices
Conclusions	There is moderate certainty that ciNPWT reduces the risk of SSIs across all surgical procedures

IMPROVEMENT IN PERFUSION

Interventions aimed at increasing perfusion, and thus the delivery of additional oxygen to the wound, are likely to improve its healing.

The first exploratory research into the effect of negative pressure on perfusion centred around porcine wounds. For example, a fourfold increase in blood flow levels in the wound and surrounding tissue were observed after the application of -125 mmHg negative pressure (Morykwas et al, 1997). Corroborating these findings, a second study, undertaken to assess the effects of different levels of negative pressure (from -10 mmHg to -175 mmHg), revealed that the maximum change in blood flow in sub-cutaneous and muscle tissue adjacent to porcine wounds was achieved with a negative pressure of -125 mmHg (Borgqvist et al, 2010). Although the findings of the reported studies are arguably more relevant to open wounds than closed surgical incisions, they paved the way for more recent research to be undertaken to evaluate the effect of ciNPWT on perfusion.

In one clinical study, laser Doppler flowmetry was used to monitor peri-sternal perfusion in 20 patients who had undergone cardiac surgery via sternotomy. ciNPWT (-125 mmHg) was applied for 4 days post-operatively to 10 patients; standard dressings were applied to the incisions of another 10 patients (controls). Perfusion increased in the patients who had ciNPWT applied but decreased in the patients who had standard dressings applied (p=0.004). Whereas mammary artery harvesting reduced peri-sternal perfusion by 27% in the control group, a 100% increase in perfusion after the harvesting was observed in those receiving ciNPWT (p=0.04; Atkins et al, 2011). Enhanced perfusion was also observed in post-bariatric wounds after the application of ciNPWT (Renno et al, 2019; Table 11).

Table 11. Featured study (Renno et al, 2019)

Aims	To investigate the short-term effects of ciNPWT on skin perfusion in post-bariatric wounds
Methods	• Patients (n=17) received ciNPWT with a continuous negative pressure of -125 mmHg for 5 days • Two intra-operative and two post-operative measurements were performed using both a combined laser Doppler spectrophotometry and indocyanine green (ICG) angiography system to determine oxygen saturation (sO_2), haemoglobin content (rHb) and perfusion patterns
Results	• At 3 days post-operatively, the sO_2 was significantly higher in the study group compared to the control group, and compared to the end of the operation • No significant alteration was noted in rHb in or between the groups, but a trend towards a correlated alteration of sO_2 and rHb • ICG angiography showed an earlier and stronger enhancement of perfusion parameters in the study group
Conclusions	ciNPWT has a positive effect on oxygen saturation and tissue perfusion, which are both associated with the wound healing process. The use of ciNPWT could therefore possibly reduce the risk of wound healing complications in this high-risk patient group

Studies involving healthy volunteers have also observed increased perfusion following the application of negative pressure. For example, in a randomised study in which the response of cutaneous blood flow in healthy intact forearm skin to varying negative pressures (from -25 mmHg to -500 mmHg) through two different types of commonly used foam dressings was evaluated, the blood flow increased in line with an increase in the amount of negative pressure applied (Timmers et al, 2005). More recently, in a study involving healthy volunteers, the application of negative pressure to intact skin resulted in an increase in tissue oxygen saturation (from 67.7% before application to 76.1% immediately after removal) and an increase in skin temperature (from 32.1°C before the application to 36.1°C immediately after removal). These results were interpreted by the research team as indicators of the ability of ciNPWT to increase tissue perfusion (Muller-Seubert et al, 2021).

As discussed in an earlier section of this supplement, ciNPWT can reduce tissue oedema which may also positively impact perfusion (Singh et al, 2019).

SINGLE-USE NEGATIVE PRESSURE WOUND THERAPY SYSTEMS

Historically, the use of NPWT was generally confined to acute care, mainly due to the size and weight of the pumps and canisters and their dependence on a mains electricity source, all features that tended to restrict patients' mobility (Gleeson and Bond, 2015; Apelqvist et al, 2017). However, the recent development of portable, single-use systems has opened up NPWT to hospital outpatients and those being cared for in the community. Compared to the traditional systems, the single-use negative pressure wound therapy (suNPWT) systems are generally smaller and lighter, do not require a mains electricity supply (instead are powered mechanically or by batteries), require less or no maintenance, are simpler to operate, and consume less clinicians' time. Their portability facilitates patient mobility, thereby enabling ambulatory patients to receive NPWT (Orlov and Gefen, 2021).

Two types of suNPWT system are currently available: canister-based (CB) and canister-free (CF). In the case of CB suNPWT systems, the inclusion of a canister in their design enables exudate and infectious material to be continually removed from the dressing that is in contact with the wound. In the absence of a canister, the dressings used in conjunction with CF suNPWT systems are only able to manage exudate by absorption and evaporation (moisture vapour transmission; Henriksson, 2021).

AVANCE® SOLO NPWT SYSTEM

Suitable for use in both acute and home care settings, the Avance® Solo NPWT System (Mölnlycke Health Care AB, Gothenburg, Sweden) is a CB suNPWT system. It comprises a pump which delivers regulated pressure (-125 mmHg) to the wound for up to 14 days; audible and visible notifications and alarms which are activated when at risk for loss of therapy; a 50 ml canister; a 'quick' connector featuring Controlled Fluid Management (CFM) Technology™ to provide controlled inflow of air which allows transportation of excess exudate to the canister from a bordered dressing (Figure 4). A foam-based wound filler is also supplied with the system. Due to its light weight and portability, the system allows patients to be mobile while delivering negative pressure (Henriksson, 2021), and is indicated for the removal of low-to-moderate exudate in a variety of wound types (Table 12).

Table 12. Intended uses of the Avance Solo NPWT System	
Surgically closed incisions	Open wounds: • Chronic, acute, traumatic, subacute and dehisced wounds • Ulcers (such as diabetic, venous or pressure) • Flaps, grafts.

With the Avance Solo NPWT System, exudate and infectious material are managed by a combination of absorption in the multi-layer bordered dressing, and transport of excess fluid to the canister, thus reducing the risk of the dressing becoming saturated and interrupting the delivery of negative pressure to the wound (Henriksson, 2021; Orlov and Gefen, 2021).

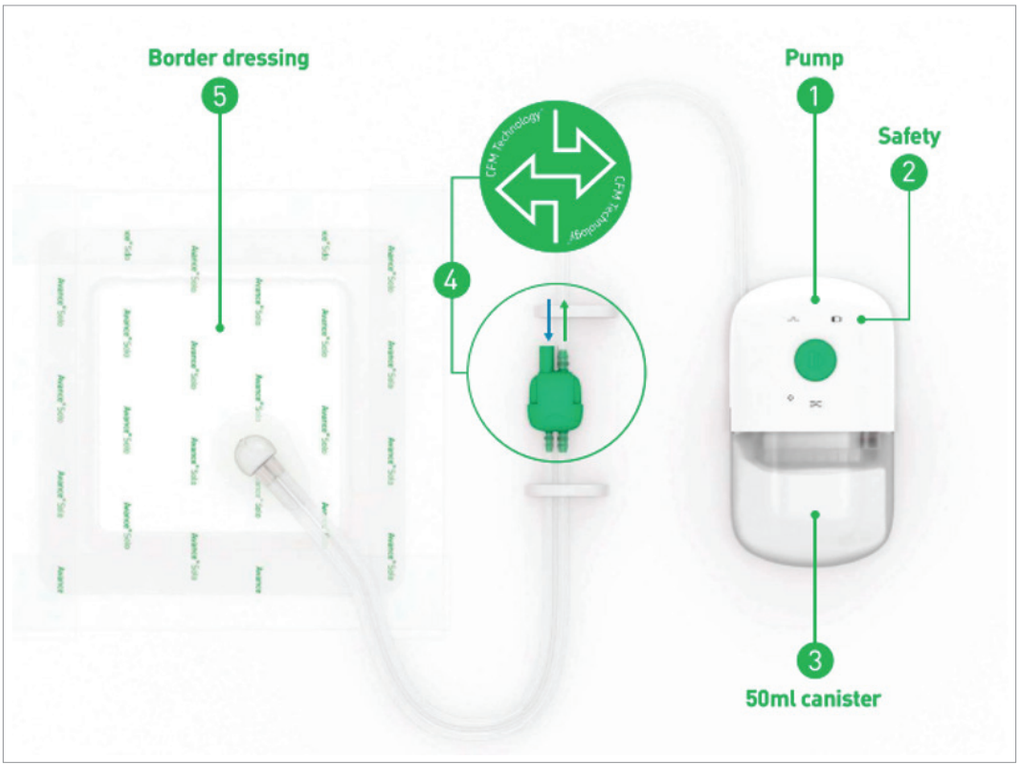


Figure 4 The Avance Solo NPWT System: (1) pump; (2) audible and visible notifications and alarms; (3) 50 ml canister; (4) 'quick' connector featuring Controlled Fluid Management (CFM) Technology™(5) bordered dressing

INVESTIGATIONS INTO THE ABILITY OF AVANCE SOLO NPWT SYSTEM TO DELIVER NEGATIVE PRESSURE

Taking into consideration the mechanisms of action described in an earlier section of this supplement (e.g. the reduction of lateral tension in the wound, achieved by decreasing skin stress concentrations around sutures), the continuous delivery of a specified level of negative pressure to the closed surgical incision is important for promoting its healing. A number of studies have compared the CB Avance Solo NPWT system with CF NPWT systems in relation to these properties (Henriksson, 2021; Orlov and Gefen, 2021).

A research team based in the Department of Biomedical Engineering at Tel Aviv University (Israel) used a laboratory-based simulated wound model, a computational modelling framework, and an *in vivo* porcine wound model to compare the performance of the Avance Solo NPWT System with a CF suNPWT system (Orlov and Gefen, 2021; Table 13).

After applying the CF suNPWT to the simulated wound model, a reduction in the negative pressure delivered to the simulated wound reduced over time from the intended negative pressure of -80 mmHg at the start of the test time, to -20 mmHg as the dressing approached saturation. In comparison, no losses of the intended negative pressure between the pump and the simulated wound were observed after the application of the Avance Solo NPWT System (-125 mmHg; Table 13). These findings are consistent with those from another research team which compared the Avance Solo NPWT System with two CF suNPWT systems (Henriksson, 2021; Table 14).

Both research teams concluded that the most likely explanation for their findings is that the CF suNPWT system relies solely on the dressings to manage fluid, and when they become saturated, they impede the delivery of the intended negative pressure. In comparison, the Avance Solo NPWT system has the capacity to transport excess exudate and infectious material from the dressing to the canister, thereby reducing the risk of dressing saturation and avoiding interruption to the delivery of the intended negative pressure.

The computational model was used to compare the Avance Solo NPWT System with a CF suNPWT system in terms of mechanical behaviour and effect on periwound skin stresses. The greater and continuous negative pressure level delivered by the Avance Solo NPWT System provided the most effective reduction of skin stress concentrations around the sutures (Table 13). These findings explain the results obtained from the *in vivo* porcine model research in which the Avance Solo NPWT System was associated with faster onset of epidermisation than the CF suNPWT system (Table 13).

Table 13. Featured study (Orlov and Gefen, 2021)

Laboratory-based simulated clinical use testing	
Aims	To compare the technical performances of a CB suNPWT (-125 mmHg) system (Avance Solo) and a CF suNPWT (-80 mmHg) system
Methods	• Wound model using horse serum as exudate simulant • Test conditions: A Test times were 3 days (72 hours) or 4 days (96 hours) to reflect the recommended dressing change frequency for the systems when used on moderately and low exudating wounds, respectively B suNPWT dressings were subjected to a volume of exudate simulant corresponding to 20%, 40%, 60% and 80% of the expected wound fluid volume when applied on a moderately exuding wound for an application time of at least 72 hours • Delivery of negative pressure from the suNPWT pump was sampled every 60 seconds using pressure transmitter sensors at multiple positions under the dressing in the simulated wound bed

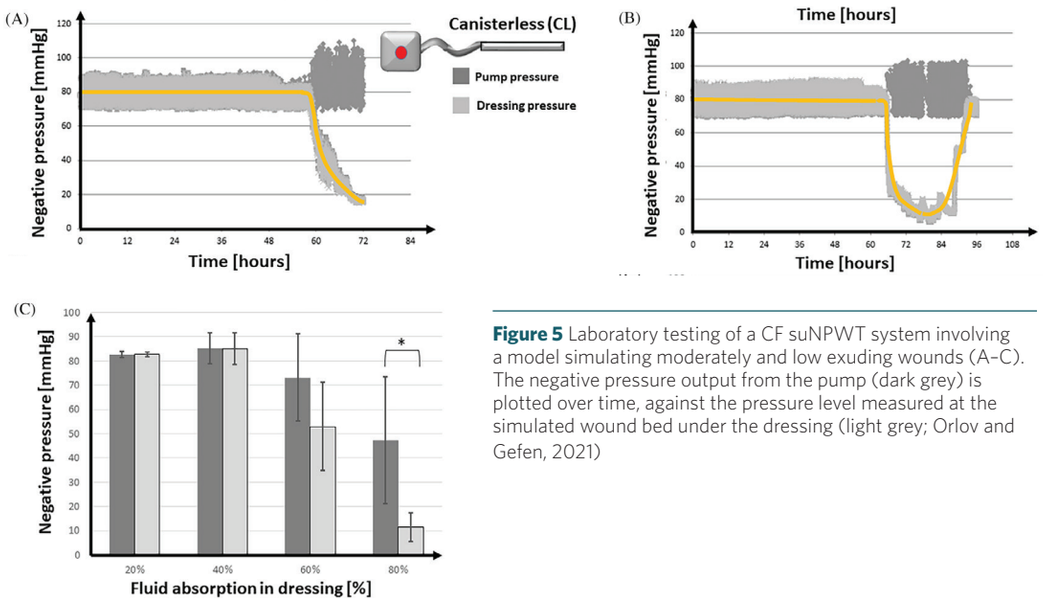
Table 13 (continued). Featured study (Orlov and Gefen, 2021)	
Laboratory-based simulated clinical use testing	
Results	CF suNPWT system: Test conditions A • Reduction in the intended negative pressure level delivered to simulated wound bed under dressing over time, after approximately 2–3 days of use from -80 mmHg to -20 mmHg (measured under dressing), as the dressing approached saturation (Figure 5a and 5b) • Reduction in the intended negative pressure level delivered to simulated wound bed from -80 mmHg to -20 mmHg for a period of a day or more, until the fluid content in the dressing was sufficiently reduced through evaporation to the environment, after which the delivery of the negative pressure produced by the system was restored (Figure 5a and 5b) Test conditions B • Mean negative pressure level in the dressing was statistically indistinguishable from that delivered by the suNPWT pump only for the cases of the dressing managing up to 40% of the exudate simulant. When managing 80% of the expected wound fluid volume of a moderately exuding wound, only 24% of the pump pressure was delivered to the simulated wound bed ($p<0.05$; Figure 5c) CB suNPWT system: • Pressure losses between the pump and the simulated wound bed were not observed  **Figure 5** Laboratory testing of a CF suNPWT system involving a model simulating moderately and low exuding wounds (A–C). The negative pressure output from the pump (dark grey) is plotted over time, against the pressure level measured at the simulated wound bed under the dressing (light grey; Orlov and Gefen, 2021)
Conclusions	• A suNPWT system which provides a greater (absolute) negative pressure magnitude, and which delivers its intended negative pressure by removing the excess exudate from the dressing throughout the time course of the prescribed therapy, is advantageous from a performance perspective • A sufficiently high and stable delivery of negative pressure via the dressing to the closed surgical incision is more likely to facilitate better clinical outcomes, particularly concerning the biomechanical quality of the repaired tissues (see computational modelling and *in vivo* study results below)
Computational modelling	
Aims	To compare the mechanical behaviour and effect on periwound skin stresses of a CB suNPWT (-125 mmHg) system (Avance Solo) and a CF suNPWT (-80 mmHg) system

Table 13 (continued). Featured study (Orlov and Gefen, 2021)	
Computational modelling	
Methods	• The model was based on an elliptically shaped surgical incision 50mm (length) x 2mm (width) x 7mm (depth) • Closure by long (5 sutures) and short (9 sutures) suturing distance and the application of the suNPWT dressing were simulated • The action of the suNPWT systems was simulated as static negative pressure. Based on the findings of the simulated clinical testing described above, a nominal negative pressure level of -125 mmHg throughout the entire period of use of the CB suNPWT system was simulated. For the CF suNPWT system, a nominal negative pressure level of -80 mmHg with occasional pressure drops was simulated
Results	• With the CF suNPWT system, the tissue stress levels around the sutures increased proportionally with the loss of pressure output • The tissue stress levels recorded with the CB suNPWT system were lower than those for the CF suNPWT (for both suturing densities) at baseline and prior to any potential pressure drop with the CF suNPWT system, as the CB suNPWT system operates on a greater (absolute) negative pressure value (Figure 6)
Conclusions	• Periwound skin stress exposures are affected by the pressure level delivered by the suNPWT system, the technology for fluid management (e.g. CB versus CF), which has consequences on the delivery of continuous negative pressure and the suturing technique used for primary wound closure • The greater, continuous and steady negative pressure level delivered by the CB suNPWT system provided the most effective reduction of skin stress concentrations around the sutures

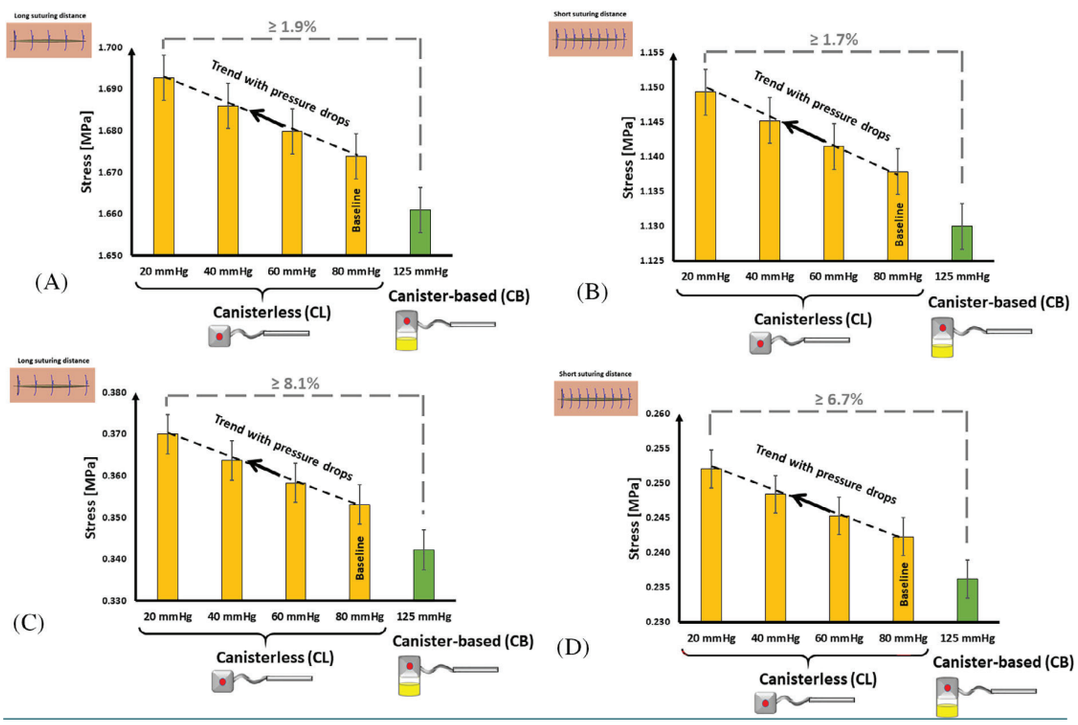


Figure 6 Mean (error bars representing standard errors) stresses around sutures after applying the CB (green bars) and CF (yellow bars) suNPWT systems, for the (A, C) long (low-density) and (B, D) short (high-density) suturing distance model configurations. The data in panels A and B represent the basal, intact (uninjured) skin stiffness, whereas that in panels C and D represent a skin stiffness that is approximately 25% of the basal value (i.e. a compromised skin stiffness at the incision site near the time of surgery; Orlov and Gefen, 2021)

Table 13 (continued). Featured study (Orlov and Gefen, 2021)	
In vivo study	
Aims	To compare wound healing performances of a CB suNPWT (-125 mmHg) system (Avance Solo) and a CF suNPWT (-80 mmHg) system
Methods	• Three incision wounds (6 cm [length] x 7–10mm [depth]) were induced contralaterally (i.e. right and left sides) on the back of pigs (*n*=6) • The two suNPWT systems were applied to the 3 wounds on each side of the back (randomised equally for the locations of the suNPWT systems of each type) • Skin biopsies taken from wounds treated with the two systems (*n*=9 for each system) and stained for histopathological and histomorphometric evaluations • Skin samples of intact (uninjured) skin, *n*=12) and skin treated with the suNPWT systems (*n*=9 for each system) were taken for biomechanical testing, i.e. ultimate tensile strain (UTS), maximum force recorded by the materials testing machine at failure (F_{max}) and structural stiffness
Results	• The biopsies extracted at days 3, 6 and 10 demonstrated normal wound healing, with angiogenesis and formation of granulation tissue evident at day 14, for both suNPWT system types • The F_{max} and UTS of the skin after treatment with negative pressure was approximately 30% and 35% of the levels measured for the intact skin, irrespective of the suNPWT system type that was used • The stiffness of the repaired skin following the use of the CB suNPWT system was 87% of that measured for the intact (uninjured), compared to 81% with the use of the CF suNPWT system (difference not statistically significant) • The CB suNPWT was associated with faster onset of epidermisation (days 3 and 6 for the CB suNPWT versus days 10 and 14 for the CF suNPWT system)
Conclusions	The results can be attributed to the difference in the reduction in stress dose around the sutures induced by each suNPWT system type, as the stress dose describes the exposure of tissues to the varying stresses over time and throughout the healing period

Table 14. Featured study (Henriksson, 2021)	
Aims	To compare the technical performances of a CB suNPWT (-125 mmHg) system (Avance Solo) and two CF suNPWT (-80 mmHg) systems in simulated clinical use tests
Methods	• Laboratory model to simulate clinical use of suNPWT on a moderately exudating wound and a 3-day dressing change regimen • Assessment of fluid management and delivery of intended negative pressure
Results	• CB suNPWT system continuously delivered the intended pressure to the simulated wound throughout the 72-hour test period, without any observed saturation of the dressing • A loss in performance of the intended negative pressure was observed as saturation of the dressings occurred during the test period with the CF suNPWT systems (Figure 7 and 8)

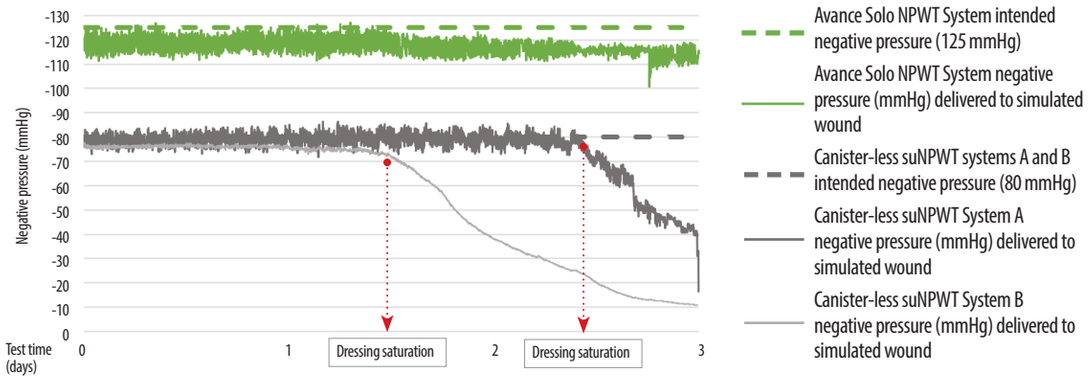
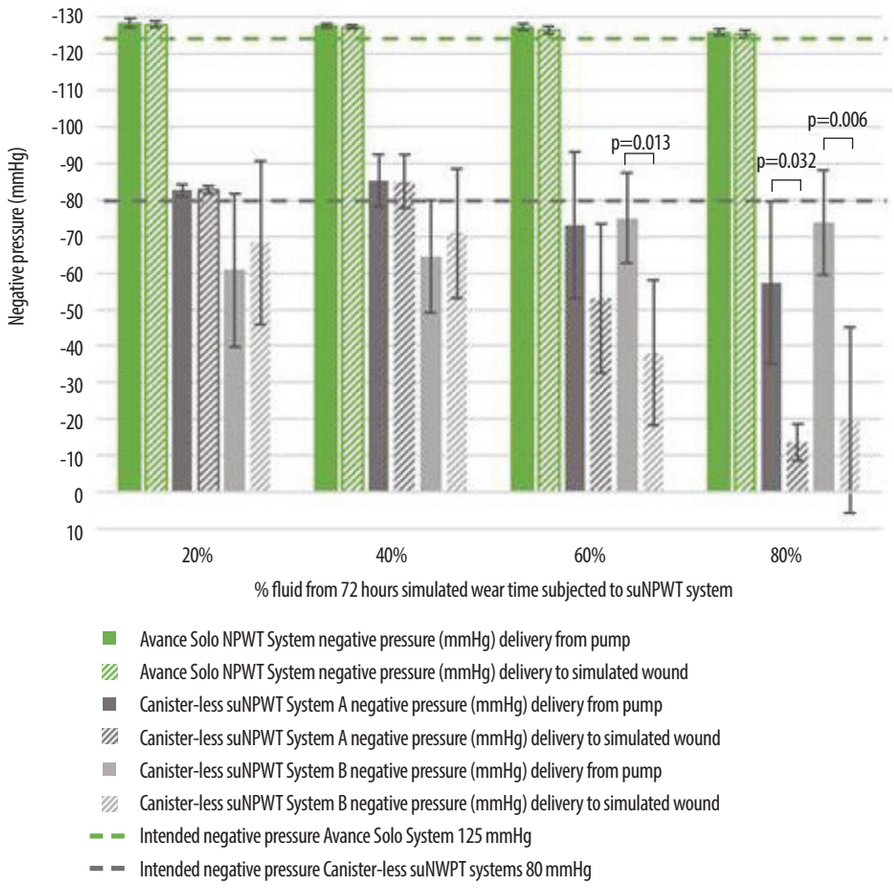


Figure 7 Ability of suNPWT systems to deliver the intended negative pressures (dotted lines) in a laboratory model simulating a moderately exudating wound with a 3-day (72 hours) dressing change regimen. Actual negative pressure delivered are represented by unbroken lines (Henriksson, 2021)

Table 14 (continued). Featured study (Henriksson, 2021)	
Results	 **Figure 8** Ability of suNPWT systems to deliver the intended negative pressure as output from the pump and delivery to the simulated wound. The negative pressure delivered from the pump of the CB suNPWT system to the simulated wound (green bars) was 100% of the intended negative pressure (-125 mmHg). In contrast, the delivery of negative pressure from the pump of the CF suNPWT systems to the simulated wound deviated from the intended pressure (-80 mmHg) as dressing saturation occurred (dark and light grey bars; Henriksson, 2021)
Conclusions	The results could be explained by the CF suNPWT systems having to rely solely on the dressings to manage fluid, and when they become saturated, they impede the delivery of the intended negative pressure. In comparison, the CB 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 and interruption in the delivery of negative pressure

While there is no guarantee that the findings from laboratory studies would be reproducible in the clinical setting, they provide clinicians with important data that should be taken into consideration. This is particularly the case for data generated from well-designed laboratory studies that closely mimic the clinical environment, such as the research presented above. The reported studies have been undertaken under closely controlled conditions (something that is very hard to do clinically due to the heterogeneity of wounds and underlying pathologies) and therefore provide a valid and reproducible means of comparing the performance of different products and technologies.

CASE STUDIES

When making decisions about clinical interventions, it is common practice to consider the relative weight of the available research data, according to the type and quality of studies from which they originate. In the hierarchy of clinical evidence, RCTs and systematic reviews are considered to be the 'gold standards' for judging the benefits of interventions (Barton, 2000; Akobeng, 2005). However, in wound care, practice-based medicine is favoured and allows flexibility as the choice of intervention is based on the individual patient (Gottrup, 2007; White et al, 2010; White and Jeffery, 2010; Kaplan et al, 2011). While this does not mean that all research data are equally valid, it does signify that all available evidence should be considered and evaluated. For example, case studies are a useful means of illustrating clinical challenges, sharing 'real-life' experiences, examining clinical practice and, as such, are much valued as educational tools (Timmons, 2006).

CASE 1. SECURED FLAP FOLLOWING SURGERY FOR PILONIDAL SINUS

***Tuula Eskelinen**, Wound Care Nurse; **Arja Korhonen**, Wound Care Nurse; **Sanna Kouhia**, Vascular Surgeon, Surgery Outpatient Clinic/Wound Outpatient Clinic, Kainuu Central Hospital, Kajaani, Finland*

Patient history

- A 31-year-old female patient with a pilonidal sinus on her sacrum was admitted for surgery (flap procedure)
- Current medical history: chronic pulmonary disease.

Wound history

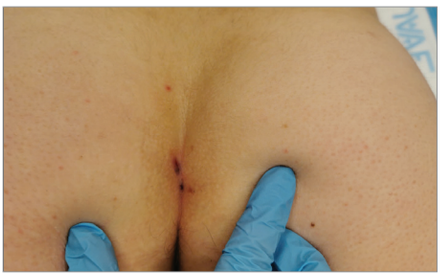
- The surgery resulted in a flap measuring 10cm x 15cm x 10cm, with a depth of 1cm
- No necrotic tissue present. The majority of the flap was attached with a small area of sloughy tissue visible
- Low levels of non-viscous, serosanguineous/bloody fluid were exuding from the surgical incision.

Treatment regimen

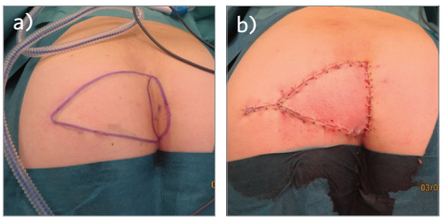
- Avance Solo NPWT System was successfully applied in the operating room and used until the wound had healed. No additional dressing fixation was required
- At every dressing change, the wound was cleansed with a wound irrigation solution containing hypochlorous acid
- No additional antibiotics were prescribed during the treatment period.

Outcome

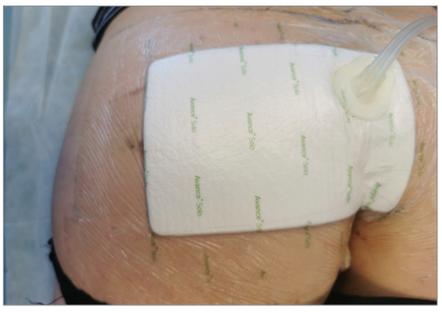
- No exudate was observed at the two subsequent follow-up visits
- There were no clinical signs of infection during the treatment period



Approximately 7 weeks prior to surgery



Day of surgery a) pre-surgery b) post-surgery



Dressing *in situ**

**Note the positioning of the tubing, i.e. in the anatomically upwards direction. If directed downwards, the functionality of the tubing could be affected and may affect the patient's lifestyle*

- The periwound region appeared healthy throughout the treatment period
- Twelve days after the surgery, the wound had completely healed.

Product performance

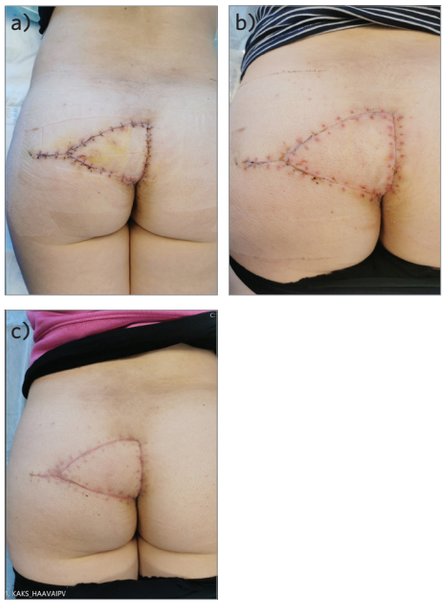
- Despite the difficult-to-dress anatomical location, the dressing was applied with full seal; no alarms were set off during the treatment period
- No additional dressing changes were required in between the scheduled follow-up visits.

Patient's experiences

- The patient reported no pain before or during dressing changes
- The patient was able to tolerate the device and perceived the device to be easy to handle and carry, giving her a sense of safety after the surgery.

Clinician's experiences

- In general, the clinician rated the device as 'very good'. Both the size and conformability of the dressing were specifically noted.



Post-operative follow-up a) day 6 b) day 12 c) day 54

CASE 2. EFFECTIVE INCISION SITE MANAGEMENT FOLLOWING VASCULAR SURGERY

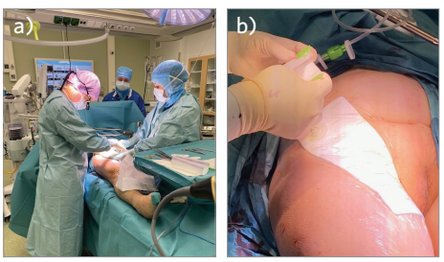
Tuula Eskelinen, Wound Care Nurse; Arja Korhonen, Wound Care Nurse; Sanna Kouhia, Vascular Surgeon, Surgery Outpatient Clinic/Wound Outpatient Clinic, Kainuu Central Hospital, Kajaani, Finland

Patient history

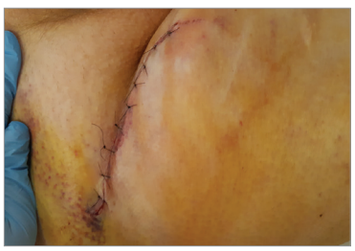
- An 82-year-old female patient was admitted for surgery (thromboendarterectomy with arterioplasty) of the right lower limb
- Current medical history: coronary disease
- Previous surgical history: coronary angioplasty.

Wound history

- The surgery resulted in an incision in the right groin measuring 16cm in length, with a depth of 1cm
- The majority (90%) of the wound was granulating, with a small amount (10%) of slough present
- Exudate levels were low.



Day of surgery (a–b)



Day 4 post-operatively

CASE 2 (CONTINUED). EFFECTIVE INCISION SITE MANAGEMENT FOLLOWING VASCULAR SURGERY

Tuula Eskelinen, WoundCare Nurse; Arja Korhonen, Wound Care Nurse; Sanna Kouhia, Vascular Surgeon, Surgery Outpatient Clinic/Wound Outpatient Clinic, Kainuu Central Hospital, Kajaani, Finland

Treatment regimen

- Avance Solo NPWT System was successfully applied in the operating room and used until the wound had healed. No additional dressing fixation was required
- At every dressing change, the wound was cleansed with a wound irrigation solution containing hypochlorous acid
- No additional antibiotics were prescribed during the treatment period.

Outcome

- Low levels of exudate were observed in the canister throughout the treatment period
- The periwound region appeared healthy throughout the treatment period
- Fifteen days after the surgery, 95% of the wound had epithelialised (5% granulation tissue) and the depth had reduced to 0.2cm
- Three weeks post-operatively, the wound had healed completely (no images available)
- At the 5-month follow-up, no seromas or other complications had been reported and blood circulation had improved.

Product performance

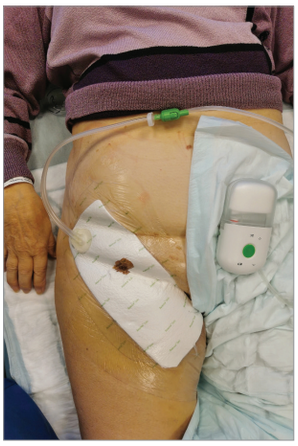
- The dressing was applied with full seal; no alarms were set off during the treatment period
- No additional dressing changes were required in between the scheduled follow-up visits.

Patient's experiences

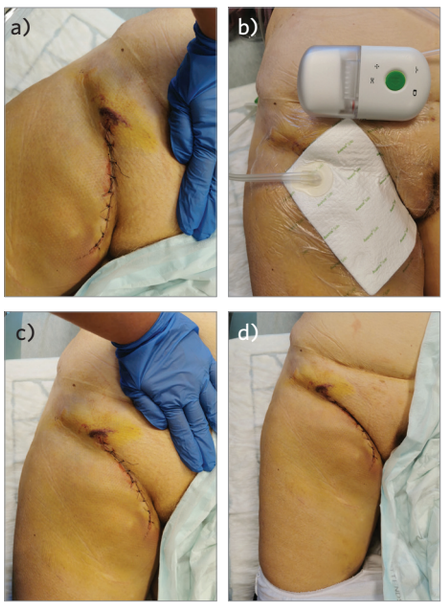
- The patient was satisfied with the device throughout the treatment period, feeling that it was uncomplicated to use and painless.

Clinician's experiences

- In general, the clinician rated the device as 'very good'. The suitability of its size was specifically noted.



Dressing *in situ*



Day 8 post-operatively (a–d)

CASE 3. EFFECTIVE INCISION SITE MANAGEMENT FOLLOWING EXPLORATORY KNEE SURGERY

Antonio Pellegrini, *Orthopaedic Surgeon, IRCCS Istituto Ortopedico Galeazzi, Centre for Reconstructive Surgery and Osteoarticular Infections, Milan, Italy*

Patient history

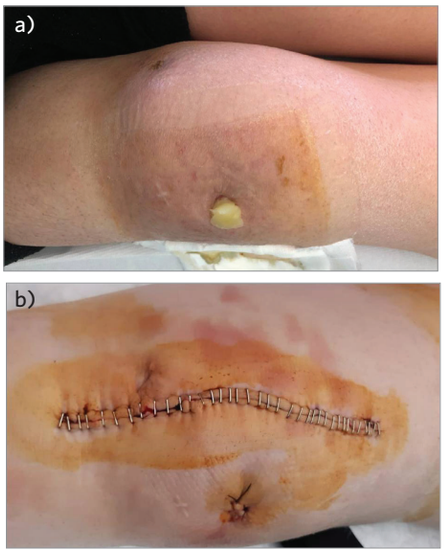
- A 35-year-old female patient developed septic arthritis of the left knee
- Joint surgery, including exploration, debridement and irrigation, was performed
- Current medical history: no chronic disease; the patient was in good health
- Previous surgical history: none, prior to exploratory knee surgery.

Wound history

- The surgery resulted in an incision on the left knee measuring 25cm in length
- The skin surrounding the incision site was ischaemic as a result of inserting the spacer in antibiotic-loaded cement
- Incision drainage was initially moderate (blood/serum) but had reduced substantially by day 2 post-operatively.

Treatment regimen

- Prior to closure, the incision site was cleansed with a wound irrigation solution containing hypochlorous acid
- Avance Solo NPWT System was successfully applied to the closed incision site on the surgical ward 24 hours after surgery and left *in situ* for 4 days
- Prior to use of the negative pressure system, povidone iodine was applied to the closed incision site and an alcohol-based disinfectant was applied to the surrounding skin to optimise adhesion. This was repeated at all subsequent dressing changes. No additional dressing fixation was required
- Systemic antibiotics were prescribed during the treatment period.



Pre- and post-surgery (a–b)

CASE 3 (CONTINUED). EFFECTIVE INCISION SITE MANAGEMENT FOLLOWING EXPLORATORY KNEE SURGERY

Antonio Pellegrini, *Orthopaedic Surgeon, IRCCS Istituto Ortopedico Galeazzi, Centre for Reconstructive Surgery and Osteoarticular Infections, Milan, Italy*

Outcome

- The incision site had completely healed by two weeks post-operatively (no images available)
- The tissue surrounding the incision site appeared healthy with no sign of skin distress
- Up to and including the 12-month post-operative follow-up, no haematoma, seroma or other complications had been reported
- There was no evidence of maceration around the incision site at any point during the treatment period
- Reduction in oedema was observed.

Product performance

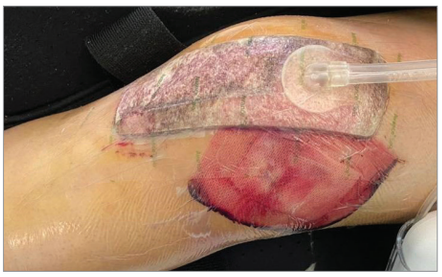
- The dressing was applied with full seal; no alarms were set off during the treatment period
- No additional dressing changes outside of the planned duration of therapy were required.

Patient's experiences

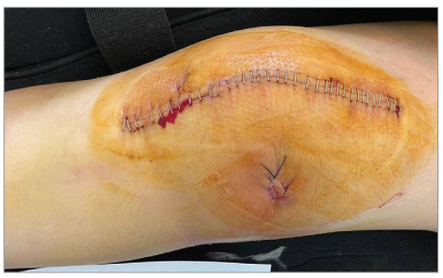
- The patient was very tolerant with therapy, finding it easy to use and comfortable. No criticalities were reported.

Clinician's experiences

- In general, the clinician rated the system as 'very good'. It was specifically noted that incision fluid continued to be transferred to the canister, even when the dressing appeared to be full of fluid. This observation, together with the clinical outcomes described above, provide clear evidence of the continued delivery of negative pressure to the incision site throughout the duration of treatment.



Day 4 post-operatively



Day 5 post-operatively

CASE 4. EFFECTIVE INCISION SITE MANAGEMENT FOLLOWING SURGICAL REMOVAL OF SPACER AND REPLANTING OF PARTIAL THICKNESS GRAFT ON THE KNEE

Antonio Pellegrini, *Orthopaedic Surgeon, IRCCS Istituto Ortopedico Galeazzi, Centre for Reconstructive Surgery and Osteoarticular Infections, Milan, Italy*

Patient history

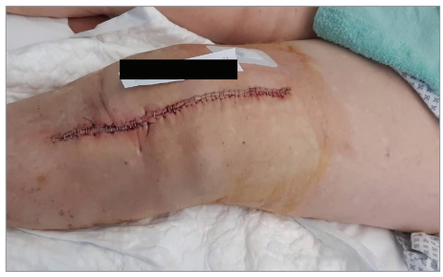
- A 79-year-old female patient required surgery of the left knee
- The surgery was performed to remove a spacer and to replant a partial thickness graft
- Current medical history: chronic anaemia
- Previous surgical history: total knee explantation surgery for fistulised periprosthetic infection (2 months before the start of this case study); other revision surgeries had taken place prior to that.

Wound history

- The surgery resulted in an incision on the left knee measuring 27cm in length
- The skin surrounding the incision site was in poor condition, due to multiple parallel incisions from previous surgeries
- Incision drainage was initially moderate (essentially blood) but had reduced substantially by day 5 post-operatively.

Treatment regimen

- Prior to closure, the incision site was cleansed with a wound irrigation solution containing hypochlorous acid
- Avance Solo NPWT System was successfully applied to the closed incision site on the surgical ward 24 hours after surgery and left *in situ* for 4 days
- Prior to use of the negative pressure system, povidone iodine was applied to the closed incision site and an alcohol-based disinfectant was applied to the surrounding skin to optimise adhesion. This was repeated at all subsequent dressing changes. No additional dressing fixation was required
- Systemic antibiotics were prescribed during the treatment period.



24 hours post-operatively

Dressing *in situ*

CASE 4 (CONTINUED). EFFECTIVE INCISION SITE MANAGEMENT FOLLOWING SURGICAL REMOVAL OF SPACER AND REPLANTING OF PARTIAL THICKNESS GRAFT ON THE KNEE

Antonio Pellegrini, *Orthopaedic Surgeon, IRCCS Istituto Ortopedico Galeazzi, Centre for Reconstructive Surgery and Osteoarticular Infections, Milan, Italy*

Outcome

- The incision site had completely healed by 3 weeks post-operatively (no images available)
- The skin surrounding the incision site was dry, with no signs of ischaemia or distress
- Up to and including the 12-month post-operative follow-up, no haematoma, seroma or other complications had been reported
- There was no evidence of maceration around the incision site at any point during the treatment period
- Reduction in oedema was observed.

Outcome

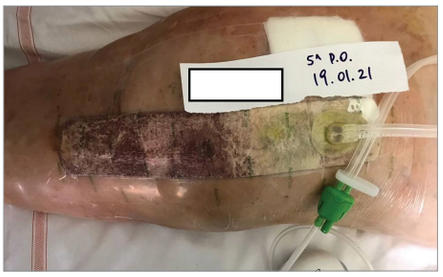
- The dressing was applied with full seal; no alarms were set off during the treatment period
- No additional dressing changes outside of the planned duration of therapy were required.

Patient's experiences

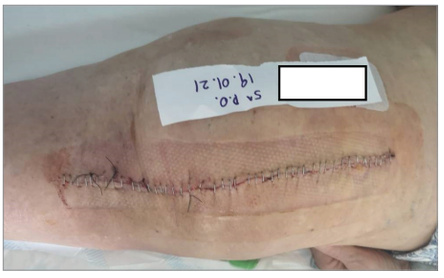
- The patient was satisfied with the device throughout the duration of therapy, feeling that it was uncomplicated to use and painless.

Clinician's experiences

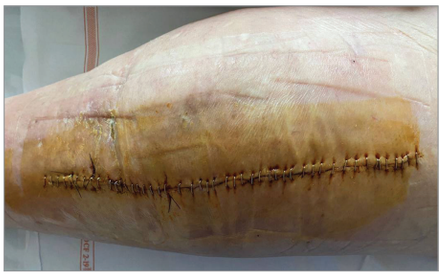
- In general, the clinician rated the system as 'very good'. It was specifically noted that incision fluid continued to be transferred to the canister, even when the dressing appeared to be full of fluid. This observation, together with the clinical outcomes described above, provided clear evidence of the continued delivery of negative pressure to the incision site throughout the duration of treatment.



Day 5 post-operatively (4 days after the start of negative pressure therapy)



Prior to (upper image) and after removal (lower image) of negative pressure therapy. No evidence of maceration. Oedema reduced



Day 18 post-operatively

CASE 5. EFFECTIVE INCISION SITE MANAGEMENT FOLLOWING EXPLANT OF PARTIAL THICKNESS GRAFT AND SPACER IMPLANT ON THE KNEE

Antonio Pellegrini, *Orthopaedic Surgeon, IRCCS Istituto Ortopedico Galeazzi, Centre for Reconstructive Surgery and Osteoarticular Infections, Milan, Italy*

Patient history

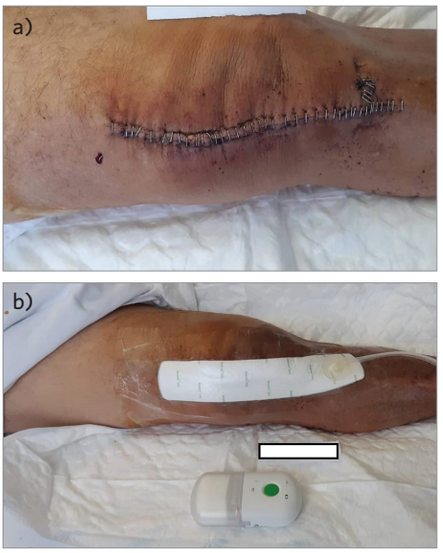
- A 79-year-old male patient required surgery of the right knee
- The surgery was performed to explant a partial thickness graft and implant a spacer
- Current medical history: obesity; lower limb venous insufficiency
- Previous surgical history: total knee replacement with difficult soft tissue healing; subsequent appearance of fistula — periprosthetic infection diagnosed then prosthesis and spacer removal surgery performed (two years prior to start of this case study)

Wound history

- The surgery resulted in an incision on the left knee measuring 26cm in length
- Skin ischaemia was observed around the distal third of the incision site
- Incision drainage was initially moderate (blood/serum) but had reduced substantially by day 5 post-operatively.

Treatment regimen

- Avance Solo NPWT System was successfully applied to the closed incision site on the surgical ward 24 hours after surgery and left *in situ* for 4 days
- Prior to use of the negative pressure system, povidone iodine was applied to the closed incision site and an alcohol-based disinfectant to the surrounding skin to optimise adhesion. This was repeated at all subsequent dressing changes. No additional dressing fixation was required
- Systemic antibiotics were prescribed during the treatment period.



24 hours post-operatively a) closed incision site with moderate drainage prior to application of therapy b) after negative pressure therapy

CASE 5 (CONTINUED). EFFECTIVE INCISION SITE MANAGEMENT FOLLOWING EXPLANT OF PARTIAL THICKNESS GRAFT AND SPACER IMPLANT ON THE KNEE

Antonio Pellegrini, *Orthopaedic Surgeon, IRCCS Istituto Ortopedico Galeazzi, Centre for Reconstructive Surgery and Osteoarticular Infections, Milan, Italy*

Outcome

- The incision site had completely healed by day 20 post-operatively (no images available), despite the poor condition of the skin around the distal end of the incision site
- The skin surrounding the incision site was dry; there were no signs of necrosis around the distal third of the incision site
- Up to and including the 12-month post-operative follow-up, no haematoma, seroma or other complications had been reported
- There was no evidence of maceration around the incision site at any point during the treatment period
- Reduction in oedema was observed.

Product performance

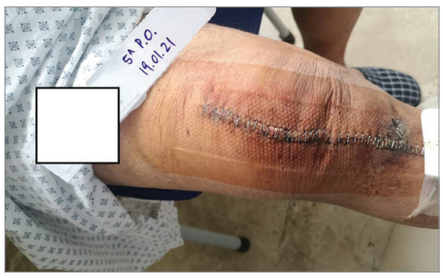
- The dressing was applied with full seal; no alarms were set off during the treatment period
- No additional dressing changes outside of the planned duration of therapy were required.

Patient's experiences

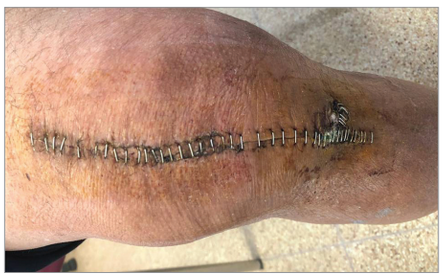
- The patient did not experience any discomfort from the therapy and was very happy that the wound healed quickly, especially given his previous history of multiple hard-to-heal incisions.

Clinician's experiences

- In general, the clinician rated the system as 'very good'. It was specifically noted that incision fluid continued to be transferred to the canister, even when the dressing appeared to be full of fluid. This observation, together with the clinical outcomes described above, provided clear evidence of the continued delivery of negative pressure to the incision site throughout the duration of treatment.



Day 5 post-operatively (4 days after the start of negative pressure therapy)



Day 19 post-operatively

CASE 6. EFFECTIVE INCISION SITE MANAGEMENT FOLLOWING FIXED RE-SPACER SURGERY ON THE KNEE

Antonio Pellegrini, *Orthopaedic Surgeon, IRCCS Istituto Ortopedico Galeazzi, Centre for Reconstructive Surgery and Osteoarticular Infections, Milan, Italy*

Patient history

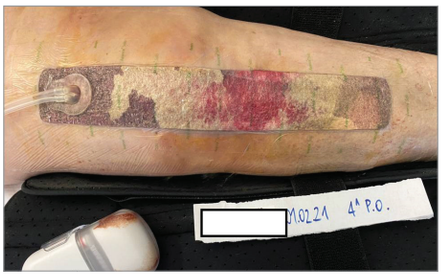
- A 66-year-old female patient presented with persistent infection of the right knee
- Fixed re-spacer surgery was performed
- Current medical history: hypertension
- Previous surgical history: numerous surgeries for recurrent periprosthetic knee infection (multi-resistant Gram-negative bacteria).

Wound history

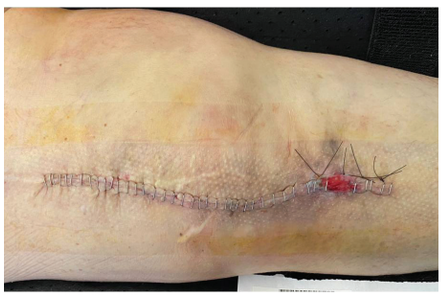
- The surgery resulted in an incision on the right knee measuring 28cm in length
- Very thin and poorly vascularised skin due to the bone plate in the distal area of the incision site
- Incision drainage was initially moderate but had reduced substantially by day 7 post-operatively (after the patient had been moved into the Rehabilitation Department.

Treatment regimen

- Avance Solo NPWT System was successfully applied to the closed incision site on the surgical ward 24 hours after surgery and left in situ for 6 days (the dressing was changed on day 3)
- Prior to use of the negative pressure system, povidone iodine was applied to the closed incision site and an alcohol-based disinfectant was applied to the surrounding skin to optimise adhesion. This was repeated at all subsequent dressing changes. No additional dressing fixation was required
- Systemic antibiotics were prescribed during the treatment period.



Day 4 post-operatively (3 days after start of negative pressure therapy)



Prior to (upper image) and after (lower image) removal of negative pressure therapy. No evidence of maceration. Oedema reduced

CASE 6 (CONTINUED). EFFECTIVE INCISION SITE MANAGEMENT FOLLOWING FIXED RE-SPACER SURGERY ON THE KNEE

Antonio Pellegrini, *Orthopaedic Surgeon, IRCCS Istituto Ortopedico Galeazzi, Centre for Reconstructive Surgery and Osteoarticular Infections, Milan, Italy*

Outcome

- The incision site had completely healed by day 18 post-operatively (no images available)
- Mild pain in the region around the distal area of the incision site, but no evidence of dehiscence or necrosis
- Up to and including the 12-month post-operative follow-up, no haematoma, seroma or other complications had been reported
- There was no evidence of maceration around the incision site at any point during the treatment period
- Reduction in oedema was observed.

Product performance

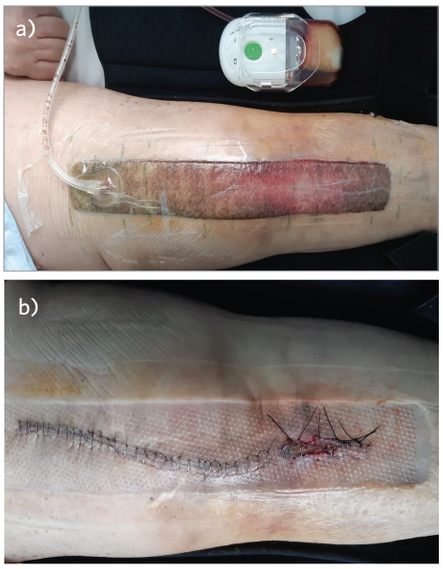
- The dressing was applied with full seal; no alarms were set off during the treatment period
- No additional dressing changes outside of the planned duration of therapy were required.

Patient's experiences

- The patient was very satisfied to have received decisive treatment on a lesion that had previously been treated many times. The perception is of a technologically advanced device.

Clinician's experiences

- In general, the clinician rated the system as 'very good'. It was specifically noted that incision fluid continued to be transferred to the canister, even when the dressing appeared to be full of fluid. This observation, together with the clinical outcomes described above, provided clear evidence of the continued delivery of negative pressure to the incision site throughout the duration of treatment.



Day 7 post-operatively (a–b; 6 days after start of negative pressure therapy)

CONCLUDING REMARKS

This supplement highlights the importance of providing good quality post-operative care for surgical incisions healing by primary intention, and the array of unwanted complications (e.g. infection [SSI], dehiscence, blistering, seroma, haematoma, and poor quality/abnormal scarring) that are associated. These complications present substantial clinical and economic challenges to health care providers, cause significant morbidity and distress to patients and their carers, and increase the risk of mortality.

From within the array of interventions aimed at providing high-quality post-operative wound care, the application of negative pressure to ciNPWT has emerged as an effective means of reducing the risk of these generally avoidable complications. An extensive programme of laboratory-based and clinical research has uncovered multiple mechanisms of action of ciNPWT and demonstrated its efficacy and safety in a wide range of clinical settings.

Historically, the use of NPWT was generally confined to acute care, mainly due to the size and weight of the systems and their dependence on a mains electricity source. The recent introduction of portable, single-use systems has now opened up NPWT to hospital outpatients and those being cared for in the community, including ambulatory patients.

The Avance Solo NPWT System is a CB suNPWT system based on CFM Technology (Figure 4). Due to its light weight and portability, the system allows patients to be mobile while delivering a regulated pressure of -125 mmHg to the wound for up to 14 days, thus making it suitable for use in both acute and home care settings. With this system, exudate and infectious material are managed by a combination of absorption in the multi-layer bordered dressing, and transport of excess fluid to the canister, thus reducing the risk of the dressing becoming saturated and interrupting the delivery of negative pressure to the wound.

In a series of laboratory-based studies, the Avance Solo NPWT System was demonstrated to be able to maintain a continuous delivery of its intended negative pressure to a simulated wound, in contrast to canister-less suNPWT systems for which reductions in the delivery of the intended negative pressure were observed as the dressings approached saturation.

Computational modelling has demonstrated that the Avance Solo NPWT system provides the most effective reduction of skin stress concentrations around the sutures, compared to a CF suNPWT system. These findings should be considered in view of the importance of a continuous delivery of a specified level of negative pressure and the reduction of stress concentrations around sutures to the healing of closed surgical incisions.

The case reports presented in this supplement refer to the use of the Avance Solo NPWT System on closed incisions resulting from a variety of different surgeries. As well as describing good wound healing progress and a lack of post-operative complications, they also reflect the positive experiences of both patients and clinicians with regard to the device. These reported outcomes are worthy of further exploration in larger studies.

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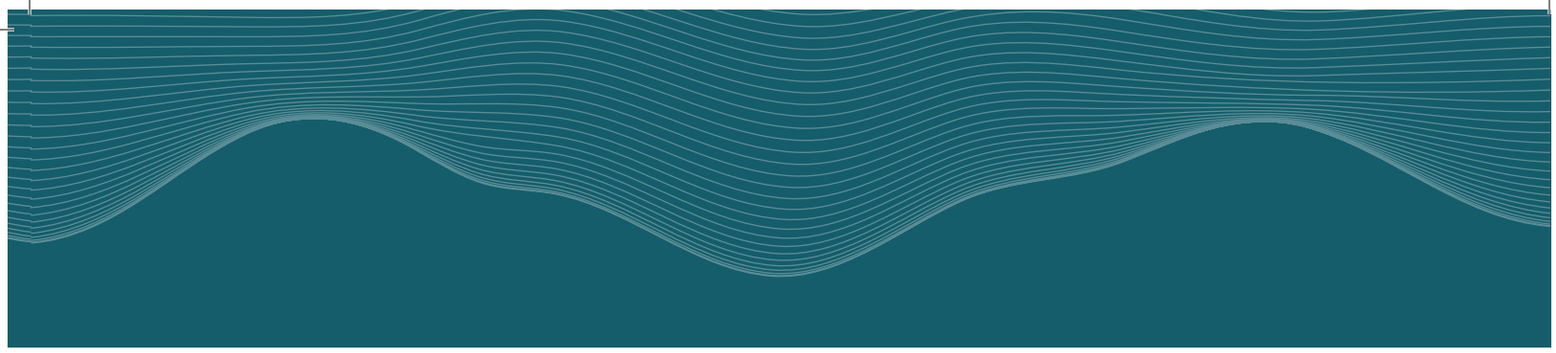

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APPENDIX: SUMMARY OF RCTS UNDERTAKEN TO EVALUATE THE EFFICACY OF ciNPWT BY SURGERY TYPE

Reference	Location Incision reason	ciNPWT (intervention group)	Control group	Main results
Abdominal surgery				
Bueno-Lledro et al (2021)	Spain Incisional hernia repair	Duration: 6 days Pressure: -80 mmHg Subjects: 72	Conventional dressings (self-adhesive, absorbent) Subjects: 74	Lower incidence of surgical incision complications in ciNPWT group at day 30 postoperatively (p<0.042) • ciNPWT: 12/72 (16.6%; SSI, n=0; dehiscence, n=2; haematoma, n=1; seroma, n=9) • Control: 22/74 (29.8%; SSI, n=6; dehiscence, n=4; haematoma, n=2; seroma, n=10) Lower incidence of SSI in ciNPWT group (p<0.0002): • ciNPWT: 0 (0%) • Control: 6/74 (8.1%)
Flynn et al (2020)	Australia Bowel resection/ laparotomy	Duration: 7 days Pressure: -80 mmHg Subjects: 96	Conventional dressings (no details given) Subjects: 92	NSS trend toward lower incidence of SSI in ciNPWT group (OR 1.1; 95% CI 0.50-2.6; p=0.74) • ciNPWT: 13/96 (13.5%) • Control: 14/92 (15.2%) Other surgical incision complication (OR 2.1; 95% CI 0.96-4.8; p=0.06) • ciNPWT: 20 (21.7%) • Control: 11 (11.5%)
O'Leary et al (2017)	Ireland Abdominal surgery (laparotomy)	Duration: 4 days Pressure: -80 mmHg Subjects: 25	Conventional dressings (transparent, waterproof dressing) Subjects: 25	Lower SSI incidence at 30 days postoperatively in ciNPWT group (p=0.043): • ciNPWT: 2/24 (8.3%) • Control: 8/25 (32.0%) Shorter length of stay (days) in ciNPWT group (p=0.019): • ciNPWT: 6.1 • Control: 14.7
Shen et al (2017)	United States of America Resection of intra-abdominal malignancies (laparotomy)	Duration: 4 days Pressure: -125 mmHg Subjects: 132	Conventional dressings (permeable, non-adhesive) Subjects: 133	No significant difference between groups in terms of SSI rate: Superficial (p>0.99) • ciNPWT: 17/132 (12.9%) • Control: 17/133 (12.8%) Deep (p>0.99) • ciNPWT: 4/132 (3.0%) • Control: 4/133 (3.0%)
Uchino et al (2016)	Japan Ileostomy closure	Duration: 14 days Pressure: -80 mmHg Subjects: 28	Conventional dressings (adhesive plaster) Subjects: 31	No significant difference between groups in terms of SSI rate (p=0.76): • ciNPWT:3/28 (10.7%) • Control: 1/31 (3.2%) No significant difference between groups in terms of time (days) to complete wound healing (p=0.18): • ciNPWT: 33.5 ± 10.0 • Control: 37.6 ± 11.7
Breast surgery				
Holford (2020)	United Kingdom Breast reduction mammoplasty	Duration: not stated Pressure: -80 mmHg Subjects: 32	Conventional dressings (fixation strips) Subjects: 32	Lower incidence of surgical incision complications (delayed healing (not closed at day 7/dehiscence/ infection within 21 days of surgery) in ciNPWT group (p<0.004; numbers not reported) Lower incidence of dehiscence in ciNPWT group (p<0.001; numbers not reported) Better scar outcomes (POSAS scale and VAS) in ciNPWT group (significant but no p value reported)

Reference	Location Incision reason	ciNPWT (intervention group)	Control group	Main results
Breast surgery				
Galiano et al (2018)	France Netherlands South Africa United States of America Reduction mammaplasty	Duration: up to 14 days Pressure: -80 mmHg Subjects: 199	Conventional dressings (adhesive tape) Subjects: 199	Lower incidence of healing complications (infection [superficial/deep], dehiscence [partial/thickness/deep/delayed healing]) in ciNPWT group (p=0.004): • ciNPWT: 113/199 (56.8%) • Control: 123/199 (61.8%) Lower incidence of dehiscence (day 21 postoperatively) in ciNPWT group (p<0.001): • ciNPWT: 32/199 (16.2%) • Control: 52/199 (26.4%) NSS trend toward lower incidence of SSI in ciNPWT group (p=0.532): • ciNPWT: 4/199 (2%) • Control: 6/199 (3%)
Muller-Sloof et al (2018)	Netherlands Breast reconstruction (donor site)	Duration: 5-7 days Pressure: -125 mmHg Subjects: 25	Conventional dressings (adhesive strips) Subjects: 26	Lower incidence of dehiscence in ciNPWT group (p=0.038): • ciNPWT: 2 (8.0%) • Control: 9 (34.6%) No significant difference between groups in terms of incidence of SSI (no p value reported): • ciNPWT: 1 (4%) • Control: 0 (0%)
Cardiovascular surgery				
Witt-Majchrzak et al (2015) Nherera et al (2018)	Poland Sternotomy	Duration: 6 days Pressure: -80 mmHg Subjects: 40	Conventional dressings (no details given) Subjects: 40	Fewer SSI in ciNPWT group (p=0.0254) • ciNPWT: 1/40 (2.5%) • Control: 7/40 (17.5%) Greater number of patients in whom primary wound healing occurred without complications in the ciNPWT group (p=0.0339): Less initiation of antibiotic therapy in the ciNPWT group (p=0.0425) ciNPWT resulted in 0.989 complications avoided compared to 0.952 with conventional care; estimated QALYs per patient were 0.8904 for ciNPWT and 0.8593 for conventional dressings Estimated mean cost per patient was €19,986 for ciNPWT compared to €20,572 for conventional care (cost saving of €586)
Colorectal surgery				
Arellano et al (2021)	Spain Colorectal surgery	Duration: 7 days Pressure: -125 mmHg Subjects: 75	Conventional dressings (surgical dressing) Subjects: 73	NSS trend towards lower incidence of SSI in ciNPWT group: Day 7 postoperatively (p=0.1170) • ciNPWT: 10/75 (13.3%) • Control: 17/73 (23.3%) Day 15 postoperatively (p=0.0621) • ciNPWT: 12/75 (16.0%) • Control: 21/73 (28.8%) 1 month postoperatively (p=0.0983) • ciNPWT: 12/75 (17.3%) • Control: 21/73 (28.8%)

Reference	Location Incision reason	ciNPWT (intervention group)	Control group	Main results
Colorectal surgery				
Di Re et al (2021)	Australia Colorectal surgery	Duration: 5–7 days Pressure -125 mmHg Subjects: 61	Conventional dressings (standard post-operative; hydrocolloid) Subjects: 63	NSS trend toward lower incidence of SSI in ciNPWT group: Superficial (p=0.1) • ciNPWT: 6/61 (9.8%) • Control: 13/63 (20.6%) Deep (p=0.98) • ciNPWT:1/61 (1.6%) • Control: 1/63 (1.6%) Organ space (p=1.00) • ciNPWT: 7/61 (11.5%) • Control: 8/63 (12.7%) Lower incidence of superficial dehiscence in ciNPWT group (p=0.03) • ciNPWT: 0/61 (0%) • Control: 6/63 (9.5%)
Murphy et al (2019)	Canada Colorectal resection (open or laparoscopic)	Duration: not stated Pressure: -125 mmHg Subjects: 144	Conventional dressings (gauze) Subjects: 140	NSS trend toward lower incidence of SSI in ciNPWT group at day 30 postoperatively (p=0.68): • ciNPWT: 46/144 (32%) • Control: 48/140 (34%)
Obstetrics and Gynaecology				
Gillespie et al (2021)	Australia Caesarean section	Duration: 5–7 days Pressure: -80 mmHg Subjects: 1017	Conventional dressings (as per standard practice at study site) Subjects: 1018	NSS trend toward lower incidence of SSI in ciNPWT group (RR 0.76; 95% CI 0.57-1.01; p=0.06): - ciNPWT: 75/1017 (7.4%) - Control: 99/1018 (9.7%) Higher incidence of blisters in ciNPWT group (RR 1.72; 95% CI 1.04-2.85; p=0.03): • ciNPWT: 40/996 (4.0%) • Control: 23/983 (2.3%)
Peterson et al (2021)	United States of America Caesarean section	Duration: 7 days Pressure: -80 mmHg Subjects: 55	Conventional dressings (non-adherent; gauze; adhesive film) Subjects: 55	NSS trend toward lower incidence of surgical incision complications (SSI, blisters, scar separation, seroma/haematoma evacuation, debridement, hospital re-admission, re-operation) in ciNPWT group (risk difference 9.1%; 95% CI -8.3-25.8%; p=0.38) • ciNPWT: 11/55 (20.0%) • Control: 16/55 (29.1%)
Hussamy et al (2019)	United States of America Caesarean section	Duration: not stated Pressure: -125 mmHg Subjects: 222	Conventional dressings (adhesive skin closures; gauze) Subjects: 219	NSS trend toward lower incidence of surgical incision complications in ciNPWT group (RR 0.9; 95% CI 0.5-1.4; p=0.54) • ciNPWT: 37/222 (16.7%; SSI, n=20; dehiscence, n=4; cellulitis, n=12) • Control: 42/219 (19.2%; SSI, n=25; dehiscence, n=1; cellulitis, n=16)

Reference	Location Incision reason	ciNPWT (intervention group)	Control group	Main results
Obstetrics and Gynaecology				
Gunatilake et al (2017)	USA Caesarean section	Duration: 5-7 days Pressure: -125 mmHg Subjects: 39	Conventional dressings (adhesive strips; film; gauze) Subjects: 43	NSS trend toward lower incidence of surgical incision site complications (local inflammatory response/prolonged drainage/fluid collection (seroma, haematoma, abscess)/dehiscence/incision intervention) in ciNPWT group (p=0.16): • ciNPWT: 2/39 (5.1%) • Control: 7/43 (16.3%) Fewer patients with less incisional pain in ciNPWT group (p<0.001): At rest • ciNPWT: 20/46 (43.5%) • Control: 39/46 (84.8%) With incisional pressure • ciNPWT: 25/46 (54.3%) • Control: 42/46 (91.3%) Lower opioid usage (morphine equivalents) in ciNPWT group (p=0.036): • ciNPWT: 55.9 mg • Control: 79.1 mg
Ruhstaller et al (2017)	United States of America Caesarean section	Duration: 3 days Pressure: -125 mmHg Subjects: 67	Conventional dressings (non-adherent pad; gauze; surgical tape) Subjects: 69	NSS trend toward lower composite of wound morbidity outcome at 4 weeks postpartum (including SSI and/or wound opening; p=0.71): • ciNPWT: 4.9% (SSI, 2/61 [3.3%]) • Control: 6.9% (SSI, 4/58 [6.9%])
Tuuli et al (2017)	United States of America Caesarean section	Duration: 4 days Pressure: -80 mmHg Subjects: 60	Conventional dressings (no details given) Subjects: 60	No significant difference between groups in terms of composite of SSI or other wound complication (RR 1.67; 95% CI 0.42-6.67; p=0.72): • ciNPWT: 5/60 (8.3%; SSI, n=3; skin separation, n=2) • Control: 3/60 (5.0%; SSI, n=2; seroma, n=1) Lower pain score (median [IQR]) in ciNPWT group (p=0.02) • ciNPWT: 0 (0,1) • Control: 1 (0,3)
Chaboyer et al (2014) Heard et al (2017)	Australia Caesarean section	Duration: 4 days Pressure: -80 mmHg Subjects: 44	Conventional dressings (hydrocolloid) Subjects: 43	NSS trend toward lower incidence of SSI in ciNPWT group (RR 0.81; 95% CI 0.39-1.68; p=0.579): • ciNPWT: 10/44 (22.7%) • Control: 12/43 (27.9%) Health care costing received by each subject: • ciNPWT: $5887 (±1038) • Control: $5754 (±1484) QALYs reported by subjects: • ciNPWT: 0.069 (±0.010) • Control: 0.066 (±0.010) ciNPWT may be slightly more costly and more effective than conventional care, with estimated ICERs of $1347 (95% CI dominant — $41,873) per SSI prevented and $42,340 (95% CI dominant — $884,019) per QALY gained

Reference	Location Incision reason	ciNPWT (intervention group)	Control group	Main results
Orthopaedic surgery				
Higuera-Rueda et al (2021)	United States of America Revision knee arthroplasty	Duration: up to 7 days Pressure: -125 mmHg Subjects: 147	Conventional dressings (silver-containing fibre) Subjects: 147	Lower incidence of surgical incision complications in ciNPWT group (OR 0.22; 95% CI 0.08–0.59; *p*=0.0013) • ciNPWT: 5/147 (3.4%; SSI, *n*=2; dehiscence, *n*=1; continued drainage, *n*=2) • Control: 21/147 (14.3%; SSI, *n*=6; dehiscence, *n*=5; seroma/haematoma, *n*=5; continued drainage, *n*=7) Lower re-admission rates in ciNPWT group (OR 0.30; 95% CI 0.11-0.86; *p*=0.0208): • ciNPWT: 5/147 (3.4%) • Control: 15/147 (10.2%) Lower mean number of dressing changes in ciNPWT group (*p*=0.0003): • ciNPWT: 1.1±0.3 • Control: 1.3±1.0
Keeney et al (2019)	United States of America Total hip/knee arthroplasty	Duration: 7 days Pressure: -80 mmHg Subjects: 185	Conventional dressings (non-adherent cover; gauze; abdominal dressing) Subjects: 213	No significant difference between groups in terms of mean surgical incision appearance scores: Day 7 postoperatively (*p*=0.51) • ciNPWT: 74.3 • Control: 73.4 Days 8-14 postoperatively (*p*=0.20) • ciNPWT: 78.1 • Control: 76.2 Day 35 postoperatively (*p*=0.72) • ciNPWT: 82.6 • Control: 83.1 No significant difference between groups in terms of incidence of late superficial or deep SSI: Superficial (*p*=0.74) • ciNPWT: 1/185 (0.5%) • Control: 4/213 (1.9%) Deep (*p*=0.76) • ciNPWT: 6/185 (3.2%) • Control: 4/213 (1.9%) Less severe wound drainage scores beyond day 14 postoperatively in ciNPWT group (*p*=0.04): • ciNPWT: 0.13±0.5 • Control: 0.23±0.6 Fewer reported dressing-related problems in ciNPWT group (*p*=0.04) • ciNPWT: 4.0% • Control: 9.1%
Newman et al (2019)	United States of American Revision hip/knee arthroplasty	Duration: 7 days Pressure: -125 mmHg Subjects: 79	Conventional dressings (silver-containing fibre) Subjects: 80	Lower surgical incision complication rate in ciNPWT group (*p*=0.022): • ciNPWT: 8/79 (10.1%) • Control: 19/80 (23.8%) After adjusting for history of prior periprosthetic joint infection and inflammatory arthritis, ciNPWT group had decreased wound complication rate (OR 0.28; 95% CI 0.11-0.68) Lower reoperation rate in ciNPWT group (*p*<0.017): • ciNPWT: 2/79 (2.5%) • Control: 10/80 (12.5%)

Reference	Location Incision reason	ciNPWT (intervention group)	Control group	Main results
Orthopaedic surgery				
Giannini et al (2018)	Italy Revision hip/knee arthroplasty	Duration: 7 days Pressure: -80 mmHg Subjects: 50	Conventional dressings (povidone iodine-gauze and patch dressing) Subjects: 50	Lower mean ASEPSIS score in ciNPWT group (p<0.001): • ciNPWT: 3.0 (median: 2.4; range: 0-9; SD: 1.89) • Control: 5.1 (median: 3.9; range: 1-17.7; SD: 3.89) Lower incidence of blisters in ciNPWT group (p<0.05): • ciNPWT: 6 (12%) • Control: 15 (30%) Fewer dressing changes in ciNPWT group (p<0.001): • ciNPWT: 45 (90%) patients had 1 dressing change • Control: 2 (4%) patients had 1 dressing change Lower mean VAS pain severity scores at dressing change in ciNPWT group (p<0.001): • ciNPWT: 2.6 (median: 2; range: 1-6) • Control: 4.8 (median: 5; range: 2-7)
Karlakki et al (2016)	United Kingdom Primary hip/knee arthroplasty	Duration: 7 days Pressure: -80 mmHg Subjects: 102	Conventional dressings (absorbent pad) Subjects: 107	NSS trend toward lower incidence of wound complications (infection [skin/wound]/prolonged wound discharge [with/without delayed healing or cellulitis]) in ciNPWT group (p=0.06): • ciNPWT: 2/102 (2.0%) • Control: 9/107 (8.8%) No significant difference between groups in terms of SSI rate: • ciNPWT: 2/102 (2.0%) • Control: 6/107 (5.6%) No significant difference in groups in terms of overall length of stay (LOS) but fewer patients with extreme LOS values in ciNPWT group (p=0.003) Fewer dressing changes in ciNPWT group (mean difference 1.7; 95% CI 0.8-2.5; p=0.002)
Manoharan et al (2016)	Australia Primary knee arthroplasty	Duration: 1-12 days Pressure: -125 mmHg Subjects: 21	Conventional dressings (dry dressings) Subjects: 33	Higher average costs in ciNPWT group (p≤0.011, ES=1.06): • ciNPWT: $396.02 • Control: $43.51 No significant difference between groups in terms of QoL factors, with the exception of: Wound leakage (p=0.019, ES=1.02) • ciNPWT: 0.14 • Control: 0.39 Wound protection (p=0.001, ES=0.021) • ciNPWT: 0.16 • Control: 0.33 NNS trend toward fewer dressing changes in ciNPWT group (p=0.317, ES=1.02) • ciNPWT: 1.19 • Control: 1.38

Reference	Location Incision reason	ciNPWT (intervention group)	Control group	Main results
Orthopaedic surgery				
Gillespie et al (2015)	Australia Primary hip arthroplasty	Duration: 5 days Pressure: -80 mmHg Subjects: 35	Conventional dressings (absorbent pad) Subjects: 35	More wound complications (bruising/bleeding/haematoma/seroma/dehiscence) in ciNPWT group (RR = 1.6; 95% CI 1.0-2.5; *p*=0.04): • ciNPWT: 24/35 (68.6%) • Control: 15/35 (42.8%) No significant difference between groups in terms of SSI rate (RR 0.67; 95% CI 0.12-3.7; *p*=0.65): • ciNPWT: 2/35 (5.7%) • Control: 3/35 (8.6%) Higher dressing costs in the ciNPWT group: • ciNPWT: $38.40/day • Control: $3.01/day
Pachowsky et al (2012)	Germany Total hip arthroplasty	Duration: not stated Pressure: -125 mmHg Subjects: 9	Conventional dressings (no details given) Subjects: 10	Lower mean seroma volume in ciNPWT group (at day 10; *p*=0.021): • ciNPWT: 1.97±3.21 ml • Control: 5.08±5.11 ml Lower incidence of seroma in ciNPWT group (no statistical analysis reported): • ciNPWT: 4/9 (44%) • Control: 9/10 (90%) Shorter mean duration of antibiotic use in ciNPWT group (*p*=0.005): • ciNPWT: 8.44 days • Control: 11.8 days
Howell et al (2011)	United States of America Total knee arthroplasty	Duration: not stated Pressure: -125 mmHg (continuous) Subjects: 24	Conventional dressings (gauze) Subjects: 36	No statistical difference between groups in terms of number of days to a dry wound: • ciNPWT: 4.3 days • Gauze: 4.1 days No significant difference between groups in terms of number of SSIs: • ciNPWT: 1/24 (4.2%) • Gauze: 1/36 (2.8%) Study was stopped prematurely due to high rate of skin blister formation in ciNPWT group: • ciNPWT: 15/24 (63%) • Gauze: 3/36 (12%)
Trauma surgery				
Costa et al (2020) Png et al (2020)	United Kingdom Trauma surgery (lower limb fractures)	Duration: not stated Pressure: -80 mmHg Subjects: 770	Conventional dressings (as per standard practice at study site) Subjects: 749	NSS trend toward lower incidence of deep SSI incidence in ciNPWT group: Day 30 postoperatively (OR 0.87; 95% CI 0.57-1.33; absolute risk difference -0.77%; 95% CI -3.19%-1.66%; *p*=0.52) • ciNPWT: 45/770 (5.84%) • Control: 50/749 (6.68%) Day 90 postoperatively (OR 0.84; 95% CI 0.59-1.19; absolute risk difference -1.76%; 95% CI -5.41%-1.90%; *p*=0.32) • ciNPWT: 72/629 (11.4%) • Control: 78/590 (13.2%) Incremental cost of conventional dressings vs ciNPWT over 6 months was £2,037 (95% CI £349-£3,724. Insignificant increment in QALYs gained in the ciNPWT group (0.005, 95% CI -0.018-0.028). Probability of ciNPWT being cost-effective at £20,000 was 1.9%

Reference	Location Incision reason	ciNPWT (intervention group)	Control group	Main results
Trauma surgery				
Crist et al (2017)	United States of America ORIF (acetabular fractures)	Duration: At least 24 hours Pressure: -125 mm Hg Subjects: 33	Conventional dressings (gauze) Subjects: 33	No significant difference between groups in terms of incidence of SSI (p=0.25) • ciNPWT: 5 (15.2%) • Control: 2 (6.1%)
Nordmeyer et al (2016)	Germany Dorsal stabilisation of spinal fractures	Duration: 5 days Pressure -80 mmHg Subjects: 10	Conventional dressings (no details given) Subjects: 10	Smaller mean seroma volumes in ciNPWT group: Day 5 (p=0.0007) • ciNPWT: 0 ml • Control: 1.9 ml Day 10 (p<0.024) • ciNPWT: 0.5 ml • Control: 1.6 ml Less wound care time for patients in ciNPWT group (p=0.0005): • ciNPWT: 13.8 ± 6 minutes • Control: 31 ± 10 minutes Fewer compresses used in ciNPWT group (p=0.0376): • ciNPWT: 11±3 • Control: 35±15
Stannard et al (2012)	United States of America Trauma surgery (fractures)	Duration: 2-8 days Pressure: -125 mmHg (continuous) Subjects: 141	Conventional dressings (standard post-operative dressings) Subjects: 122	Lower SSI incidence in ciNPWT group (p=0.049): • ciNPWT: 14/141 (9.9%) • Control: 23/122 (18.9%) Relative risk of developing SSI 1.9 times higher in control group than in ciNPWT group (95% CI, 1.03-3.55) Lower incidence of dehiscence in ciNPWT group (p=0.044): • ciNPWT: 12 (8.6%) • Control: 20 (16.5%)
Stannard et al (2006)	United States of America Study 1: Haematoma drainage Study 2: Fractures (calcaneus, pilon, tibial plateau)	Duration: not stated Pressure: not stated Subjects: 13 Duration: not stated Pressure: not stated Subjects: 20	Conventional dressings (pressure dressings) Subjects: 31 Conventional dressings (standard post-operative dressings) Subjects: 24	Shorter mean drainage time in ciNPWT group (p=0.03): • ciNPWT: 1.6 days • Control: 3.1 days No significant difference between groups in SSI rate: • ciNPWT: 1/13 (7.7%) • Control: 5/31 (16%) Shorter mean drainage time in ciNPWT group (p=0.02): • ciNPWT: 1.8 days • Control: 4.8 days No significant difference between groups in SSI rate: • ciNPWT: 3/20 (15.0%) • Control: 3/24: (12.5%) No significant difference between groups in WD rate: • ciNPWT: 1/20 (5.0%) • Control: 1/24 (4.2%)

Reference	Location Incision reason	ciNPWT (intervention group)	Control group	Main results
Vascular surgery				
Hasselmann et al (2020	Sweden Vascular surgery with groin incision	Duration: 7 days Pressure: -80 mmHg Subjects: 59 with unilateral incisions; 19 with bilateral incisions	Conventional dressings (adhesive film with absorbent pad) Subjects: 61 with unilateral incisions; 19 with bilateral incisions	Lower incidence of SSI in ciNPWT group (unilateral and bilateral groups combined; *p*=0.02): Unilateral group (*p*=0.024) • ciNPWT: 7/59 (11.9%) • Control: 18/61 (29.5%) Bilateral group (*p*=0.125) • ciNPWT: 1/19 (5.3%) • Control: 5/19 (26.3%)
Bertges et al (2020)	United States of America Vascular surgery with groin incision	Duration: not stated Pressure: -125 mmHg Subjects: 118	Conventional dressings (gauze) Subjects: 124	No significant difference between groups in terms of 30-day surgical incision complication (SSI, major non-infectious complication, graft infection) rate (*p*=0.55) • ciNPWT: 31% • Control: 28%
Engelhardt et al (2018)	United States of America Vascular surgery with groin incision	Duration: 5 days Pressure: -125 mmHg Subjects: 64	Conventional dressings (absorbent adhesive) Subjects: 68	NSS trend toward lower incidence of SSI in ciNPWT group: Day 42 postoperatively (*p*=0.055) • ciNPWT: 9/64 (14%) • Control: 19/68 (28%) Day 5 postoperatively (*p*=0.125) • ciNPWT: 4/64 (6%) • Control: 10/68 (15%)
Gombert et al (2018)	Germany Vascular surgery with groin incision	Duration: 5-7 days Pressure: -125 mmHg Subjects: 98	Conventional dressings (non-adherent, absorbent) Subjects: 90	Lower incidence of SSI in ciNPWT group (absolute risk difference -20.1 per 100; 95% CI -31.9-8.2; *p*=0.0015): • ciNPWT: 13/98 (13.2%) • Control: 30/90 (33.3%) Less antibiotic usage in ciNPWT group (*p*=0.004): • ciNPWT: 13/98 (13.2%) • Control: 28/90 (31.1%)
Kwon et al (2018)	United States of America Vascular surgery with groin incision	Duration: 5 days Pressure: -125 mmHg Subjects: 59	Conventional dressings (gauze) Subjects: 60	Lower incidence of major surgical incision complications (SSI, dehiscence, haematoma, lymph leak) in ciNPWT group (*p*<0.001): • ciNPWT: 7/59 (11.9; SSI, *n*=6; dehiscence, *n*=1] • Control: 16/60 (26.7%; SSI, *n*=12; dehiscence, *n*=1; haematoma, *n*=1; lymph leak, *n*=2) Fewer subjects requiring re-operation/re-admission in ciNPWT group: Re-operation (*p*=0.05) • ciNPWT: 5/59 (8.5%) • Control: 11/60 (18.3%) Re-admission (*p*=0.04) • ciNPWT: 4/59 (6.8%) • Control: 10/60 (16.7%) ciNPWT associated with a saving of $6045 per patient

Reference	Location Incision reason	ciNPWT (intervention group)	Control group	Main results
Vascular surgery				
DiMuzio et al (2017)	USA Vascular surgery with groin incision	Duration: not stated Pressure: -125 mmHg Subjects: 59	Conventional dressings (gauze) Subjects: 60	Lower incidence of surgical incision site complications in ciNPWT group: Number of SSIs (p<0.001) • ciNPWT: 6/59 (10.02%) • Control: 15/60 (25.0%) Reoperation rates (p<0.05) • ciNPWT: 8.5% • Control: 18.3% Readmission rates (p<0.05) • ciNPWT: 6.8% • Control: 16.7% Length of stay (days; NSS; p value not reported) • ciNPWT: 10.6 • Control: 10.6 ciNPWT associated with a reduction in mean total inpatient cost per patient of $6045
Lee et al (2017a)	Canada Saphenous vein harvest	Duration: up to 7 days Pressure: -125 mmHg Subjects: 33	Conventional dressings (gauze) Subjects: 27	No significant difference between groups in terms of SSI rate: • ciNPWT: 0/31 (0%) • Control: 1/17 (5.9%) Earlier discharge (6 vs 10 days, p=0.008), increased ability for self-care (p=0.0234), better quality of life at initial assessment (p=0.039), and increased mobility at initial (p=0.0117) and follow-up assessment (p=0.0123) in ciNPWT group vs control group
Lee et al (2017b)	Canada Vascular surgery with groin incision	Duration: up to 8 days Pressure: -125 mmHg Subjects: 53	Conventional dressings (gauze) Subjects: 49	NSS trend toward lower incidence of SSI in ciNPWT group (p=0.24): • ciNPWT: 6/53 (11.3%) • Control: 9/49 (18.4%) Shorter mean duration of hospital stay (days) in ciNPWT group (p=0.01): • ciNPWT: 6.4 • Control: 8.9
Sabat et al (2016)	United States of America Vascular surgery with groin incision	Duration: 5 days Pressure: -125 mmHg Subjects: 30	Conventional dressings (gauze; film) Subjects: 33	NSS trend toward lower incidence of SSI in ciNPWT group (p=0.09): • ciNPWT: 2/30 (6.67%) • Control: 7/33 (21.2%) No significant difference between groups in terms of number of dehiscence (p=0.95): • ciNPWT: 1/30 (3.3%) • Control: 1/33 (3.0%)
Suh and Hong (2016)	Korea Superficial circumflex iliac artery perforator flap harvest (closed donor sites)	Duration: 5 days Pressure: -50 to -125 mmHg Subjects: 50	Conventional dressings (foam; gauze) Subjects: 50	Shorter duration (p=0.0077) and smaller amount (p=0.0004) of closed suction drainage in ciNPWT group: • ciNPWT: 3.34 ± 1.35 days (median, 3 days; range, 2 to 4 days)/23.28 ± 18.36 cc (median, 20 cc) • Control: 6.12 ± 4.99 days (median, 4 days; range, 3 to 8 days)/100.47 ± 140.69 cc (median, 42 cc) Greater skin perfusion (day 5) observed in ciNPWT group (p=0.0223) No significant difference between groups in terms of occurrences of dehiscence (p value not reported): • ciNPWT: 0 • Control: 1

Reference	Location Incision reason	ciNPWT (intervention group)	Control group	Main results
Multiple surgeries				
Masden et al (2012)	United States of America Various surgery types (abdomen; back; groin; above/below knee amputation; knee disarticulation; Chopart's amputation/ transmetatarsal amputation)	Duration: not stated Pressure: -125 mmHg Subjects: 44	Conventional dressings (silicone wound contact layer; silver-coated absorbent dressing) Subjects: 37	NSS trend toward lower incidence of SSI in ciNPWT group (p=0.46): • ciNPWT: 3/44 (6.8%) • Control: 5/37 (13.5%) No significant difference between groups in terms of time to development of SSI (no p value reported) No significant difference between groups in terms of incidence of dehiscence (p=0.54): • ciNPWT: 16/44 (36.4%) • Control: 11/37 (29.7%) No significant difference between groups in terms of time to dehiscence (p value not reported)

Key: ASEPSIS = Additional treatment, Serous drainage, Erythema, Purulent exudate, Separation of deep tissue, Isolation of bacteria and Stay as inpatient prolonged over 14 days; CI = confidence interval; ciNPWT = closed incision negative pressure therapy; ES = effect size; ICER = incremental cost-effectiveness ratio; IQR = interquartile range; NSS = not statistically significant; OR = odds ratio; ORIF = open reduction internal fixation; POSAS = Patient Observer and Scar Assessment Scale; QALY = quality-adjusted life year; QoL = quality of life; RR = risk ratio; VAS = visual analogue scale

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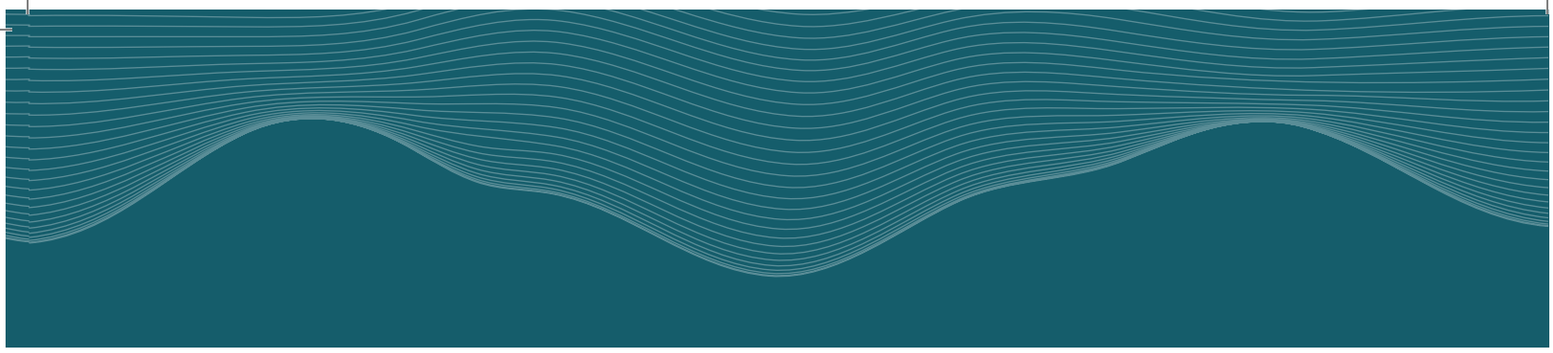

Wounds

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