Evaluation of single-use negative pressure wound therapy systems under simulated clinical conditions

Anette Svensson Henriksson Mölnlycke® Health Care AB Mölndal, Sweden

INTRODUCTION

Negative pressure wound therapy (NPWT) is widely used in clinical practice to support healing of surgical incisions.

NPWT SURGICAL INCISION

- Reduced postoperative complications such as infection and dehiscence[1-3]
- Reduced incisional tissue strain and oedema[3-5]
- Improved perfusion[3, 6]

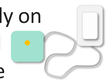
QUALITY OF LIFE AND HEALTH COSTS

In addition to the clinical benefits, NPWT has been demonstrated to improve quality of life for the patient and to reduce health costs.[7-8]

Since their first introduction, NPWT systems have evolved from large reusable pumps with foam or gauze dressing to compact single-use NPWT (suNPWT) devices with multilayer absorptive (MLA) or peel-and-place (PP) foam dressings, with or without a canister connected to the pump for fluid collection.

CANISTER–LESS (CL) suNPWT SYSTEMS

Exudate management relies solely on dressing absorption capacity and moisture-vapor transmission rate



CANISTER–BASED (CB) suNPWT SYSTEMS

Exudate is transported from the wound site and collected in the canister to minimize fluid accumulation within the dressing

SCOPE

The clinical effectiveness of NPWT may be impaired if pressure delivery or fluid handling is compromised, thus increasing the risk of complications.[9] In this study, the pressure distribution and fluid management of single-use NPWT (su NPWT) systems with MLA dressings with or without a canister, is evaluated under simulated clinical use.

MATERIALS AND METHODS

Materials

CL suNPWT System A	CL suNPWT System B	CB suNPWT System C
-80 mmHg	**-80 mmHg**	**-125 mmHg**
Superabsorbent dressing	**Fiberbased dressing**	**Superabsorbent dressing**

Method – Performance test

WOUND MODEL	• Simulating a moderately exuding wound • 72-hour (3-day) wear period of the dressing
WOUND FLUID	• Horse serum simulating exudate viscosity, osmolarity, pH • Infused to the suNPWT system from beneath the dressing • Flow rate of 1.1 g/cm²/24 h[10]
PERFOR MANCE	• Negative pressure was measured at multiple positions (pump, simulated wound) • Sampled every 60 seconds throughout the test time

Method – Proof of concept

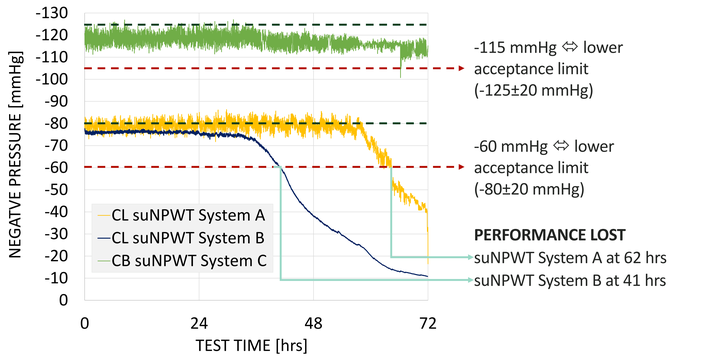
WOUND MODEL	• 14 day porcine incision model[11] • Wound depth to the deep fascia
STUDY ARMS	• CL suNPWT System A @ -80 mmHg • CB suNPWT System C @ -125 mmHg
PERFOR MANCE	• Sampling full wounds and biopsies • Local tissue effects • Quality of repaired tissue

RESULTS

Performance

CL suNPWT Systems A and B showed progressive loss of performance from the intended negative pressure 80±20 mmHg measured at the simulated wound bed. The loss of performance (at -60 mmHg) developed over time and as a function of fluid inlet to the system and is hypothesized to be due to increased saturation of the dressing.

CB suNPWT System C showed sustained performance of the intended −125 ± 20 mmHg throughout the test time, independently of increased fluid volume and without saturation of the dressing.



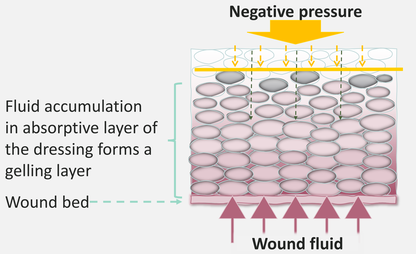
The graph shows the performance of the suNPWT Systems in the simulated use test with the actual pressure each system delivered to the simulated wound bed.[12]

- - - intended negative pressure for each suNPWT system

- - - lower threshold of performance according to system specifications

Loss of negative pressure performance in CL suNPWT Systems A and B, could be explained by fluid accumulation in the dressing causing the wound pad to swell and form a gelling layer blocking[13]

- fluid transport to the backing film
- negative pressure from reaching the wound bed

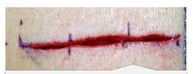


As saturation continues, swelling compresses the remaining dry material, further slowing fluid movement. At this point, therapy is lost and the dressing must be changed.

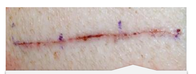
Proof of concept

WOUND HEALING

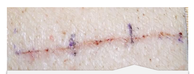
Incisions (6 cm length) were created down to the deep fascia and closed with 3 sutures. (N = 18 per study arm) Wound healing progress with complete epithelialization at study termination. [11, 14]



Day 0
Incision closed with 3 sutures



Day 6
Majority of wounds showed complete skin apposition

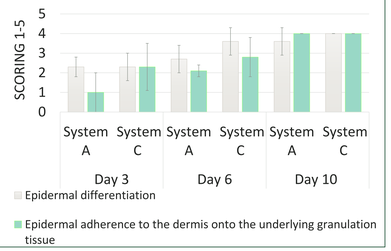


Day 14
Epithelialization confirmed by histopathology at study termination

WOUND QUALITY

Qualitative histopathology analysis of tissue samples showed faster onset of re-epithelialization for wounds applied with CB suNPWT System C

- **Day 6** CB suNPWT System C higher scoring for epidermal differentiation and epidermal adherence to the dermis onto the underlying granulation tissue
- **Day 10** CB suNPWT System C higher scoring for epidermal differentiation



CONCLUSIONS AND KEY FINDINGS

EFFECTIVE FLUID MANAGEMENT ENABLES UNINTERRUPTED NEGATIVE-PRESSURE THERAPY

In **a comparative performance evaluation** simulating clinical use of suNPWT on closed incision, active removal of wound fluid from the wound bed and dressing to a canister (System C) proved to be important for continuous delivery and distribution of intended negative pressure from the system pump through the dressing to the wound bed. The suNPWT systems designed without a canister (Systems A and B), showed loss of performance over time and fluid absorption in the dressing. The canister-based System C showed sustained performance throughout the test time.

Proof of concept was established in a pre-clinical wound-healing porcine model for closed incision, comparing the wound healing performance for closed incisions applied with CL suNPWT System A or CB suNPWT System C.

Qualitative histopathological assessment of parameters for re-epithelialization suggested an overall faster onset for wounds treated with System C with a more rapid epidermal differentiation and adherence to the underlying granulation tissue, as compared to wounds that had System A applied.

1. Apelqvist J, et al. Negative Pressure Wound Therapy: Future Perspectives. *EWMA Journal*. 2017;18(2):33-36. 2. Wilkes R, et al. Effects of dressing type on 3D tissue microdeformations during negative pressure wound therapy: a computational study. *J Biomech Eng*. 2009;131(3):031012-1-031012-12. doi:10.1115/1.2947358. 3. Scalise A, et al. Improving wound healing and preventing surgical site complications of closed surgical incisions: A possible role of Incisional Negative Pressure Wound Therapy. A systematic review of the literature. *Int Wound J*. 2016;13(6):1260–1281. doi:10.1111/iwj.12492. 4. Stannard JP, et al. Incisional Negative Pressure Wound Therapy After High-Risk Lower Extremity Fractures. *J Orthop Trauma*. 2012;26(1):37-42. 5. Apelqvist J, et al. Negative Pressure Wound Therapy: An Update for Clinicians and Outpatient Care Givers. *J Wound Management*. 2024;25(2 Sup1): 1-56 DOI 10.35279/jowm2024.25.02.sup01. 6. Kilpadi DV, et al. Evaluation of closed incision management with negative pressure wound therapy (CIM): Hematoma/seroma and involvement of the lymphatic system. *Wound Repair Regen*. 2011;19(5):588–596. 7. Dowsett C. Management of wound exudate. *Independent Nurse*. 2012 Available at: www.independentnurse.co.uk/clinical-article/management-of-wound-exudate/63637/ (accessed 16/10/2021). 8. Dowsett C, et al. The economic benefits of negative pressure wound therapy in community-based wound care in the NHS. *Int Wound J*. 2012;9(5): 544-52. 9. Schultz G, et al. WUWHS consensus document. Wound exudate-effective assessment and management. *Wounds Int*. Published February 1, 2019. Available from: https://www.woundsinternational.com. 10. Malmsjö M, et al. Biological effects of a disposable, canisterless negative pressure wound therapy system. *Eplasty*. 2014;14:e15. 11. The study was conducted under approval no. 01063.03 of the NAMSA Medical Device Testing Ethical Committee registered by the French Department of Agriculture (Chasse-sur-Rhône, France). 12. Svensson Henriksson A. Single use negative pressure wound therapy (suNPWT) system with controlled fluid management technology – an evaluation of performance. *Wounds International*. 2021;12(4):62-68. 13. Wack H, et al. Method and Model for the Analysis of Gel-Blocking Effects during the Swelling of Polymeric Hydrogels. *Ind. Eng. Chem. Res*. 2007; 46(1); 359-364. 14. Data on File (GLP Report Study 272024, 2021).

PARC# MHC 2026 000800