

Negative Pressure Wound Therapy

Clinical and Case Studies



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Negative pressure wound therapy (NPWT) is the use of sub atmospheric pressure to remove exudate and debris from wounds to promote wound healing. NPWT has been utilized since the 1950's; originally to remove purulent material and exudate from surgical wounds. The physicians later discovered that NPWT also increased healing rates while removing infectious material. The initial research focused on the increase of granulation tissue at a pressure setting of negative 125 mmHg¹ and the exudate management and wound contraction of a cutaneous fistula at negative 60-80 mmHg². It should be noted that the most common used pressure level of negative 125 mmHg is based on a limited study performed on swine in the 1990's¹. The assertion of the use of one pressure in treating all wounds has been regarded with skepticism by some investigators. Kairinos et al.³, suggests that the level of negative pressure should be adapted to suit the consistency and type of tissue, and the perfusion status of the wound. Despite this debate, NPWT has repeatedly been shown to be an effective local care method for stimulating better and more rapid healing of acute wounds and benefits chronic ulcers. The current empirical data substantiates the initial NPWT study results, thereby concluding NPWT to be an efficacious therapy for general wound management^{4,5}. Moreover, studies have begun to focus on a broader base of clinical benefits utilizing different variables such as pressure settings, wound fillers, drains, and contact layers⁴. The medical community also supports the utilization of NPWT to assist wound clinicians with treatment goals, which include but are not limited to: accelerated wound closure, decrease in pain, fistula management, decrease in odor, an increase in patient's quality of life, physical protection of wound, decreased bioburden, graft adherence, exudate management, and cost containment^{4,5,6}. This document provides a conclusive overview of objective CLINICAL DATA for the use of NPWT and the Medela NPWT systems. Medela has been a pioneer and state of the art manufacturer in medical suction for over 50 years and is a leading provider of NPWT systems.

¹ Argenta, L. & Morykwas (1997). Vacuum-assisted closure: a new method for wound control and treatment: animal studies and basic foundation. *Annals of Plastic Surgery*, 38, 553-562.

² Chariker, M., Jeter, K., Tintle, T., & Bottsford, J. (1989). Effective management of incisional and cutaneous fistulae with closed suction wound drainage. *Contemporary Surgery*, 34, 59-63.

³ Kairinos, N., Solomons, M., Hudson, D. (2009) Negative-pressure wound therapy i: the paradox of negative-pressure wound therapy. *Plastic Reconstructive Surgery*, 123(2): 589-98; discussion 599-600

⁴ Sorensen, Malmso, Rome, et al. Evidence-based recommendations for negative pressure wound therapy: treatment variables (pressure levels, wound filler and contact layer) steps towards an international consensus. *Journal of Plastic, Reconstructive and Aesthetic Surgery*. 2011; 64: S1-S16

⁵ Agency for Healthcare Research and Quality. Negative pressure wound therapy devices: technology assessment report.

Available at:<http://archive.ahrq.gov/research/findings/ta/negative-pressure-wound-therapy/negative-pressure-wound-therapy.pdf>. Accessed March 2nd, 2016.

NPWT Clinical Evidence

Citation	Key Points	Study Type	Wound Etiology							Wound Filler		
			Surgical	Trauma	Burn	Flap/Graft	Enteric Fistula	Diabetic Foot	Pressure Ulcer	Venus Ulcer	Arterial Ulcer	Foam
<p>Koppes P, Krohs U, Mares A, Harlacher S, Bowe M, Paglinawan R, Marquardt C.</p> <p>Secondary suture in complication management of subcutaneous surgical site infections after colorectal surgery: A prospective case series using NPWT with PHMB gauze. Presented at the Annual Symposium on Advanced Wound Care (SAWC) Spring, April 23–27, 2014, Orlando, FL, US.</p>	<ul style="list-style-type: none"> Subcutaneous infections after median laparotomy for colorectal surgery were treated by (negative pressure wound therapy) NPWT with a PHMB gauze system and finally closed by secondary suture. Hypothesis: NPWT provides shorter treatment time, minimal pain as well as cost savings for the total treatment when compared to standard treatment (moist-to-dry) dressing treatment with gauze plus 0.04% PHMB solution. Conclusion: PHMB gauze under NPWT proved to be a powerful system for treating SSI, provided a comfortable dressing that was noted to be in a “minimal pain level range” during dressing changes, and lowered overall treatment time and costs. 	Prospective case series	●									●
<p>Malmisjo M, Ingemansson R.</p> <p>Green foam, black foam or gauze for NPWT: effects on granulation tissue formation. Journal of Wound Care. June 2011; 20(6): 296-301.</p>	<ul style="list-style-type: none"> Green foam and black foam (both polyurethane (PU), reticulated open pore foam dressings) have similar biological effects on the wound bed. Bleeding and exudate can be more easily monitored when using green foam or gauze. Differences in the wound bed tissue morphology when using foam or gauze plus NPWT support clinical observations that granulation tissue under foam is thick but fragile, whereas that under gauze is thinner but denser. 	Porcine wound model								●	●	
<p>Wyndam-White C, Rosset C, Paglinawan R, Reed S.</p> <p>The use of gauze based NPWT system to assist wound closure. Presented at the Annual (SAWC) Spring, April 17– 20, 2010, Orlando, FL, US</p>	<ul style="list-style-type: none"> Three patients with chronic wounds were treated with a gauze based NPWT system to assist granulation formation and wound closure. All wounds responded well in all three patients. 	Case Series				●		●				●
<p>Marquardt C, Krohs U, Bil E, Schiedeck Th, Jurczok A, Paglinawan R, Simon M.</p> <p>Challenge in Wound Care: The Open Abdomen with Intestinal Fistula and Stoma. Presented at the 23rd Annual Symposium on Advanced Wound Care & Wound Healing Society (SAWC/WHS), Orlando, Florida, US April 17-20, 2010.</p>	<ul style="list-style-type: none"> The NPWT system with PHMB gauze demonstrated an outstanding capacity in treating challenging postoperative abdominal wounds with intestinal fistula. During treatment, patients were mobile with a high degree of comfort. 	Case Series	●				●					●

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<p>Ammar A, Paglinawan R, Chariker M, Simon M. Healing rates in patients receiving negative pressure wound therapy. Presented at the 22nd Annual Clinical Symposium on Advanced Wound Care/Wound Healing Society (SAWC/WHS), April 26-29, 2009 Dallas, TX. US.</p>	<ul style="list-style-type: none"> • A retrospective analysis of archived data from wounds of 55 patients treated with a gauze-based NPWT system was subjected to data quality assessment and statistical analysis. • On average, wounds were 62.7% of their initial areas and 24.28% of their initial volumes at the end point of therapy. • Demonstrated the gauze based NPWT system is effective in accelerating wound healing. 	Retrospective data analysis																			
<p>Paglinawan R, Colic M, Simon M. A comparative of various dressings coupled to a negative pressure wound therapy system to study effects on wound healing. Presented at the 22nd Annual Clinical Symposium on Advanced Wound Care /Wound Healing Society (SAWC/WHS), April 26-29, 2009 Dallas, TX. US.</p>	<ul style="list-style-type: none"> • A comparison of various existing dressing types in combination with a negative pressure wound therapy system. Studied the influence on both wound closure and granulation tissue formation in wounds of porcine. • Results suggest that healing is taking place with each one of the dressings used in combination with NPWT on porcine wound model. 	Porcine wound model																			
<p>Chadwick P, Haycocks S, Watts K. Use of a new negative pressure wound therapy system in the treatment of foot ulcers: a case study series Salford Royal NHS Foundation Trust, Hope Hospital, Salford, UK. 2011.</p>	<ul style="list-style-type: none"> • To evaluate the performance of a NPWT system in the management of foot ulcers associated with diabetes and/or neuropathy. • The findings indicate that the new system is highly flexible, portable and effective, although larger clinical studies need to be undertaken in order to confirm this. 	Case Series																			
<p>Pritchard B, Cadwaladr B. Clinical experience with a new negative pressure wound therapy system in the treatment of a variety of different wound types. University Health Board, Wrexham Maelor Hospital, Wrexham, UK. 2011.</p>	<ul style="list-style-type: none"> • Results of a study that set out to assess the effectiveness of a (NPWT) system in the treatment of a variety of different wound types in both hospital and home care settings. • Highlights that the NPWT system is a highly flexible and portable means of applying negative pressure to a variety of different wound types. 	Case Series																			

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<p>Chadwick P, Bamford A, Harrison M, Pritchard B. Multicenter clinical Evaluation of a new negative pressure wound therapy system in the treatment of complex, hard to heal wounds. Salford Royal NHS Foundation Trust, Hope Hospital, Salford, UK. University Hospitals Birmingham NHS Foundation Trust, Birmingham, UK. Royal Liverpool and Broadgreen University Hospital Trust, Liverpool, UK Betsi Cadwaladr University Health Board, Wrexham Maelor Hospital Wrexham, UK. 2011.</p>	<ul style="list-style-type: none"> The results of a multicenter case series that was undertaken to evaluate the performance of a new (NPWT) system in the management of a variety of complex, hard-to-heal wound types, all of which are associated with significant disability and mobility as well as having a considerable impact on health care resources. The new NPWT system is a highly flexible and portable means of applying negative pressure to a variety of different wound types. Its effective use and patient acceptability has been demonstrated in the treatment of a wide range of wound types. 	Case Series	●	●	●				●	●	●	●
<p>Bowe M, Watson P, Tucker H, Moore C, Paglinawan R. A case series featuring a new NPWT device well suited for Home Healthcare. Presented at the Annual Symposium on Advanced Wound Care (SAWC) Spring, April 24 – 26, 2014, Orlando, FL, US.</p>	<ul style="list-style-type: none"> An ultra-portable device can be used effectively on the majority of wounds for which NPWT is indicated and in all care settings. A device that promotes freedom and mobility helps patients resume normal daily activities which in turn improves patient care. Patients found the system to be light, portable, easy to use and comfortable. 	Case Series	●					●			●	●
<p>Koppes P, Harlacher S, Bowe M, Paglinawan R, Marquardt C. Complex wounds: A new portable NPWT pump efficiently supports wound healing. Presented at the 26th Annual Clinical Symposium on Advanced Wound Care Spring/Wound Healing Society May1-5, 2013, Denver, CO. US.</p>	<ul style="list-style-type: none"> Three patients with complicated post-operative wound infections treated with a NPWT portable device utilizing a sequential therapy program utilizing both foam and gauze. Demonstrated that the use of the portable pump provided the possibility to discharge mobile patients managed with the sequential NPWT regimen and to perform dressing changes and secondary suture in the ambulatory care setting. Demonstrated the usefulness of the portable pump in the successful treatment of wounds in a variety of healthcare settings. 	Case Series	●								●	●

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Agency for Health Care Research and Quality, (May, 2009), Negative Pressure Wound Therapy Devices, AHRQ Technology Assessment Report, Project ID: WNDT1108	<ul style="list-style-type: none"> AHRQ Technology Assessment published in May 2009 states after extensive literature review of all existing NPWT research they were not able to identify a significant therapeutic distinction of one NPWT system or component over another through the use of head-to-head comparison. (page 95) No NPWT system has been proven to be superior by means of randomized control trials. There is no evidence to date demonstrating a singular component of this complete system is more important in Wound Care than any of the others. 	AHRQ Technical Assessment														
Armstrong DF, Lavery LA Negative pressure wound therapy after partial diabetic foot amputation: a multicentre, randomized controlled trial. Lancet 2005 366:1704-1710.	<ul style="list-style-type: none"> Investigated whether NPWT improves the proportion and rate of wound healing after partial foot amputation in patients with diabetes. NPWT was found to be a safe and effective treatment for complex diabetic foot wounds, and could lead to a higher proportion of healed wounds, faster healing rates, and potentially fewer re-amputations than standard care. 	Randomized controlled trial		●					●			●				
Blume PA, Walters J, Payne W, Ayala J, Lantis J. Comparison of Negative pressure wound therapy using vacuum assisted closure with advanced moist wound therapy in the treatment of diabetic foot ulcers: a multicenter randomized controlled trial. Diabetes Care.2008 Apr;31(4): 631-6.	<ul style="list-style-type: none"> The purpose of this study was to evaluate safety and clinical efficacy of (NPWT) compared with advanced moist wound therapy (AMWT) to treat foot ulcers in diabetic patients. A greater proportion of foot ulcers achieved complete ulcer closure with NPWT (73 of 169, 43.2%) than with AMWT (48 of 166, 28.9%) within the 112-day active treatment phase (P = 0.007). CONCLUSIONS: NPWT appears to be as safe as and more efficacious than AMWT for the treatment of diabetic foot ulcers. 	Randomized controlled trial											●		●	●

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<p>Birke-Sorensen H, Malmsjo M, Rome P, et. al.</p> <p>Evidence-based recommendations for negative pressure wound therapy: Treatment variables (pressure levels, wound filler and contact layer) - Steps towards an international consensus.</p> <p>Journal of Plastic, Reconstructive and Aesthetic Surgery. 2011.June 64, S1-S16.</p>	<ul style="list-style-type: none"> A global expert panel was convened to develop evidence based recommendations describing the use of NPWT. Results of the assessment of evidence relating to the different NPWT treatment variables: different wound fillers (principally foam and gauze); when to use a wound contact layer; different pressure settings; and the impact of NPWT on bacterial bioburden. In general, there is relatively weak evidence on which to base recommendations for any one NPWT treatment variable over another. Overall, 14 recommendations were developed: five for the choice of wound filler and wound contact layer, four for choice of pressure setting and five for use of NPWT in infected wounds. 	Systematic literature review	●	●					●	●	●	●	●	●
<p>Moisisdis E1, Heath T, Boorer C, Ho K, Deva AK</p> <p>A prospective, blinded, randomized, controlled clinical trial of topical negative pressure use in skin grafting.</p> <p>Plast Reconstr Surg. 2004 Sep 15;114(4):917-22.</p>	<ul style="list-style-type: none"> This study aimed to assess whether split-thickness skin graft take is improved qualitatively or quantitatively with topical negative pressure therapy compared with standard bolster dressings. Although the quantitative graft take was not significant, the qualitative graft take was found to be significantly better with the use of topical negative pressure therapy ($p < 0.05$). Topical negative pressure significantly improved the qualitative appearance of split-thickness skin grafts as compared with standard bolster dressings. 	Blinded, prospective, randomized trial				●						●		
<p>Lonie, S., Hallam, J., Yii, M., Davis, P., Newcomb, A., Nixon, I., Rosalion, A., & Ricketts, S.</p> <p>Changes in the management of deep sternal wound infections: a 12 year review.</p> <p>ANZ Journal of Surgery 2015 July16: 878-881. doi: 10.1111/ans.13279</p>	<ul style="list-style-type: none"> The purpose of this study was to observe the clinical outcomes of patients with a Deep Sternal Wound Infection (DSWI) prior to and after the adoption of utilizing NPWT as a treatment option. NPWT was introduced in the management of DSWI at St Vincent's Hospital Melbourne in 2006. The analysis revealed there were less flap use and less post-operative complications after the implementation of NPWT. The use of NPWT minimizes the use of muscle or omental flaps therefore an optimal therapy to add to the algorithm for managing DSWI. 	Retrospective analysis	●										●	

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<p>Dunn, R., Hurd, T., Chadwick, P., Cote, J., Mole, T., & Smith, J. Factors associated with positive outcomes in 131 patients treated with gauze based negative pressure wound therapy. International Journal of Surgery. 2011 258-262</p>	<ul style="list-style-type: none"> Investigate the clinical outcomes of a gauze based NPWT to measure the improvement of a wound and when the wound is considered appropriate to stop NPWT. Outcomes where measured based on the reduction of wound dimensions (area, depth, volume), the increase in granulation tissue, and management of exudate. All wound dimensions were significantly reduced ($p < 0.001$) with a median of area 33%, depth, 50% and volume 66.3%. The increase of granulation tissue was also significant ($p = 0.007$) 90% of the wound base was filled with granulation tissue. 	Prospective Multi-center evaluation	●	●		●		●	●	●		●		
<p>National Pressure Ulcer Advisory Panel (NPUAP). Negative Pressure Wound Therapy Guidelines for Pressure Ulcers. 2014, Prevention and treatment of Pressure ulcers: Clinical Practice Guidelines</p>	<ul style="list-style-type: none"> Consider NPWT as an early adjunct therapy for stage III and IV wounds. Ensure debridement of necrotic tissue prior to use. Utilize a clean technique during dressing application/removal Evaluate the pressure ulcer with each dressing change (dressing change intervals are clinically dependent). To decrease pain utilize a non-adherent interface dressing under foam or consider utilizing a gauze medium. 	NPUAP Suggested NPWT Guidelines										●	●	●

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