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Negative pressure wound therapy efficacy: Summary

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Specific Care Questions: What are the outcomes from the use on Negative Pressure Wound Therapy (NWPT) in pediatrics? Is there published information comparing various NWPT systems?

Team Members: Manager Wound Ostomy Care (WOC) Team: Kristi Foster, RN, MS, APRN, BC (Team Leader), **Value Analysis Manager:** Robin Starr. RN, **Evidence Based Scholars:** Elizabeth Carlson, RN, Kate Collum, RN, Jackie Bartlett, MSN, MBA-HCA, RN, Jarrod Dusin, MS, RD, LD, CNSC and Nancy Allen, MS, RD, LD, CNSC

Significance and Importance of the Question:
NPWT has been used in treating wounds in the pediatric population. Case studies, case summaries and retrospective reviews report favorable outcomes of the therapy in children. Randomized control trials in children have not been done, and few have been reported in adults. Adverse effects of the therapy (bleeding, infection and death) have been reported. Due to the lack of information in pediatrics the FDA updated the statement on NPWT and states there is no NPWT system that has been cleared in infants and children. This review is completed at the request of the Value Analysis Team and the Wound, Ostomy, Care Team to guide product selection and guideline development for use of this product.

Search Strategy and Results:
April 12, 2011
"Negative-Pressure Wound Therapy"[Mesh] AND ("paediatrics"[All Fields] OR "pediatrics"[MeSH Terms] OR "pediatrics"[All Fields])

Method Used for Appraisal and Synthesis:
For the 2 RCTs RevMan 5.1 was used to analyze the studies
For other studies, systematic review was completed and study description and assessment of bias was done with RevMan 5.1. Data was summarized on a Critically Appraised Topic (CAT) template.
Outcomes:
Comparison one:
Vacuum assisted closure v Normal saline and gauze dressings

Outcomes:

a. > 95% graft “take”, count of subjects
b. > 80% graft “take”, count of subjects
c. Hospital stay < 20 days, count of subjects
d. Hospital stay< 28 days, count of subjects
e. < 2 weeks to complete healing, count of subjects
f. < 4 weeks to complete healing, count of subjects
g. Total infections (acute +late), count of subjects

Results: Data is lacking to compare NPWT products. However, information is available to assist in guideline development.

Summary:
The two randomized controlled trials found were done in adult populations. For the identified outcomes, data could not be pooled. The results of single studies are not amenable to meta-analysis. However, the remaining papers (mostly retrospective reviews) give guidance on pressure settings for pediatrics. Specifically the Baharestani 2009 and McCord 2007 contain information that is useful for the purpose of guideline development.

If you have questions regarding this Specific Care Question – please contact Kristi Foster, MS, RN, APRN-BC, CWOCN klfoster@cmh.edu

References:

Characteristics Included Studies

Baharestani, M.M. (2007). Use of negative pressure wound therapy in the treatment of neonatal and pediatric wounds: A retrospective examination of clinical outcomes. *Ostomy Wound Management*. 53, 6, 75-85.

Baharestani, M., Amjad, I., Boookout, K., Fleck, T., Gabriel, A., Kaufman, D., McCord, S.S., Moores, D.C., Olutoye, O.O., Salazar, J.D., Song, D.H., Teich, S., & Gupta, S.(2009). V.A.C.® therapy in the management of paediatric wounds: Clinical review and experience. *International Wound Journal*, 6,1-26.

Fleck, T., Simon, P., Bruda, G., Wolner, E., & Wollenek, G. (2006). Vacuum assisted closure therapy for the treatment of sternal wound infections in neonates and small infants. *Interactive Cardiovascular and Thoracic Surgery* [doi- 10.1510/icvts.2005.122424]

McCord, S. S., Naik-Mathuria, B.J., Murphy, K.M., McLane, K.M., Gay, A.N., Basu, C.B., Downey, C.R., Hollier, L.H., & Olutoye, O.O. (2007). Negative pressure therapy is effective to manage a variety of wounds in infants and children. *Wound Repair and Regeneration*. 15, 296-301.

Saaiq, M., Hameed-ud-Din, Kan, M.I., Chaudhery, S.M. (2010). Vacuum-assisted closure therapy as a pretreatment for split thickness skin grafts. *Journal of the College of Physicians and Surgeons Pakistan.* 20, 10, 675-679.

Stannard, J.P., Volgas, D A., Stewart, R, McGwin, G., & Alonso, J.E. (2009). Negative pressure wound therapy after severe open fractures: A prospective randomized study. *Journal of Orthopedic Trauma* 2009, 23, 8,552-557.

Saaiq 2010

Methods	Single Blinded Randomized Controlled Trial
Participants	Adult Patients of either gender with acute traumatic wounds. 50 patients were allocated to each group. 86% of the patients were male. The age range was 13-65 years, with a mean of 33.07 ± 13.60.
Interventions	Treatment group: 10 days of vacuum-assisted closure therapy prior to split thickness skin graft (two VAC dressing each maintained for 5 days). Control group: 10 days of normal saline gauze dressing in the control group prior to split thickness skin graft.
Outcomes	Primary outcome: graft take Secondary outcomes: wound healing time, need for any re-grafting and duration of hospital stay.
Notes	Patients who needed flap coverage as the primary intervention, and those with either diabetes, malignancy or bleeding diathesis with excluded. Pakistan

Risk of Bias Table

Bias	Scholars' Judgment on Risk of Bias	Support for Judgment
Random sequence generation (selection bias)	High risk	"Lottery method", but then they were matched with the other group by age, gender and wound size and wound site
Allocation concealment (selection bias)	High risk	Allocation concealment was not identified.
Blinding of participants and personnel (performance bias)	High risk	Subjects only were blinded,
Blinding of outcome assessment (detection bias)	High risk	Appears those who evaluated the wound after grafting were not blinded and they could have been.
Incomplete outcome data (attrition bias)	Low risk	
Selective reporting (reporting bias)	Low risk	None identified.
Other bias	Unclear risk	

Stannard 2009

Methods	Prospective RCT
Participants	Age greater than 18 years with presence of a severe open fracture that required serial surgical debridements; 19 females and 39 miles were enrolled at one hospital.
Interventions	Control: saline wet to moist dressings over the open fracture N=23 pts with 25 fractures Treatment: NPWT VAC dressing over the open fracture- N= 35 patients with 37 fractures. All patients underwent identical treatment protocols with the exception of the dressing over the open fracture.
Outcomes	infection
Notes	1. Exclusion criteria: Exclusion criteria included: • Open fractures that could be closed after the initial surgery and did not require serial debridements • Infected open fractures, • Surgical incisions that cannot be treated with NPWT prisoners • Pregnant females • Patients or family members who are unable or unwilling to sign study consent • Anyone unable to complete the treatment protocol including NPWT. 2. Patients were also followed clinically regarding union of their fracture and the development of a late infection or wound dehiscence. *Infection is the only outcome that is reportable in this review. Supported by KCI.

Risk of Bias Table

Bias	Scholars' Judgment on Risk of Bias	Support for Judgment
Random sequence generation (selection bias)	Low risk	A random sampling algorithm was used to assign patients to receive either NPWT or control in a 1:1 ratio.
Allocation concealment (selection bias)	Unclear risk	A random sampling algorithm was used to assign patients to receive either NPWT or control in a 1:1 ratio. It would be known which assignment the second of each group of two would

		be assigned.
Blinding of participants and personnel (performance bias)	Unclear risk	Blinding is not mentioned. Difficult to blind.
Blinding of outcome assessment (detection bias)	High risk	They said they were going to report on presence or absence of deep wound infection or osteomyelitis, wound dehiscence, and fracture union as primary outcomes. Infection was the only outcome that could be put into RevMan.
Incomplete outcome data (attrition bias)	High risk	One patient, not certain which group was dropped from the study.
Selective reporting (reporting bias)	Unclear risk	They do comment multiple times that their outcome should only be considered for severe open fractures.
Other bias	Unclear risk	Excluded most open fracture patients, including type IIIA fractures, they were closed after surgery.

Studies Without Data

Author, date, country, and industry of funding	Significant Results
Baharestani 2007	Narrative review of 24 pediatric patients (14 days to 18 years) who received V.A.C. therapy. All but one were inpatient only. All inpatients were crib or bed bound unrelated to V.A. C. therapy. Data included: presence of infection, osteomyelitis, and antibiotic usage. Data was analyzed by wound type (6 types), pediatric age sub-groups, type of dressing used, Did not include wound dimension d/t inconsistency of reporting in the EMR. Findings: 14 female and 10 males, average age 11 years. At baseline, 20% (12) wounds were infected. Closure: 22 wounds closed in a median time of 10 days (range 2-25 days) Flap closure 45.8% (n= 11) Split thickness skin graft 12.5% (n=3) Primary closure 16.7 (n=4) Secondary closure 16.7% (n=4) Transfer to rehab 8.3% (n=2) In 18 subjects, NPWT was discontinued when 100% granulation was achieved. One death, not related to NPWT. One complication: enteric fistula formation in a 36 week GA with abdominal wound dehiscence. Pressure setting recommendations. Dressing change every 48 hours Three types of dressings- black, polyurethane ether foam (n=18); white polyvinyl alcohol foam (n=5); and black polyurethane ether foam microbonded with silver (n=1)

Baharestani 2009	Narrative review of 27 reports of VAC therapy. All reports are either, case description, prospective series with historical control, retrospective chart review, or prospective case series. Methods to identify studies included are not described. The paper includes a table with recommended pressure settings for various pediatric wounds/conditions. It lists 5 major and 5 minor complications of the therapy. Four precautions when using NWPT in pediatrics are presented.
Fleck, 2006	Case series of 3 neonates who underwent NPWT with V.A.C. for sternal wound infection. (isolated organisms: C. albicans (subject 1); S, aureus (subject 2) and MSRA (subject 3) Outcomes: Infection, secondary wound closure and preservation of sternal bone. Selection Bias: there was no control group, all received the therapy Performance Bias and Detection Bias: there was no blinding Attrition Bias: No data, they did not report on the outcomes identified in the methods. Findings: In the three subjects, VAC therapy lasted 11.3 days (range 10-12 days); no further surgery; and no blood loss during therapy or debridement. No adverse effects on heart rate blood pressure or respirator sequence (used as an indicator of pain). Quality rating: Very low quality. We are very uncertain about the estimate of the effect of the study
McCord 2007	Methods: Retrospective chart review Subjects: Pediatrics. 68 children with 82 wounds. Intervention: all treated with NPWT. Outcomes: Calculated would volumetric measurements at the start and end of therapy, duration of therapy complications. Data collected: demographics, wound type, dates of NPT use, type of sponge, amount of negative pressure used, wound measurements, outpatient use, indication for discontinuation of NPT, and complications. Patients were grouped according to their wound types into six categories: pressure ulcers, extremity wounds, dehisced surgical wounds, open sternal wounds, wounds with fistulas, and abdominal wall defects. For each subgroup: age, % wound decrease, duration of therapy calculated. Findings: Average age 8.5 years (range 7 days to 18 years) 29% were < 2 years of age, 8 neonates. Average duration of therapy: 23 days, Closure: 67% (n= 55) closed by secondary intention 4% (n=3) closed by delayed primary closure 13% (n=11) closed with skin grafts 7% (n=6) covered with rotational muscle flaps Reasons for discontinuation in wounds not closed: 2% (n=1) patient expired (2 wounds) Transitioned to home NPWT 24% (n=16) Volumetric data: wound volumes at the end of NPWT were 80% less than volume at the start of therapy. No major complications, specifically, no infectious complications, pain, not discontinued d/t parent request It was discontinued in one neonate with large abdominal wall defect who developed a coagulopathy. Minor complications skin maceration form the adhesive (n=10) and minimal bleeding with dressing change (n=6), and pain with dressing change (n=6).
Mooney 2000	Retrospective Review, primarily descriptive.
Stannard 2009	Study description is in the Synopsis. Wound irrigations:

	Vacuum group required a mean of 2.7 wound irrigations and debridements before closure. Saline group required a mean of 2.4 wound irrigations and debridements before closure. Days to reach Grade A status (ready for closure) Vacuum Group 4.0 days, range(2-11 days) Saline Group 3.2 days, range (2-9 days) Days in the hospital Vacuum Group 11.7 days Saline Group 9.5 days
Zillmer 2006	Not NPWT- effects of repetitive removal of adhesive dressings. Subjects-: Patients aged 18 years with open venous leg ulcer(N=29) or venous leg ulcer that healed (N=16) in the last 6 months. DX of venous insufficiency. No arterial insufficiency. Excluded wounds with heavy exudate, uncontrolled diabetics (HbA1C >8%) glucocortosteroids in the last 14 days. Intervention: 4 dressings were randomly placed in peri-wound (healed or nonhealed) positions and nonwound positions on the same patient (control). The four treatments were: DuoDerm Extra Thin (ConvaTek), Biatain (Coloplast) with a hydrocolloid border, Tielle (Johnson& Johnson) and Mepilex Border (Mölnlyke Health Care). Outcomes: Transepidermal water loss (TEWL), electrical conductivity and erythema, adverse effects including eczema, and skin maceration Attrition Bias: a total of six subjects dropped out, not certain which group they were in. The results from the drop-outs were not included in the analysis. (Per protocol analysis). Bias due to funding: The Mölnlyke Health Care of Göteborg, Sweden funded the study. Data was reported as medians and cannot be used. Findings: Quality rating: Very low quality. We are very uncertain about the estimate of the effect of this study.

Updated 4/12/2011, 5/13/2011

Chart 1.1. - Vacuum assisted closure v Normal saline and gauze dressings, Outcome: > 95% graft "take", count of subjects

	Vacuum		Saline			Odds Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% CI
Saaiq 2010	45	50	9	50	100.0%	41.00 [12.70, 132.40]
Total (95% CI)		**50**		**50**	**100.0%**	**41.00 [12.70, 132.40]**
Total events	45		9			

Heterogeneity: Not applicable
Test for overall effect: Z = 6.21 (P < 0.00001)

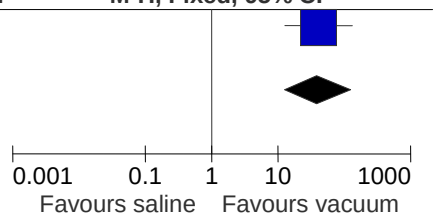

Chart 1.2. - Vacuum assisted closure v Normal saline and gauze dressings, Outcome: > 80% graft "take", count of subjects

	Vacuum		Saline			Odds Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% CI
Saaiq 2010	49	50	41	50	100.0%	10.76 [1.31, 88.47]
Total (95% CI)		**50**		**50**	**100.0%**	**10.76 [1.31, 88.47]**
Total events	49		41			

Heterogeneity: Not applicable
Test for overall effect: Z = 2.21 (P = 0.03)

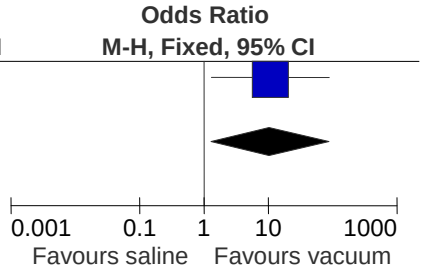

Chart 1.3. - Vacuum assisted closure v Normal saline and gauze dressings, Outcome: Hospital stay < 20 days, count of subjects

	Vacuum		Saline			Odds Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% CI
Saaiq 2010	45	50	9	50	100.0%	41.00 [12.70, 132.40]
Total (95% CI)		**50**		**50**	**100.0%**	**41.00 [12.70, 132.40]**
Total events	45		9			

Heterogeneity: Not applicable
Test for overall effect: Z = 6.21 (P < 0.00001)

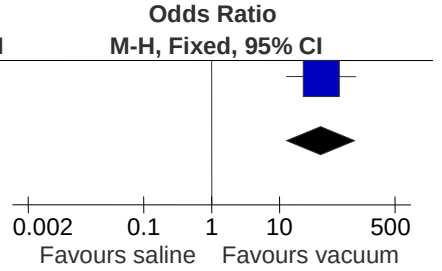

Chart 1.4. - Vacuum assisted closure v Normal saline and gauze dressings, Outcome: Hospital stay< 28 days, count of subjects

Study or Subgroup	Vacuum Events	Vacuum Total	Saline Events	Saline Total	Weight	Odds Ratio M-H, Fixed, 95% CI
Saaiq 2010	50	50	41	50	100.0%	23.12 [1.31, 409.13]
Total (95% CI)		**50**		**50**	**100.0%**	**23.12 [1.31, 409.13]**
Total events	50		41			

Heterogeneity: Not applicable
Test for overall effect: Z = 2.14 (P = 0.03)

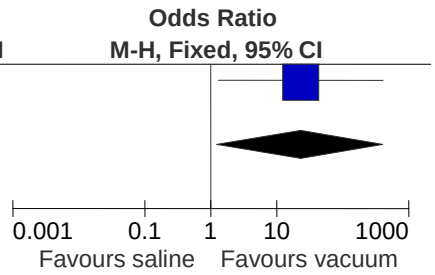

Chart 1.5. - Vacuum assisted closure v Normal saline and gauze dressings, Outcome: < 2 weeks to complete healing, count of subjects

Study or Subgroup	Vacuum Events	Vacuum Total	Saline Events	Saline Total	Weight	Odds Ratio M-H, Fixed, 95% CI
Saaiq 2010	45	50	9	50	100.0%	41.00 [12.70, 132.40]
Total (95% CI)		**50**		**50**	**100.0%**	**41.00 [12.70, 132.40]**
Total events	45		9			

Heterogeneity: Not applicable
Test for overall effect: Z = 6.21 (P < 0.00001)

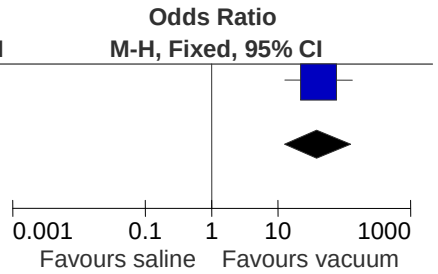

Chart 1.6. - Vacuum assisted closure v Normal saline and gauze dressings, Outcome: < 4 weeks to complete healing, count of subjects

Study or Subgroup	Vacuum Events	Vacuum Total	Saline Events	Saline Total	Weight	Odds Ratio M-H, Fixed, 95% CI
Saaiq 2010	48	50	45	50	100.0%	2.67 [0.49, 14.44]
Total (95% CI)		**50**		**50**	**100.0%**	**2.67 [0.49, 14.44]**
Total events	48		45			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.14 (P = 0.26)

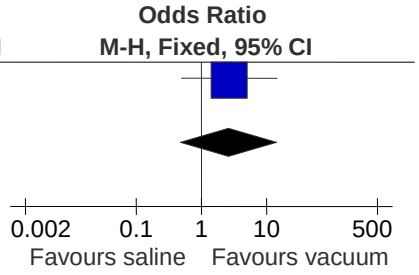

Chart 1.7. - Vacuum assisted closure v Normal saline and gauze dressings, Outcome: Total infections (acute +late), count of subjects

	Vacuum		Saline			Odds Ratio
Study or Subgroup	**Events**	**Total**	**Events**	**Total**	**Weight**	**M-H, Fixed, 95% CI**
Stannard 2009	2	35	7	23	100.0%	0.14 [0.03, 0.74]
Total (95% CI)		**35**		**23**	**100.0%**	**0.14 [0.03, 0.74]**
Total events	2		7			

Heterogeneity: Not applicable

Test for overall effect: Z = 2.30 (P = 0.02)