

# NEGATIVE PRESSURE WOUND THERAPY IN DIABETIC FOOT WOUNDS

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# OBJECTIVES

1. Describe theory, process, and usage of Negative Pressure Wound Therapy (NPWT).

**How does it work?**

2. Summarize relevant research on NPWT, including Randomized Control Trials, systematic reviews, and Medicare part B data.

**What does the research say?**

3. Demonstrate relative value of NPWT compared to moist dressings

**Is it worth it?**

**Side note on research**

**Failure? : Bar = low**

# P - PATIENT

P.R. — 60 year old female.



OUTCOME?



# I – INTERVENTION

(WHAT IS IT?)



What

- Negative Pressure Wound Therapy (**NPWT\***) is a therapy that utilizes open cell foam padding and a vacuum system to purportedly decrease tissue healing time

How

- NPWT is theorized to remove exudate and other fluids from the wound bed, while also increasing wound perfusion and drawing together wound edges.

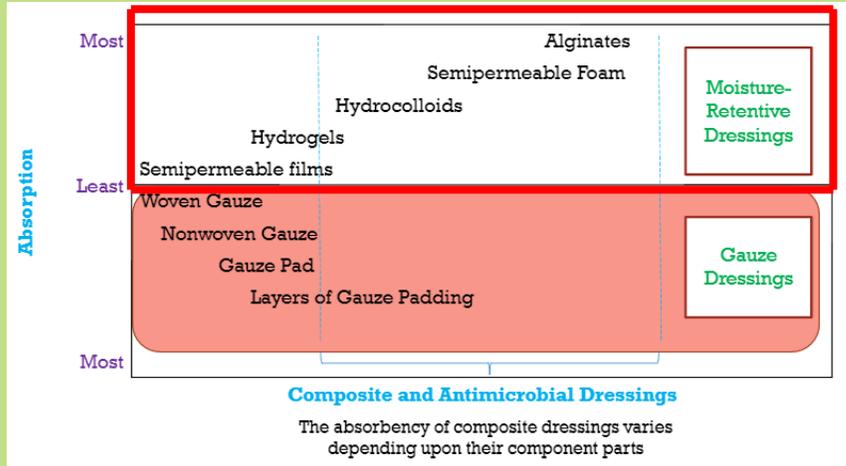
When

- This intervention is often used for complex and chronic wounds. Dressings were changed **every other day\*\***.

\***NPWT** is commonly referred to as a “wound vac” in clinics.

\*\* Flagstaff Medical Center bills insurance \$379 per visit. Please consider how much money that is.

# C – COMPARISON



- Moist wound therapy is a broad term for wound treatments that seek to keep the wound bed at the optimal moisture level to promote healing
- Differences in wound type gave rise to dressings that increase or decrease amount of moisture present

- Moist wound care dressings vary in price, but are on the whole much more affordable\* than NPWT

\*Alginate dressing - \$23  
Hydrocolloid dressing - \$22

## 0 - OUTCOME



- PR ceased NPWT 2 months ago
- Wound size is reduced to “dime sized”
- Patient is managing wound at home with use of 4”x 4” bandages and topical antibiotic.

**P** — IN A 60-YEAR-OLD DIABETIC FEMALE WITH A  
FOOT WOUND FROM SURGICAL EXCISION OF A  
HEMATOMA

**I** — IS NEGATIVE PRESSURE WOUND THERAPY MORE  
EFFECTIVE THAN

**C** — MOIST WOUND THERAPY

**O** — IN ACHIEVING COMPLETE WOUND CLOSURE.

# SIDE NOTE ON MEDICARE AND NPWT

An NPWT pump and supplies are covered when either criterion A or B is met:

## A) Ulcers and Wounds in the Home Setting:

The patient has a chronic Stage III or IV pressure ulcer, neuropathic (for example, diabetic) ulcer, venous or arterial insufficiency ulcer, or a chronic (being present for at least 30 days) ulcer of mixed etiology. A complete wound therapy program described by criterion 1 and criteria 2, 3, or 4, as applicable depending on the type of wound, should have been tried or considered and ruled out prior to application of NPWT.

1) For all ulcers or wounds, the following components of a wound therapy program must include a minimum of all of the following general measures, which should either be addressed, applied, or considered and ruled out prior to application of NPWT:

- a) Documentation in the patient's medical record of evaluation, care, and wound measurements by a licensed medical professional, and
- b) Application of dressings to maintain a moist wound environment, and
- c) Debridement of necrotic tissue if present, and
- d) Evaluation of and provision for adequate nutritional status.

3) For neuropathic (for example, diabetic) ulcers:

- a) The patient has been on a comprehensive diabetic management program, and
- b) Reduction in pressure on a foot ulcer has been accomplished with appropriate modalities.

RULES 2 AND 4 REMOVED FOR BREVITY



## FOR WOUNDS IN GENERAL

- a. You have to document what you're doing, including size of the wound
- b. You have to have used moist dressings
- c. You have to have removed any dead tissue in the wound
- d. You have to decide if they have an appropriate diet, and if they don't, educate them

## FOR DIABETIC ULCERS

- a. The patient is receiving treatment for their diabetes
- b. They're not full weight bearing on the wound

# 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.

BLUME PA, WALTERS J, PAYNE W, AYALA J, LANTIS J.

DIABETES CARE. 2008 APR;31(4):631-6.

**OBJECTIVE:** Determine efficacy of NPWT compared to advanced moist wound therapy (AMWT).

**LEVEL OF EVIDENCE\*:** 1b (Randomized Control Trial)

**METHODS:** Multicenter RCT with n = 342 patients. Random assignment to NPWT or AMWT, with offloading WB as necessary. Measured time until complete wound closure (100% epithelization.)

**RESULT:** Greater number of complete wound closures in NPWT group (p = 0.007), and fewer amputations (p = 0.035). No difference in infection, cellulitis, and osteomyelitis at 6 months.

**CONCLUSION:** NPWT is as safe and more effective than AMWT.

## Strengths:

- High level of evidence.
- Addresses co-morbidity
- High number of participants

## Weaknesses:

- Sponsored by KCI
- Not blinded

WHAT DOES THE RESEARCH SAY?

# A COMPARISON OF DIABETIC FOOT ULCER OUTCOMES USING NEGATIVE PRESSURE WOUND THERAPY VERSUS HISTORICAL STANDARD OF CARE.

LIVERY LA, BOULTON AJ, NIEZGODA JA, SHEEHAN P.

INTERNATIONAL WOUND JOURNAL. 2007 JUNE;4(2):103-13.

**OBJECTIVE:** Using Medicare part B data, determine if NPWT is a more effective treatment than wet-to-moist therapy.

**LEVEL OF EVIDENCE:** 2C  
(Outcomes research)

**METHODS:** Analysis compared patients with Medicare part B that had received NPWT\* to patients receiving wet-to-moist therapy from a meta analysis. Matched for age and wound length (time).

**RESULTS:** Patients using NPWT achieved a higher proportion of successful treatment than the standard care group ( $p = 0.001$ ). Wounds of any size were more likely to reach wound closure.

**CONCLUSION:** NPWT decreases healing time for wounds compared to standard care (wet-to-moist dressings)

**Strengths:** Can be difficult to get “real world” results from RCT- this takes data from real patients and compares it to moist dressing.

**Weaknesses:**  
-Does not adjust for location of wound  
-Follows Medicare for NPWT  
-Sponsored by KCI

# NEGATIVE PRESSURE WOUND THERAPY FOR TREATING FOOT WOUNDS IN PEOPLE WITH DIABETES MELLITUS.

DUMVILLE JC, HINCHLIFFE RJ, CULLUM N, GAME F, STUBBS N, SWEETING M, PEINEMANN F  
 COCHRANE DATABASE OF SYSTEMATIC REVIEWS 2013, ISSUE 10.

**Objective:** To determine if all relevant data indicates that NPWT is a more effective treatment than moist wound therapy.

**Level of Evidence:** 1a (Systematic Review with homogeneity of RCTs)

**Methods:** Analysis of 5 papers which compared the effect of NPWT to moist dressings on diabetic foot wound healing (n=605)

**Results:** 2 studies showed significant improvement in wound healing when using NPWT (CI = 1.03 – 2.01, 1.11 – 2.01), but were noted to be at risk for performance bias. The remaining 3 studies were at unclear risk of bias, as well as having small sample sizes.

**Conclusion:** There is some evidence that NPWT is more effective than moist wound therapy in treating diabetic foot wounds. However, the risk of bias in current evidence makes it impossible to give a definitive answer on its efficacy.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Other bias
Armstrong 2005	+	+	?	?	+	+
Blume 2008	+	+	?	?	?	+
Karatepe 2011	+	?	?	?	?	+
Mody 2008	+	?	?	?	+	?
Novinščak 2010	?	?	?	?	?	?



## DID I ANSWER MY PICO?

### So what conclusions should we draw?

- Read research with a critical eye
- NPWT is expensive, but potentially beneficial to patients with diabetic foot wounds
- However, it may not be the best first option for these wounds.



# IS IT WORTH IT?



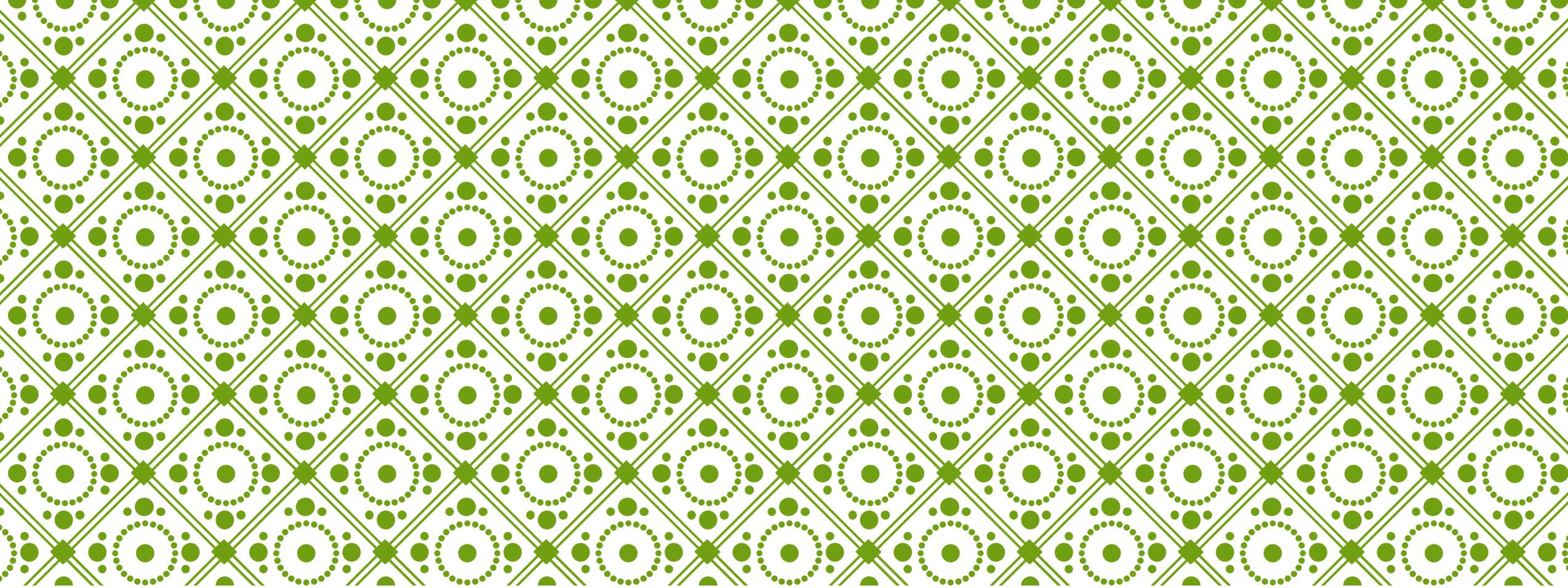
- Value = Outcomes/Cost
- At this point, we don't have clear evidence that it actually works, but we do know that it costs significantly more
- We need better evidence to understand the real value

- Average time to NPWT treatment wound closure according to Blume et al. – 96 days
- Say NPWT reduces wound healing time by 50%
- Dressing changes 3 days per week
- And say both groups get selective debridement every other treatment
- NPWT – \$20,979
- MWT – \$12,909

# I HAVE A LOT OF IDEAS

- While blinding is difficult, attaching a similarly bulky device would not be.
- Ensure all participants meet Medicare Criteria for NPWT
- Match for wound size/location/age

→ BECAUSE NPWT MIGHT HAVE IMMENSE VALUE, BUT IF WE DON'T RECOGNIZE WHEN EVIDENCE IS LACKING AND DEMAND HIGHER QUALITY, THEN WE DON'T ACTUALLY KNOW.



**QUESTIONS?**



# REFERENCES

1. Jain, Tarang. "Wound Care Dressing Selection". 2015. Lecture.
2. 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.
3. Lavery LA, Boulton AJ, Niezgoda JA, Sheehan P. A comparison of diabetic foot ulcer outcomes using negative pressure wound therapy versus historical standard of care. *International Wound Journal*. 2007 Jun;4(2):103-13.
4. Dumville JC, Hinchliffe RJ, Cullum N, Game F, Stubbs N, Sweeting M, Peinemann F. Negative pressure wound therapy for treating foot wounds in people with diabetes mellitus. *Cochrane Database of Systematic Reviews* 2013, Issue 10. Art. No.: CD010318. DOI: 10.1002/14651858.CD010318.pub2.
5. Oxford Centre for Evidence-based Medicine – Levels of Evidence. Center for Evidence Based Medicine. Retrieved from <http://www.cebm.net/oxford-centre-evidence-based-medicine-levels-evidence-march-2009/>. March 2009.