

A Randomized Controlled Trial Evaluating the Outcomes for Incisional Application of Negative Pressure for Non-Traumatic Lower Extremity Amputations: A Pilot Study

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Background

Peripheral artery disease (PAD) affects more than 200 million people worldwide. The demographic most affected by PAD has higher risk for lower extremity wounds, making them susceptible to amputation. **While amputation is never the desired course of treatment, sometimes it is unavoidable.** Our study aimed to assess **the effects of NPWT on closed incisions** of patients who underwent amputation. Clinical outcomes were assessed, specifically: Hematoma, Seroma, Dehiscence, Maceration, Edema, and Drainage.

Methods

- Patients were randomized into two cohorts of postoperative closed incisional dressing Cohort A received the standard dry dressing. Group B received Foam, Drape, and NPWT.
- The device was placed over the closed incision, with negative pressure set to 125mmHG.
- After 5 days patients were allowed to receive any type of incisional dressing per surgeon preference.
- Patient assessments were performed on 5, 30, and 90 day post-op visits to notate any complications or adverse events after application of randomized dressings.
- All variables were evaluated using statistical analysis
- Continuous variables are presented in the form of means (standard deviations)
- Categorical variables are presented in the form of counts (percentage)
- T-tests and Chi squared tests are used for comparison of the baseline characteristics of continuous and categorical variables respectively

Results

Of the 108 patients enrolled, 47 patients (43.5%) did not complete the study. Data were analyzed for the remaining 30 patients who received dry dressing and 31 in the NPWT group. There were **no demographic differences between cohorts**. The **dry dressing group had significantly higher rates of ESRD** (40% vs. 12.9%), **PAD** (66.7% vs. 19.4%), **PVD** (60% vs. 19.4%), and **CAD** (26.7% vs. 6.5%). Amputation type was similar between groups. **No difference** in rates of wound complications was observed between the NPWT and dry dressing groups at all postoperative time points

Table 1. Summary of results 5, 30, and 90 days after surgery

Surgical Outcome	P Value (5 days)	P Value (30 days)	P Value (90 days)
Wound dehiscence	0.48	1.00	0.61
Hematoma	-	-	0.59
Seroma	-	-	0.41
Maceration	1.00	1.00	0.41
Edema	0.73	0.36	0.35
Drainage	0.80	0.61	0.31

Conclusion

We can conclude that the NPWT does not beneficially impact the post-operative course in closed wounds in our study. We **cannot** rule out the potential impact at other surgical sites or with patients with less complex disease processes and comorbidities. Additionally, it is important to note that our study had small participant size. We would encourage further exploration of the topic to expand the scope of IVAC application beyond our lower limb focused paper.