Original Article

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Improvement of Granulation Tissue Formation through "Low Cost" Intermittent Negative Pressure Wound Therapy (NPWT): Randomized Controlled Trial

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Abstract:

Objective: Intermittent negative pressure wound therapy (NPWT) may enhance granulation, but commercial systems are costly. This study evaluated a low-cost, improvised intermittent NPWT system.

Material and Methods: A randomized controlled trial was conducted with 32 patients having open wounds unsuitable for primary closure. Participants were allocated to intermittent NPWT (5 minutes on/-125 mmHg, 2 minutes off; n=16) or continuous NPWT (n=16) using an improvised system. The primary outcome was the percentage of granulation tissue coverage, assessed by blinded plastic surgeons on days 0, 3, 6, and 9. A linear mixed model was used for analysis.

Results: The intermittent NPWT group demonstrated significantly greater granulation tissue formation than the continuous group (Group main effect: F(1)(1,30)=5.297, p-value=0.028). By day 9, the estimated marginal mean granulation coverage was 94.6% (95% CI: 88.0, 101.1) for intermittent NPWT versus 82.8% (95% CI: 76.3, 89.4) for continuous NPWT, with a significant between-group difference of 11.7% (p-value=0.029). Pain scores at day 9 did not differ between groups (p-value=0.876).

Conclusion: An improvised intermittent NPWT system significantly improved granulation tissue formation compared to continuous NPWT, without increasing patient pain. Clinically, this accelerated granulation implies earlier readiness for definitive wound closure or skin grafting. This low-cost approach offers a practical and accessible solution for improving wound care in resource-constrained settings.

Keywords: continuous mode, intermittent mode, negative pressure wound therapy, vacuum dressing

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Introduction

When negative pressure wound therapy (NPWT) was first described in the late 1990s[1], this technology rapidly transformed wound care management. The basic principle is straightforward: a foam dressing is placed over the wound, sealed with transparent film, and connected to a vacuum system that creates negative pressure[2]. Most clinicians work within a range of 75–150 mmHg, with 125 mmHg emerging as a clinical optimum[3,4].

NPWT is effective across diverse wound types, from surgical dehiscence and partial-thickness burns to pressure ulcers and diabetic wounds. It is particularly valuable when preparing beds for skin grafts or flaps, where healthy granulation tissue can make or break surgical success[5]. However, NPWT is contraindicated in malignant wounds, ischemic tissue, active uncontrolled infections, undebrided necrosis, and situations where major vessels or joints are exposed[2,3].

The mechanisms behind NPWT's success are multifaceted. Negative pressure pulls wound edges together, while mechanical forces stimulate the growth of granulation tissue. Meanwhile, constant drainage removes exudate and debris, creating conditions that appear to favor wound growth. The reduction in edema and improved perfusion are almost immediate benefits that most clinicians notice within the first dressing change[1,5]. NPWT can be delivered continuously, intermittently, or with variable patterns[6]. While researchers continue exploring which approach works best for specific situations, there is growing interest in improvised systems that make this technology more accessible. Cost considerations drive much of this innovation, especially in resource-limited settings where commercial NPWT systems may be prohibitively expensive[7–12]. Several research groups have tackled the question of optimal pressure delivery patterns. Borgquist's team used pig models to compare intermittent cycling (0 to −75 or −125 mmHg) with variable pressure (cycling between −10 and −75 or −125 mmHg)[13]. Both approaches improved wound blood flow and granulation compared to continuous pressure. Malmsjö's group found similar results, with intermittent and variable modes producing better wound contraction and more granulation tissue within just 72 hours[14]. Lessing and colleagues did not find significant differences in granulation thickness between the three NPWT modes by day seven; however, they discovered that adding instillation therapy accelerated the process[15]. Sogorski's work in healthy volunteers showed that intermittent NPWT clearly improves microcirculation and oxygen delivery, findings that help explain the clinical benefits many of us observe[16].

At Buriram Hospital, we developed a low-cost, improvised NPWT system using foam dressings, nasogastric (NG) tubing, transparent film, and programmable timers with motorized valves connected to standard hospital wall suction. However, it remains unclear whether intermittent negative-pressure delivery provides superior granulation compared with continuous mode when both are delivered using the same improvised system. Therefore, this randomized controlled trial compared granulation tissue formation between intermittent and continuous NPWT—using the same low-cost improvised system—to determine whether intermittent pressure cycling offers a clinically meaningful advantage in wound bed preparation for subsequent reconstructive procedures, while maintaining affordability and accessibility.

Material and Methods

Study design

This prospective randomized controlled trial compared granulation tissue formation rates between patients treated with continuous-mode NPWT and those treated with improvised intermittent-mode NPWT. The study was approved by the Ethics Committee of Buriram Hospital (Protocol No. BR 0033.102.1/72) and registered with the Thai Clinical Trials Registry (TCTR20240703007).

Sample size determination

This randomized controlled trial compared the proportion of wounds achieving predefined granulation coverage between intermittent and continuous NPWT with a 1:1 allocation. Sample size was calculated using an unpooled two-proportions approach with a two-sided α of 0.05 and 80% power. Based on the prior literature, the expected proportions were conservatively set at 0.99 for the intermittent group and 0.63 for the continuous group, yielding a minimum sample size of 13 per group. Allowing for an anticipated 10% attrition rate, the planned sample size was 15 participants per group. In practice, 32 participants (16 per group) were enrolled, exceeding the minimum required sample size.

Patients and group allocation

A paired sequential enrollment strategy was used to maintain comparability between groups. Patients were enrolled consecutively and paired by admission order (e.g., Patient 1 with 2, 3 with 4, etc.), then randomized into two treatment arms: intermittent or continuous NPWT. Randomization was conducted independently using a two-step process to ensure allocation concealment. Two sets of labeled slips were prepared, one for "odd" or "even" numbered pairs and another for "intermittent" or "continuous" assignment. An independent individual drew one slip from each set, and the resulting combination determined treatment allocation for all pairs. For example, if "odd = intermittent" was drawn, all odd-numbered patients received intermittent NPWT and even-numbered patients received continuous NPWT. This method ensured balanced, unbiased assignment while preserving the paired structure of the trial.

Inclusion and exclusion criteria

Inclusion criteria were adults aged 18 years or older with open wounds unsuitable for primary closure and capable of giving informed consent. Exclusion criteria comprised malignant wounds, exposed bone, major vessels, tendons, or hardware, chronic wounds (>6 weeks), extensive necrotic tissue (>50% of the wound bed), uncontrolled or untreated infection, uncontrolled diabetes, peripheral vascular disease affecting perfusion, psychiatric disorders, severe malnutrition, or inability to provide consent. Wounds with infection were eligible if the infection had been adequately controlled following appropriate surgical debridement and antibiotic therapy prior to NPWT initiation. All participants provided written informed consent, including permission for clinical photographs, prior to enrollment.

Operative procedures

Wounds were cleaned and irrigated. Sterile foam was placed over the wound with an NG tube (16 Fr) inserted centrally as a suction conduit. The foam was sealed with a sterile transparent adhesive drape (Steri-Drape®), ensuring an airtight closure. For continuous mode, the NG tube was connected to wall suction at 125 mmHg continuously (Figure 1A). For intermittent mode (Figure 1B), a programmable timer (Zolftech DH48S-Z) and motorized valve (DN15-220 VAC) (Figure 2) cycled pressure on for 5 minutes and off for 2 minutes. During the off phase, suction was completely discontinued, returning the wound to atmospheric pressure (0 mmHg), while maintaining an airtight dressing seal.

All patients received standardized wound care, including appropriate surgical debridement prior to NPWT initiation, systemic antibiotics when indicated, and dressing changes every 3 days.

Postoperative assessment

The primary outcome of this study was the rate of granulation tissue formation, assessed on days 0, 3, 6, and 9 by two experienced plastic surgeons who were not involved in patient care or wound management. Granulation tissue coverage was assessed by direct visual inspection at

the bedside and estimated as the percentage of the wound bed occupied by healthy granulation tissue. Nonviable tissue, slough, and exposed structures were excluded from the granulation estimate. The total wound surface area was defined by the wound margins, which were measured using a sterile ruler to ensure consistency. Prior to study initiation, both assessors were trained on a standardized visual assessment approach. Assessments were performed independently and blinded to treatment allocation, and inter-rater agreement was calculated.

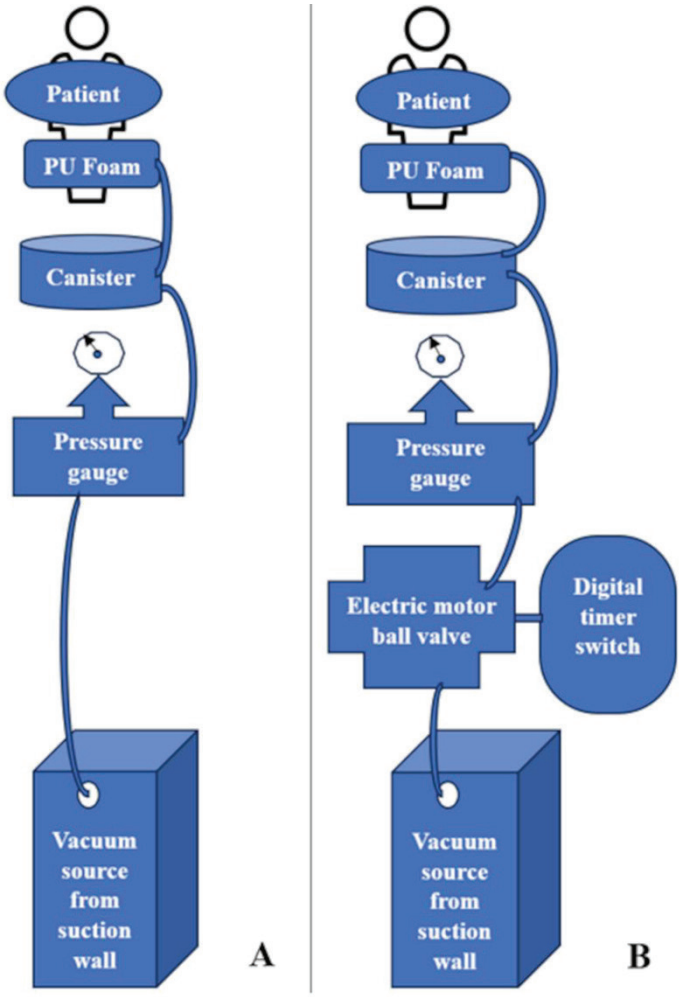

Figure 1 (A) Diagram of a makeshift continuous negative pressure wound therapy (NPWT) system. The setup uses a sponge under a sterile adhesive drape to seal the wound. A nasogastric (NG) tube is connected to a fluid collection bottle and then to a wall suction unit, providing continuous negative pressure. (B) Diagram of the self-constructed intermittent NPWT system. An automatic timer-switch and a motorized ball valve are installed between the pressure gauge and the wall suction unit to control the on/off cycling of the suction automatically.

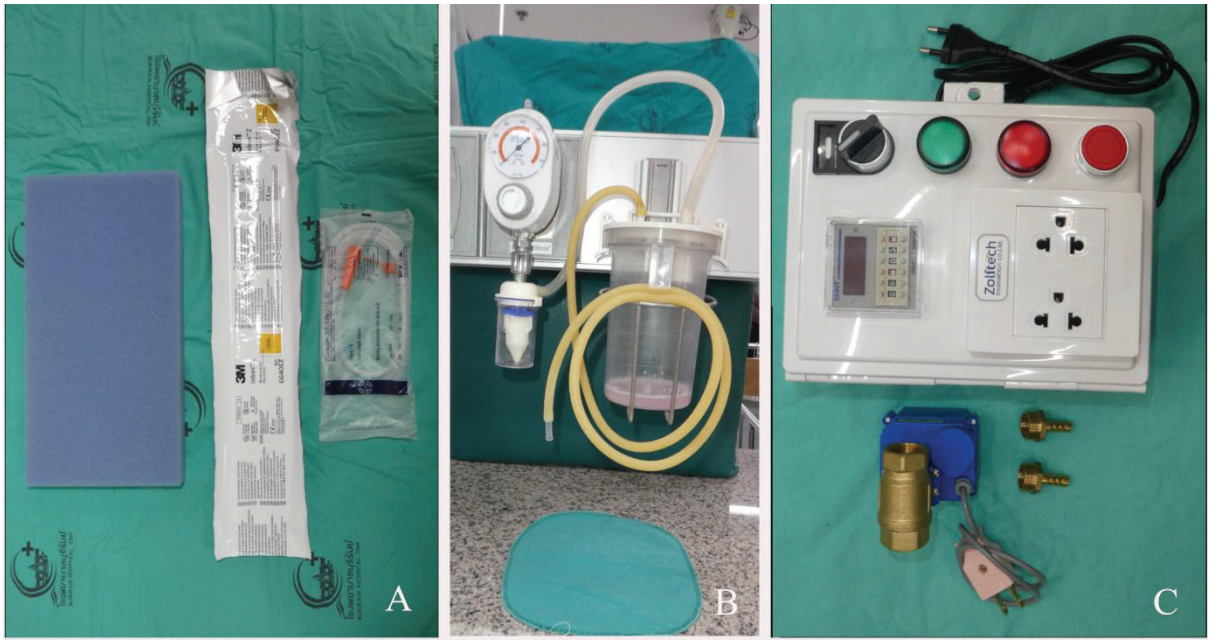

Figure 2 Materials for the self-made NPWT setup. (A) Dressing components (sponge, sterile adhesive drape, 16 Fr NG tube). (B) Fluid management (canister and wall suction unit). (C) Intermittent mode components (motorized ball valve and brass male threaded hose barb fittings (8 mm-1⁄2 inch)).

The secondary outcome was pain experienced during dressing changes and NPWT operation, measured using the Numeric Rating Scale (NRS), ranging from 0 to 10. Pain levels were assessed and recorded at the end of the NPWT course (day 9). Adverse events, including bleeding requiring intervention, wound maceration, worsening infection, or device-related failure, were actively monitored throughout the study period.

Statistical analysis

Data were analyzed using JASP (version 0.95.2.0). Normality was tested with the Shapiro-Wilk test. Baseline characteristics were compared using independent *t*-tests or Mann–Whitney *U* tests for continuous variables and Chi-square tests or Fisher's exact test for categorical variables, as appropriate.

Because granulation data at days 0, 3, 6, and 9 violated normality (Shapiro-Wilk p-value<0.05), a linear mixed-effects model with random intercepts was used as the primary analysis. This model, robust to non-normality and suitable for repeated measures, included fixed effects for Group, Time, and their interaction. Models were estimated by REML, and fixed effects were evaluated using Type III sums of squares with Satterthwaite degrees of freedom. Estimated marginal means and pairwise contrasts were derived from the fitted model.

For the secondary outcome, day-9 pain scores (NRS) were compared between groups using the Mann–Whitney *U* test. Statistical significance was defined as p-value<0.05, and Holm correction was applied for multiple pairwise comparisons.

Results

Between November 2023 and September 2025, 32 eligible participants were enrolled. None declined participation or were excluded after screening. All were randomized 1:1 to intermittent NPWT (n=16) or continuous NPWT (n=16), received the assigned treatment, and completed follow-up for intention-to-treat analysis without losses or protocol deviations. A CONSORT flow diagram summarizes enrollment, randomization, allocation, follow-up, and analysis (Figure 3).

Inter-rater reliability

Prior to data collection, the inter-rater reliability for granulation tissue formation rate was evaluated using a two-way fixed-effects model with absolute agreement. The average-measure Intraclass Correlation Coefficient (ICC) was 0.95 (95% CI: 0.81–0.99), demonstrating excellent agreement between raters. Consequently, the mean of both raters' scores was used for subsequent analyses.

Baseline characteristics

Baseline characteristics were well-balanced. Mean age was similar (58.1±19.4 years intermittent vs 58.9±17.3 continuous). Males comprised 75% of the intermittent group versus 56.3% of the continuous. BMI was comparable (22.1±4.5 vs 22.0±4.2 kg/m^2). Comorbidities varied slightly: hypertension was more common in the intermittent group (50% vs 18.8%), while diabetes was more prevalent in the continuous group (12.5% vs 6.3%). Most wounds were post-surgical/disease/infection etiology (50% vs 62.5%), followed by burn injuries (43.7% vs 31.2%). Lower limb wounds predominated in both groups (68.7% vs 43.7%). Median wound area was 57.9 cm^2 (IQR 36.9–105) for intermittent and 74.5 cm^2 (IQR 47.3–126) for continuous (Table 1).

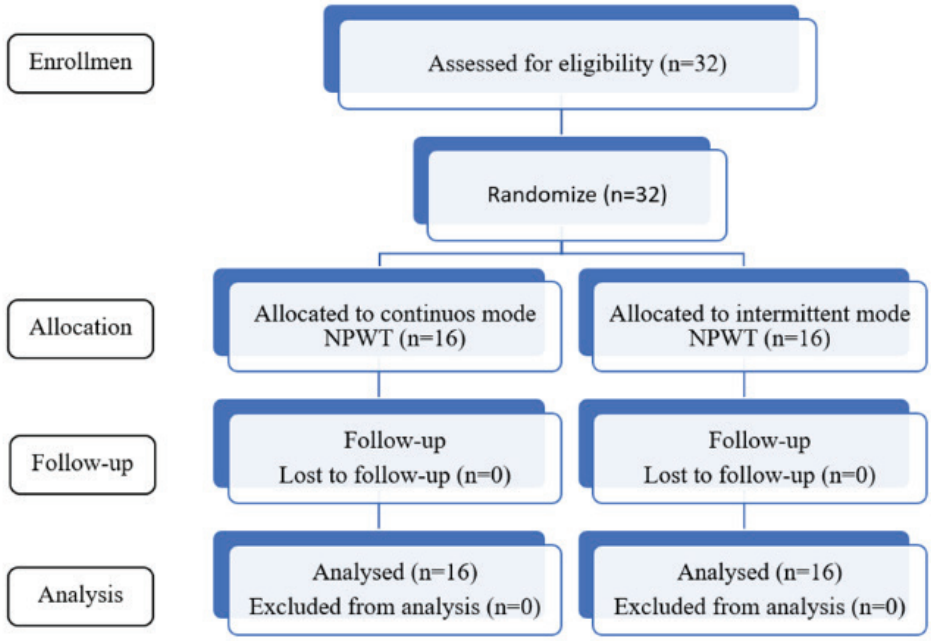

Figure 3 CONSORT diagram for the trial

Table 1 Baseline characteristics of participants by randomized group

Characteristic	Intermittent NPWT (n=16)	Continuous NPWT (n=16)	p-value
Age, years, mean (S.D.)	58.1 (19.4)	58.9 (17.3)	0.901
Sex, n (%)			0.458
Male	12 (75)	9 (56.3)	
Female	4 (25)	7 (43.7)	
BMI, kg/m^2, mean (S.D.)	22.1 (4.5)	22 (4.2)	0.655
Underlying disease, n (%)			0.149
Diabetes mellitus	1 (6.3)	2 12.5)	1.000
Hypertension	8 (50)	3 (18.8)	0.135
Chronic kidney disease	3 (18.8)	0 (0)	0.226
Etiology of wound, n (%)			0.851
Trauma	1 (6.3)	1 (6.3)	
Burn	7 (43.7)	5 (31.2)	
Other (post-surgical/disease/infection)	8 (50)	10 (62.5)	
Anatomical site, n (%)			0.035*
Lower limb	11 (68.7)	7 (43.7)	
Upper limb	2 (12.5)	2 (12.5)	
Trunk and back	0 (0)	6 (37.5)	
Scalp and forehead	3 (18.8)	1 (6.3)	
Wound area, cm^2, median (IQR)	57.9 (36.9-105)	74.5 (47.3-126)	0.497

p-values were calculated using the Mann-Whitney *U* test for continuous variables and Fisher's exact test for categorical variables
*Statistically significant (p-value<0.05), BMI=body mass index, IQR=interquartile range, NPWT=negative pressure wound therapy

Although imbalances were noted in hypertension (p-value=0.135) and anatomical sites (p-value=0.035), these imply a conservative bias. Specifically, the intermittent group had significantly more lower limb wounds (68.7% vs 43.7%), which are physiologically harder to heal due to dependent drainage. The fact that the intervention outperformed the continuous mode despite this disadvantage, and despite the balanced distribution of diabetes (p-value=1.000), underscores the robustness of the primary outcome.

Primary outcome

Longitudinal analysis using a linear mixed model revealed a significant main effect of the treatment group (F (1,30)=5.297, p-value=0.028), indicating that intermittent NPWT resulted in significantly higher overall granulation tissue formation than continuous NPWT. While the omnibus group-by-day interaction was not statistically significant (F (3,90)=1.968, p-value=0.124)—suggesting similar growth rates over time—the significant effect of time (F (3,90) =428.441, p-value<0.001) confirmed progressive healing in both groups.

Estimated marginal means showed progressive increases in both arms and higher levels with intermittent mode at day 9; specifically, the day-9 estimate was 94.6% (SE 3.3%; 95% CI 88.0-101.1%) for intermittent versus 82.8% (SE 3.3%; 95% CI 76.3-89.4%) for continuous, and the between-group difference at day 9 was statistically significant (difference 11.7%±5.3%; df=90.0; t=2.22; p-value=0.029) (Table 2), underscoring the clinical superiority of intermittent NPWT in achieving near-complete wound coverage. Representative clinical images illustrating NPWT applications in each mode are shown for context (Figure 4A-B).

Table 2 Granulation tissue formation by treatment group and day (estimated marginal means, 95% CI)

Day	Intermittent NPWT, % (95% CI)	Continuous NPWT, % (95% CI)	Between-group p-value*
0	0.0 (-6.5 to 6.5)	0.0% (-6.5 to 6.5)	-
3	40.6 (34.1 to 47.2)	31.6% (25.0-38.1)	0.090
6	72.7 (66.2 to 79.3)	62.8% (56.3-69.4)	0.063
9	94.6 (88.0 to 101.1)	82.8% (76.3-89.4)	0.029*

*p-value<0.05. Between-group p-values from interaction contrasts in linear mixed model.
CI=confidence interval, NPWT=negative pressure wound therapy

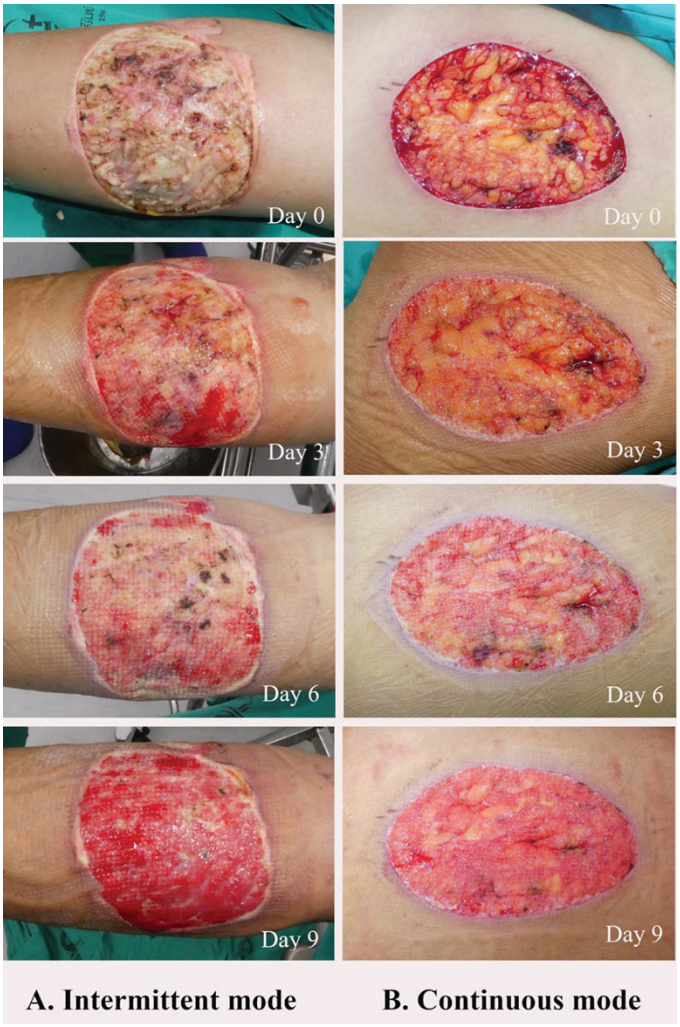

Figure 4 Clinical photographs of NPWT applications at day 0, 3, 6, and 9 by mode: (A) intermittent; (B) continuous; images are de-identified and acquired under standardized conditions to illustrate serial granulation and wound appearance

Secondary outcomes

Pain intensity on day 9 showed no significant difference between intermittent and continuous NPWT groups (Mann–Whitney *U*=123.5, p–value=0.876; median NRS 3.0 vs 3.5, respectively) (Table 3), indicating that superior granulation tissue formation was achieved without increased patient discomfort.

Discussion

This randomized controlled trial shows that a low–cost intermittent NPWT system significantly improved granulation compared with continuous mode (94.6% vs 82.8% by day 9; difference 11.7%, p–value=0.029). The superior healing occurred without increased pain, supporting the effectiveness of intermittent pressure cycling delivered through an improvised, affordable system.

Our findings align with prior evidence showing the superiority of intermittent over continuous NPWT. In porcine models, Borgquist et al. reported that intermittent cycling (0 to –125 mmHg) improved perfusion and granulation compared with continuous pressure[13], and Malmsjö et al. observed greater wound contraction and granulation within 72 hours[14]. Extending these preclinical results, our trial demonstrated sustained clinical benefit in humans over nine days with an 11.7–point gain in granulation, a clinically meaningful improvement suggesting faster wound closure and shorter treatment duration. While some studies reported minimal differences between modes[15], our data indicate that the timing and amplitude of pressure cycles may be key determinants of efficacy.

The superior performance of intermittent NPWT likely results from improved microcirculation during pressure cycling. Sogorski et al. showed that intermittent NPWT enhances microcirculation and tissue oxygenation in healthy volunteers[16], consistent with our observed acceleration of granulation. The 5–minute on⁄2–minute off cycle used here may balance mechanical stimulation and reperfusion, creating favorable conditions for cell proliferation and angiogenesis. Clinically, achieving nearly 95% granulation by day 9 suggests earlier wound closure readiness and reduced treatment costs, even with minimal equipment investment.

Randomized trials and systematic reviews have consistently supported the clinical value of NPWT. Meta–analyses in open fractures and wounds healing by secondary intention confirm reductions in infection rates and faster granulation compared with conventional dressings[18,19]. A randomized trial in difficult–to–heal wounds similarly demonstrated significantly accelerated closure with NPWT[20]. Cochrane review data emphasize that, despite heterogeneity, NPWT can improve wound outcomes while highlighting the need for higher–quality trials[21]. Case reports and small series further suggest that intermittent cycling may provide additional benefits in challenging clinical scenarios[22]. Our findings add to this body of evidence by demonstrating, in a randomized design, that intermittent NPWT achieves superior granulation without added pain burden compared with continuous suction.

Table 3 Pain intensity (NRS) at day 9

Outcome	Intermittent NPWT (n=16)	Continuous NPWT (n=16)	p–value
NRS score, median (IQR)	3.0 (2–5)	3.5 (2–5)	0.876

*Between–group comparison by Mann–Whitney u test, NPWT=negative pressure wound therapy, NRS=numeric rating scale, IQR=interquartile range

Beyond its clinical advantages, this study addresses the primary barrier to advanced wound care in low-resource settings—cost. At the same time, a standard commercial NPWT unit costs approximately 300,000 THB (~$8,820 USD), and our improvised intermittent system costs only ~2,460 THB (~$72 USD). This specific hardware cost comprises an industrial-grade timer switch (1,600 THB), a motor ball valve (800 THB), and brass fittings (60 THB), resulting in a >99% reduction in device acquisition costs. It is important to note that this comparison focuses strictly on hardware costs; it excludes wall suction infrastructure and nursing staff time, which were utilized identically in both groups. Additionally, while commercial systems often require proprietary, higher-cost canisters and dressing kits, our locally assembled configuration is compatible with standard, low-cost hospital consumables (generic gauze and polyurethane film), suggesting that the actual long-term savings may be even greater. Prior studies have similarly shown that improvised NPWT systems provide outcomes comparable to commercial platforms at a fraction of the cost[10-12,21,23], with timer-controlled hospital suction and devices like the AquaVac achieving equivalent healing results.

Our findings show that intermittent NPWT maintains its biological advantage even when delivered through an improvised, low-cost system, demonstrating that efficacy and cost-effectiveness can coexist. This balance of affordability and performance supports broader adoption across healthcare settings and may help reduce global disparities in surgical and wound care.

Limitations include reliance on visual granulation estimates, which, though assessed by blinded surgeons, lack the precision of volumetric or histologic methods; the 9-day follow-up captured early but not long-term healing; and single-center recruitment limits generalizability. Additionally, the dependence on a stationary wall suction source restricts patient mobility during active therapy. Optimal cycling parameters remain undefined and may vary by wound type. Finally, given the open-label nature of the intervention regarding the surgical team, the potential for allocation predictability cannot be entirely ruled out, although outcome assessors remained blinded.

Strengths include the randomized controlled design with blinded assessment, intention-to-treat analysis, complete follow-up, and concurrent pain assessment, confirming superior efficacy without added discomfort. Importantly, this study demonstrates that effective intermittent NPWT can be delivered through a low-cost system, addressing barriers in resource-limited settings.

Future studies should confirm these results in multicenter trials comparing improvised and commercial systems, define optimal cycling parameters for different wound types, and assess long-term cost-effectiveness and biological mechanisms underlying enhanced granulation.

Conclusion

This study demonstrates that an improvised intermittent NPWT significantly enhances granulation tissue formation compared with continuous therapy without increasing pain, offering an accessible, cost-effective alternative in resource-limited settings. However, these findings represent early outcomes from a single center, and multicenter validation is recommended to confirm broader generalizability.

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Conflict of interest

All authors declare no conflicts of interest. None has any financial interests in the devices mentioned in this manuscript, and no funding was received for this article.

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