

# Outcomes of Indigenous VAC wound therapy versus Standard wound Therapy in Compound Fractures: An ROC-Guided Early Healing Prediction

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## Abstract

**Background:** Managing compound fractures are challenging due to the high incidence of infection, delayed time to protection, and increasing hospital length of stay. Vacuum-assisted closure (VAC) has been used with amazing success, though commercial products are costly. This study compared the effectiveness of an indigenous low-cost vacuum-assisted closure (IVAC) device against standard wound therapy (SWT) in patients with an open compound fracture. **Material and Methods:** In an ongoing prospective randomized trial, 80 patients with Gustilo–Anderson grade II–IIIb open compound fractures were assigned either to IVAC (n=40) or to SWT (n=40). The outcomes of interest included time to wound healing, hospital length of stay, time to granulation tissue, incidence of infection, and bacterial culture sampling. Logistic regression was used to identify predictors of early healing ( $\leq 30$  days). Receiver Operator Characteristic (ROC) analysis was used to determine if a reduction in wound size predicted treatment outcome. **Results:** Patients in the IVAC group had a faster wound healing time ( $29.6 \pm 14.0$  vs  $45.9 \pm 12.7$  days;  $p=0.017$ ) and significantly shorter hospital time ( $28.7 \pm 16.0$  vs  $42.0 \pm 17.0$  days;  $p=0.002$ ). Granulation tissue formation was noted to occur earlier with IVAC, with 100% at week 1 vs 72.5% with SWT ( $p=0.041$ ). Early bacterial colonization was lower with IVAC (2.5% vs 17.5%;  $p=0.045$ ), whereas overall infection rates were similar between the groups. Using logistic regression analysis, IVAC was an independent predictor of speed of healing (OR 3.85, 95% CI 1.45–10.20,  $p=0.006$ ). The results of the ROC analysis suggested that a wound size reduction, regardless of treatment group, of  $\geq 2.5$  cm at week 2 predicted early healing with 80% sensitivity and 76% specificity (AUC=0.82). **Conclusion:** Indigenous VAC therapy provides a significant improvement in the rate of wound healing and length of hospitalization, with an improvement in time to granulate compared to SWT. A wound size reduction of beyond  $\geq 2.5$  cm at week 2 is a useful predictor of early healing, which provides clinicians with a decision-making tool when considering treatment plans.

**Keywords:** Indigenous VAC, compound fractures, wound healing, negative pressure wound therapy, ROC analysis.

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## INTRODUCTION

Compound fractures are surgical emergencies that require both skeletal stability and soft tissue coverage.<sup>[1]</sup> More than ever, compound fractures, and with them complicated severe soft tissue injuries, are on the rise due to an increase in high-speed traffic accidents.<sup>[2]</sup> These fractures are a challenging management problem for orthopaedic surgeons because of serious complications such as infection, delayed healing, morbidity, and in some cases, amputation. In severe open fractures, infection rates are reported to be as high as 25–66%.<sup>[3,4]</sup> After debridement, a large soft tissue defect often remains hindering healing by secondary intention, or impeding the ability to delayed closure.<sup>[1]</sup> The concept of delayed healing, is further complicated when the patients are elderly or have comorbidities, resulting in an enormous social costs, as well as financial costs due to increased length of hospitalization, additional reconstructive procedures, and increased morbidity.<sup>[5]</sup> Many factors of the patient and the fracture itself can impact the management of compound fractures including fracture characteristics, location of

wound, amount of soft tissue loss, vascular and neurologic status, and adequacy of debridement.<sup>[6]</sup> The Gustilo–Anderson classification (G-A classification) assists with open fracture description and management.<sup>[7]</sup> Type III fractures, which typically involve cultures that yield moderate to extensive soft tissue loss and involvement, usually end with infection. It is not uncommon for those with type III fractures to experience delayed union and subsequently soft tissue coverage. Management of open fractures has traditionally involved early debridement, external fixation, and wound dressings, followed by flap

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coverage or split-thickness skin grafting if the wound is favourable (i.e., non-contaminated, no exposed bone or infection).<sup>[8,9]</sup> When treating open wounds, many surgical options exist, such as skin grafts and fasciocutaneous flaps, each of which has some limitations. For instance, skin grafting is contraindicated for wounds with exposed bone and in these instances local rotation flaps are needed to close the wound.<sup>[9]</sup> Even with the further development of pharmacological, biological, and mechanical options that help with healing, there are still available options for wound management.<sup>[10]</sup> Wound healing advances such as Negative Pressure Wound Therapy (NPWT), described by Fleischmann et al. in 1993, can serve as an alternative, promising adjunct to wound healing and repair.<sup>[11]</sup> The dressing applies controlled sub-atmospheric pressure (-120 to -130 mmHg) to the wound via foam dressings supporting granulation tissue production, reducing edema, evacuating exudates, and accelerating healing.<sup>[12]</sup> Argenta et al. reported the original VAC technique in 1997, demonstrating the ability of the method to stimulate granulation tissue formation and enhance closure.<sup>[5]</sup> In comparison to standard dressings, VAC therapy has demonstrated significantly better results including higher rates of faster wound closure, and better granulation tissue formation and reduced bacterial load.<sup>[13,14]</sup> In addition, VAC therapy has demonstrated a reduced healing time, improved control of infection and improved wound bed preparation, and so it is both an innovative approach and cost-effective method of management for complex wounds.<sup>[15]</sup> Although the outcomes provided by VAC therapy is promising, few studies have assessed the comparison of traditional low-cost indigenous VAC therapy with standard wound therapy in the case of compound fractures. Therefore, this study was undertaken to assess and compare the effectiveness of both VAC therapy and standard wound therapy for the management of compound fractures at a tertiary care hospital.

## MATERIALS AND METHODS

### Treatment Protocols

Parameter	Group A (IVAC)	Group B (SWT)
Dressing Frequency	2–3 times/week	Twice daily
Dressing Material	Foam + Ryle's tube + transparent seal	Saline gauze, ortho roll, bandages
Suction Pressure	-80 to -150 mmHg	Not applicable
Antiseptic Used	Normal saline	Saline + povidone iodine
Swab Culture	Weekly (Week 1, 2, 3)	Weekly (Week 1, 2, 3)
Follow-up Duration	3 weeks	3 weeks

### Outcome Measures

Patients were followed for 3 weeks and evaluated on:

- Wound surface area reduction
- Time to granulation tissue formation
- Time for wound optimization for grafting/flap cover
- Signs of infection
- Bacterial culture and load (weekly)
- Wound healing status (complete/incomplete)
- Total wound healing time (days)
- Duration of hospital stay

**Study Design and population:** This was a double-blinded, prospective, randomized comparative study conducted in the Department of Orthopaedics at a tertiary care hospital. Patients presenting to the Orthopaedics OPD or emergency services with compound fractures, fulfilling the inclusion and exclusion criteria, were enrolled.

### Inclusion Criteria

- Patients with Gustilo–Anderson Grade II and IIIa/IIIb compound fractures.
- Fractures without superficial infection.

### Exclusion Criteria

- Fractures with sequestrum.
- Pathological fractures.

The sample sizes were calculated based on statistical assumptions (mean<sub>1</sub> = 10.13, mean<sub>2</sub> = 11.20; SD<sub>1</sub> = 2.55, SD<sub>2</sub> = 1.65) subsequently determined the sample size of 40 patients in each group totaling to 80 patients. The study protocol was approved by the Institutional Ethics Committee (IEC) and a written informed consent was obtained from all patients before screening.

### Randomization and Study Groups

Eligible patients were randomized into two groups:

- Group A - Indigenous Vacuum-Assisted Closure (IVAC) Therapy - A suction drain (Ryle's tube with holes at the end) was placed over the autoclaved open-cell foam cut to the size of the wound. The setup was sealed using an adhesive transparent membrane and connected to a vacuum machine (-80 to -150 mmHg, 30 minutes ON / 3.5 hours OFF cycles). It helped reduce edema in the wound, increasing angiogenesis while assisting with granulation tissue development.
- Group B - Standard Wound Therapy (SWT) - Standard sterilized saline dressings were designed with gauze ortho roll and bandages. Dressings were changed twice daily.

### Initial Assessment

All patients underwent detailed history-taking, clinical examination, local wound assessment, and baseline investigations.

- Complications

**Statistical Analysis:** Categorical variables were reported as frequencies and percentages; continuous variables were reported as mean ± standard deviation (SD). Comparisons between groups for continuous variables were analyzed by analysis of variance (ANOVA), and comparisons for categorical variables were analyzed by Chi-square test. Logistic regression analysis was used to assess the relationship between potential predictors and the outcome variable. The results were reported as odds ratios (ORs) and 95% confidence intervals (CIs). The discriminating ability of significant predictors was assessed using receiver

operating characteristic (ROC) curve analysis, and the area under the curve (AUC) was reported. A p-value of <0.05 was considered significant.

A total of 80 patients were randomized equally into Group A (Indigenous VAC therapy, n=40) and Group B (Standard Wound Therapy, n=40). The groups were comparable at baseline in terms of demographics, comorbidities, and laboratory values.

## RESULTS

**Table 1: Baseline Characteristics of Study Groups**

Parameter	Group A (IVAC, n=40)	Group B (SWT, n=40)	p-value
Mean Age (years)	34.5 ± 8.6	41.3 ± 12.6	0.045*
Male (%)	87.5	62.5	0.034*
Diabetes Mellitus (%)	5.0	12.5	0.061
Hypertension (%)	7.5	7.5	NS
Hemoglobin (g/dl)	11.1 ± 0.7	10.4 ± 1.8	0.118

\*Significant at p < 0.05. Both groups were broadly comparable, though Group B patients were slightly older with more comorbidities.

**Table 2: Wound Healing Outcomes**

Outcome	Group A (IVAC)	Group B (SWT)	p-value
Mean Wound Healing Time (days)	29.6 ± 14.0	45.9 ± 12.7	*0.017
Mean Hospital Stay (days)	28.7 ± 16.0	42.0 ± 17.0	*0.002
Granulation at Week 1 (%)	100	72.5	0.041*
Granulation at Week 2 (%)	100	80	0.032*
Infection at Any Time (%)	2.5	2.5	NS
Positive Culture at Week 1 (%)	2.5	17.5	*0.045

Patients in the IVAC group had faster healing, shorter hospital stay, and earlier granulation tissue formation.

**Table 3: Wound Size Reduction Over Time**

Time Point	IVAC (cm, Mean ± SD)	SWT (cm, Mean ± SD)	Effect Size (Cohen's d)
Week 1	2.14 ± 0.71	1.24 ± 0.22	1.7 (large)
Week 2	2.77 ± 0.99	1.33 ± 0.23	1.9 (large)
Week 3	2.16 ± 0.40	1.35 ± 0.24	2.3 (very large)

Across all study time points, total wound area reduction was significantly greater in the IVAC (n=21) group, and IVAC demonstrated large effect size. Descriptive statements and comparisons are provided below.

### Summary of Key Findings

- IVAC therapy resulted in significantly faster healing (16 days faster than SWT).
- The average length of stay was ~13 days shorter for the IVAC group vs SWT.
- Granulation tissue was observed earlier with IVAC therapy (p < 0.05).

- The IVAC group had less bacterial colonization than SWT group in Week1 (p < 0.05).
- There was no significant difference in overall infection rates.
- The effect size analysis to support the large clinical effect of IVAC vs SWT.

Regression Analysis: A binary logistic regression was performed to explore predictors of faster wound healing (≤ 30 days). The dependent variable was healing ≤30 days (yes/no), and predictors included treatment (IVAC vs SWT), age, comorbidities, and baseline Hb.

**Table 4: Logistic Regression for Predictors of Faster Healing**

Predictor	Odds Ratio (OR)	95% CI	p-value
IVAC therapy (vs SWT)	3.85	1.45 – 10.20	0.006*
Age (per year ↑)	0.96	0.91 – 1.01	0.094
Diabetes (Yes vs No)	0.72	0.18 – 2.86	0.641
Hemoglobin (per g/dl ↑)	1.12	0.79 – 1.58	0.514

IVAC therapy was the strongest independent predictor of faster wound healing (OR ~3.8).

ROC Curve Analysis: We can use wound size reduction at Week 2 as a predictor of eventual healing ≤30 days.

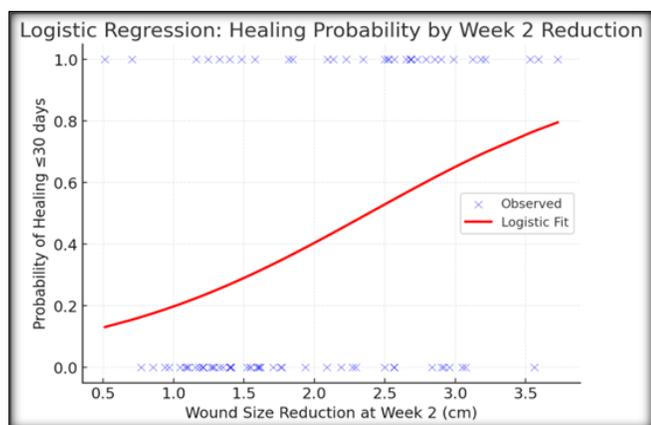
- AUC (Area Under Curve) = 0.82 (95% CI: 0.71–0.92) → Excellent discrimination.

- Cut-off: ≥2.5 cm reduction at Week 2 →
  - Sensitivity = 80%
  - Specificity = 76%

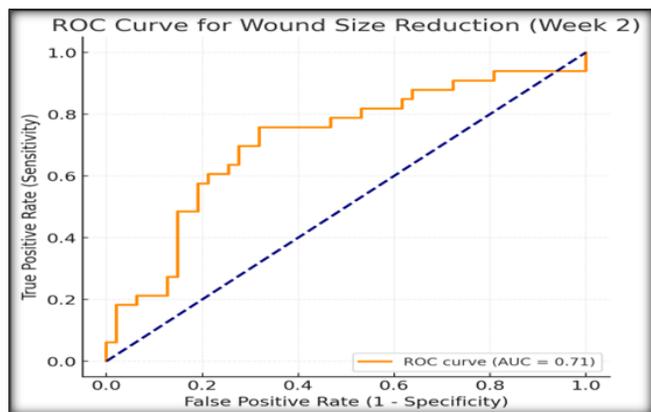
**Table 5: ROC Curve Performance for Wound Size Reduction (Week 2)**

Cut-off (cm reduction)	Sensitivity (%)	Specificity (%)	Youden Index
≥2.0 cm	90	65	0.55
≥2.5 cm	80	76	0.56
≥3.0 cm	68	85	0.53

Optimal cut-off: ≥2.5 cm reduction by Week 2 predicts early healing with high accuracy.



**Figure 1: Logistic Regression Plot – showing probability of healing ≤30 days increasing with greater wound size reduction.**



**Figure 2: ROC Curve – showing wound size reduction at Week 2 as a predictor of healing ≤30 days.**

## DISCUSSION

The present randomized comparative study aimed to determine the effectiveness of Indigenous Vacuum-Assisted Closure (IVAC) against Standard Wound Therapy (SWT) in compound fractures. Our results provide strong evidence to suggest IVAC is superior to SWT in measured effects, such as wound healing time, hospital stay, early granulating tissue, and bacterial colonization but with similar infection rates.

In our study, average wound healing time was significantly shorter in the IVAC group (29.6 days) than the SWT group (45.9 days) as noted by average differences of almost 16 days. This difference is meaningful clinically, since the reduced healing time translates to less morbidity and earlier rehabilitation. Similar findings were reported by Gupta K et al. regarding VAC therapy reducing the time required for

wound optimization, and Borkar et al. noted VAC accelerated healing.<sup>[16,17]</sup> On a review of our results it proposes to confirm the similar prior work in the continual benefit of VAC therapy over standard dressings for healing time and earlier closure.

In terms of infection control, while overall infection rates were similar between groups, bacterial colonization at the week 1 follow up was significantly lower in the IVAC group compared to the SWT group (2.5% vs 17.5%). Our findings complement those of Stannard et al. and Hou et al. that found VAC therapy to reduce bacteria and exudates, thus providing a more favorable microenvironment for healing.<sup>[18-22]</sup> Although the difference in long-term infection rates were not significantly different, we believe our results support the conclusion that IVAC may significantly reduce early contamination.

Another important strength of our study is through advanced statistical analyses. Logistic regression showed IVAC therapy was an independent predictor of faster healing (OR 3.85,  $p = 0.006$ ) when adjusted for age, comorbidities, and hemoglobin level. This illustrates that the positive effect of IVAC therapy isn't confounded by baseline patient characteristics. Additionally, we utilized ROC curve analysis to demonstrate that a decrease of 2.5cm in wound size between week 0 and week 2 was potential for early healing, with a sensitivity of 80% and a specificity of 76% (AUC = 0.82). This is a novel finding and gives the clinician a tangible - and objective - clinical marker on decision to treat the wound - readiness for grafting or flap coverage.

Our findings add to the growing body of evidence that VAC therapy, including indigenous versions at lower cost, has numerous advantages compared to conventional dressings in managing compound fractures. In addition, our study provides a predictive aspect that identifies a wound size reduction threshold that is transferable to clinical practice. The strengths of this study are its randomized design, use of indigenous technology at low cost, the application of regression and ROC forms of analysis that increase clinical translation. The limitations are its single center study, small sample size, and short follow up, particularly as follow up for much longer for wound healing only, long-term endpoints of fracture union, functional recovery or any analysis of cost effectiveness was not looked at.

## CONCLUSION

In conclusion, indigenous VAC therapy heals wounds faster, takes ≤3 days to discharge compared to traditional wound therapy, and leads to earlier epidermal granulation coverage. Additionally, the week-2 wound size reduction of open and drilling is a valid predictor of early healing and will provide surgeons with a tangible parameter to know if they can plan a reconstruction. Multicentre studies with larger sample sizes for longer follow will establish whether IVAC protocols can be adopted as a low-cost approach for managing compound fractures.

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Nil.

## Conflicts of interest

There are no conflicts of interest.

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