

Functionality of lower limb with exposed bone using VAC® negative pressure wound therapy vs. medial calf flap

Enrique Antonio Chau Ramos* ^{1,2,a,b,c}

ABSTRACT

Objective: To compare two reconstructive surgery techniques for lower limb injury with exposed bone and demonstrate that the VAC® (vacuum-assisted closure) negative pressure wound therapy is an alternative for potential recovery showing no significant changes that could lead to functional compromise.

Materials and methods: An analytical, prospective, quantitative and longitudinal study conducted with all the patients of Clínica Stella Maris with traumatic injuries of the lower limb and exposure of the middle third of the tibia treated with the VAC® system and the medial calf flap in 2019.

Results: The measurement obtained with the functional ambulation categories (FAC) scale showed better results among the patients treated with the VAC® technique (since 50 % got grade V) than those who underwent the flap technique (50 % got grade IV), being the differences statistically significant ($p < 0.05$). It was observed that the time to closure was longer with the VAC® technique due to the progressive regeneration process consisting of the complete filling or coverage of the lesion area. On the other hand, the difference in the postoperative pain intensity between the two techniques was evident, being moderate to severe with the flap technique and mild, for the most part, with the VAC® technique.

Conclusions: The VAC® suction system is effective for bone coverage in traumatic defects of the anterior middle third of the tibia. It is an alternative for potential recovery that does not change the anatomical structures because it provides better functional results and fewer complications. It is a useful and safe option that stimulates wound closure and minimizes the need for surgical treatment.

Keywords: Wound Healing; Lower Extremity; Rehabilitation; Therapeutics (Source: MeSH NLM).

Funcionalidad del miembro inferior con exposición ósea con el uso de terapia con presión negativa VAC® vs. colgajo de gemelo medial

RESUMEN

Objetivo: Comparar dos técnicas de cirugía reconstructiva para lesión en miembro inferior con exposición ósea y, a través de ella, diferenciar que la técnica de VAC® (*Vacuum Assisted Closure*, cierre asistido con presión negativa) es una alternativa con beneficio de recuperación potencial sin alteraciones significativas que pudieran llevar a un compromiso funcional.

Materiales y métodos: Estudio de tipo analítico con corte prospectivo, cuantitativo y longitudinal, en el que se desarrolló la terapia con el uso del sistema de VAC® y de colgajo gemelar medial en todos los pacientes de la Clínica Stella Maris que presentaron heridas traumáticas de miembro inferior con exposición ósea de tercio medio tibial durante el periodo 2019.

Resultados: Se evidenció que la medición con la escala funcional de la marcha (FAC, por sus siglas en inglés) fue mejor en los pacientes con la técnica de VAC® (dado que el 50 % tiene grado V) respecto a la técnica de colgajo (50 % en grado IV); las diferencias fueron estadísticamente significativas ($p < 0,05$). Se apreció que el tiempo de cierre fue mayor en la técnica de VAC® debido al proceso de regeneración progresiva hasta llenar o cubrir la zona completa de la lesión; por otro lado, se evidenció la diferencia de la intensidad del dolor posoperatorio entre las dos técnicas: de moderado a intenso con la técnica de colgajo y leve, en su mayoría, con la técnica de VAC®.

Conclusiones: El sistema de aspiración VAC® es eficiente para la cobertura ósea en defectos traumáticos del tercio medio tibial anterior, por lo que constituye una alternativa con potencial beneficio de recuperación sin alteración de estructuras anatómicas, ya que brinda mejores resultados funcionales y menores complicaciones. Es una opción útil que actúa de forma segura porque estimula el cierre de la herida y minimiza las necesidades de un tratamiento quirúrgico.

Palabras clave: Cicatrización de Heridas; Extremidad Inferior; Rehabilitación; Terapéutica (Fuente: DeCS BIREME).

1 Sociedad Peruana de Cirugía Plástica Reconstructiva (Peruvian Society of Plastic, Reconstructive and Aesthetic Surgery), full member. Lima, Peru.

2 Clínica Stella Maris. Lima, Peru.

a Master's degree in Plastic and Reconstructive Surgery.

b Plastic surgeon.

c PhD in Medicine.

*Corresponding author.

INTRODUCTION

Nowadays, many work activities involving multiple risks are carried out, which leads to an increase in the number of accidents such as lower limb injuries with exposed bone, among others. These accidents frequently cause traumatic injuries that can worsen in some cases since there are no soft tissues—such as muscles—that protect the pretibial surface, as in the posterior compartments of the leg. Therefore, the recovery or regeneration of tissues in this area may be slow, which demands and prolongs healing time, involving the potential risk of infection due to the exposed bone surface ^(1,2).

In order to recover the function of the affected area, there are different surgical techniques to cover the exposed lower limb bone that end up in long recovery processes with variable grade of functional limitation, which even lead to temporary or permanent disability of the affected extremity.

There is a therapeutic possibility of lower risk of infection since it is a closed vacuum system: the VAC[®] technique achieves motor recovery without muscle structure displacements that may cause temporary or permanent functional limitation because it provides coverage in the event of soft tissue loss with pretibial exposed bone ⁽³⁻⁵⁾. The negative pressure wound therapy (NPWT) is a mechanical treatment used as an adjuvant in wound healing. It can be administered in a continuous or intermittent basis, for both acute and chronic lesions, and is an alternative to the traditional healing methods since it is quick, effective and easy to use ⁽⁶⁻⁸⁾.

The VAC[®] technique prepares the wound bed for closure, reduces edema, promotes granulation tissue formation, reduces the bacterial load, keeps hydration (by removing exudate and reducing the bruise surface area), improves healing rates and reduces the hospital stay. The technique is carried out by placing a dressing—which can be of gaze or polyurethane foam—in the injury, sealing it with a semi-occlusive dressing and applying subatmospheric pressure through a drainage tube connected to a computerized pump, which is useful to promote wound healing ⁽⁹⁻¹²⁾.

Several international studies on the VAC[®] technique conducted in the last twenty years satisfactorily agree with the results obtained with NPWT, a technique that is more frequently used in private hospitals ⁽¹⁶⁾. Clinical cases with complicated lesions were successfully treated with this method in complex areas of exposed tissue—particularly the lower extremities—with good functional results, which allowed patients to return to their daily activities in less time and without secondary complications compared to other treatments that cause functionality problems ⁽¹³⁻¹⁵⁾.

De Juan Pérez, in his study conducted in 2010, used the VAC[®] therapy in lower limb complex trauma, resulting in the reduction of infection and acceleration of lesion granulation, which helped to improve the prognosis of risk of lower limb amputation and be of benefit to serious open fractures ⁽¹⁾.

MATERIALS AND METHODS

Study design and population

Out of all the patients with traumatic lower limb injuries with exposure of the medial third of the tibia treated at Clínica Stella Maris during 2019, ten were treated with the VAC[®] technique and eight with the medial calf flap technique. The study sample consisted of 18 patients, with ages that ranged between 19 and 65 years, most of whom were males. The research included patients diagnosed with traumatic lower limb injuries with exposed bone and without osteomyelitis.

Medical records were used as study tool, and the data thereof were included in a data collection sheet created for that purpose. Said sheet consisted of the demographic characteristics of the patients such as age and sex, percent distribution of insurance type by technique, time of treatment administration, presence of infection, complications and adverse effects, as well as the functionality of lower limbs assessed with the functional ambulation categories (FAC) test, a questionnaire about the ability to perform daily activities. Patients were evaluated by a third party to avoid bias.

The functional assessment was conducted using the FAC test, designed to evaluate the patients' ambulation ability, determine their progression and establish the treatment guidelines. The test score is as follows:

- Score 0 (no ambulation): patients cannot walk, even with external assistance.
- Score 1 (basic ambulation): patients are dependent ambulators who require permanent assistance from another person.
- Score 2 (ambulation at home): patients are able to walk only indoors on level and horizontal surfaces, generally within a known and controlled area like home.
- Score 3 (ambulation in home surroundings): patients are able to walk both indoors and outdoors on irregular surfaces and go up an occasional step or stairs.
- Score 4 (independent ambulation in the community): patients are able to walk on all kinds of irregular surfaces; they can go up and down stairs, ramps, curbs, etc.
- Score 5 (normal ambulation): walking is totally normal regarding distance and surface appearance, both at home and outdoors, with unlimited distance; there is no aesthetic anomaly or lameness ⁽¹⁹⁾.

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Variables and measurements

This was an observational study since it was limited to the measurement of the study variables by the researcher. According to the scope, this was an analytical study because it demonstrated a relationship between the variables by comparing the functionality of lower limbs through two techniques. Moreover, this was a longitudinal study since the wound closure was followed-up at several times. Regarding the time of data collection, this was a prospective study because it was conducted from the exposure to the techniques to the wound closure.

Statistical analysis

IBM SPSS Statistics V23 was used for data processing; the demographic variables were analyzed using descriptive statistics and the results were shown in a frequency table according to the Vancouver style. The mean and standard deviation of the numerical data and the percentage of the qualitative data were calculated. As statistical test to differentiate ratios, the chi-square test for the comparison of independent ratios at a confidence level of 100 % was used. The Mann-Whitney *U* test was used to compare changes in the mean values.

Ethical considerations

This research work complied with the ethical principles of respect for individuals, assistance and fairness. The confidentiality of personal data and photographs collected was ensured; likewise, patients confirmed their participation before surgery by signing an informed consent form.

The research had the permission of the clinic's ethics committee. Permission from the pertinent leadership, i.e., the director and the head of the Plastic Surgery Department of Clínica Stella Maris, was requested to conduct the study.

RESULTS

The results confirmed the objective of the study. The functional grade was evaluated with the VAC® system technique and the medial calf muscle flap coverage technique.

The research was conducted in patients with traumatic lower limb injuries, where vacuum therapy was confirmed as a useful and safe option. The VAC® method is a mechanical closure system that applies sustained negative force to the whole wound, thus avoiding its retraction and promoting the constant reduction of its diameter. This eliminates interstitial fluid, which may contribute to reduce edema. As a result, there is an enhanced blood flow to the wound (Figure 1).

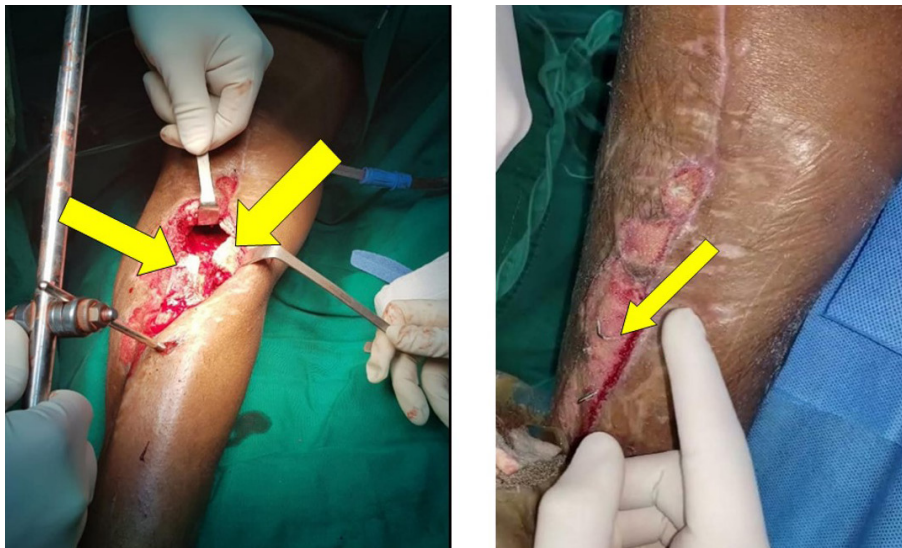


Figure 1. Lower right limb with exposed bone before starting the VAC® technique and (solved) areas with exposed bone covered by granulation tissue after using the vacuum therapy

Source: researcher's photographs.

The main immediate complications from the two techniques were determined, finding more complications in the patients treated with the flap technique compared to those treated with the VAC® technique (37.5 % and 10 %, respectively); such differences were statistically significant ($p < 0.05$) (Table 1).

Table 1. Distribution of complications by technique

Patient	Age - sex	Technique type	Complications
1	30 years - male	VAC®	NO
2	19 years - male	VAC®	NO
3	31 years - female	VAC®	NO
4	37 years - male	VAC®	BLEEDING
5	60 years - female	VAC®	NO
6	59 years - male	VAC®	NO
7	39 years - male	VAC®	NO
8	33 years - female	VAC®	NO
9	48 years - male	VAC®	NO
10	35 years - male	VAC®	NO
1	61 years - male	Medial calf flap	NO
2	59 years - female	Medial calf flap	NO
3	40 years - male	Medial calf flap	BLEEDING
4	39 years - male	Medial calf flap	NO
5	47 years - male	Medial calf flap	BLEEDING
6	33 years - female	Medial calf flap	BLEEDING
7	61 years - female	Medial calf flap	INFECTION
8	28 years - male	Medial calf flap	NO

The time to wound closure was longer with the VAC® technique compared to the flap technique, showing significant differences ($p < 0.05$) (Table 2 and Figure 2).

Table 2. Mann-Whitney *U* test results

Variable	Technique	N	Mean	Standard deviation	Z	p
Time to closure in days	VAC®	10	35.80	5.514	4.14	0.01
	FLAP	8	19.38	10.993		

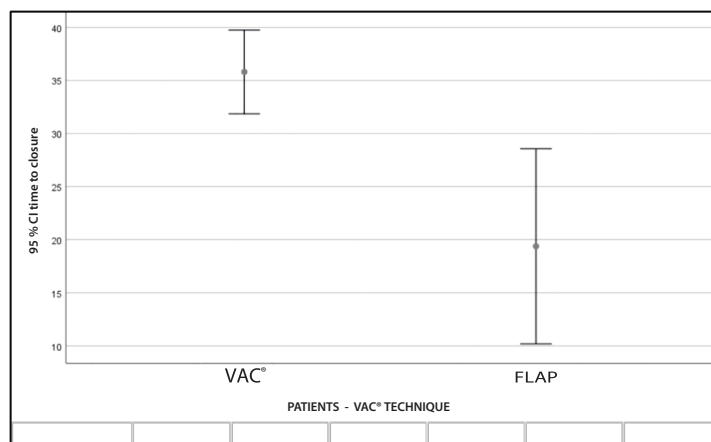


Figure 2. Comparison of time to closure by technique type

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Moderate to severe pain was reported: pain was higher in patients who underwent the flap technique compared to those who underwent the VAC® technique (0 % and 100 %, respectively), being the differences statistically significant ($p < 0.05$) (Table 3).

Table 3. Distribution of pain intensity by technique

Patients	Technique type	VAS: Pain intensity:		
		Mild (0-3)	Moderate (4-6)	Severe (7-10)
1	VAC®			MILD 2/10
2	VAC®			MILD 2/10
3	VAC®			MILD 3/10
4	VAC®			MILD 2/10
5	VAC®			MILD 1/10
6	VAC®			MILD 2/10
7	VAC®			MILD 3/10
8	VAC®			MILD 1/10
9	VAC®			MILD 2/10
10	VAC®			MILD 2/10
1	Medial calf flap			MODERATE 5/10
2	Medial calf flap			MODERATE 4/10
3	Medial calf flap			MODERATE 4/10
4	Medial calf flap			SEVERE 7/10
5	Medial calf flap			MODERATE 4/10
6	Medial calf flap			MODERATE 5/10
7	Medial calf flap			MODERATE 5/10
8	Medial calf flap			MODERATE 4/10

The attending physician should periodically examine the wounds treated with the VAC® NPWT. The dressings were changed every 48 to 72 hours: dressing change intervals were established by continuous wound evaluation (Table 4).

Table 4. Number of changes with the VAC® system

Variable	Technique	N	Mean	Deviation
Number of changes	VAC®	10	4.70	1.059

Sample	Number of changes with the VAC® technique	Time to wound closure
1 Patient		25 days
2 Patient		37 days
3 Patient		37 days
4 Patient		36 days
5 Patient		43 days
6 Patient		31 days
7 Patient		43 days
8 Patient		37 days
9 Patient		36 days
10 Patient		31 days

The average number of changes with the VAC® technique is 4.70 with a variability of 1.06 changes.

The results of the FAC scale revealed that the patients were satisfied with the VAC® technique, with prevalence of functional grade V (50%), compared to the medial calf muscle flap coverage technique, which showed a prevalence of functional grade IV (50%). Statistically significant differences were found in the overall results ($p < 0.05$) (Figure 3).

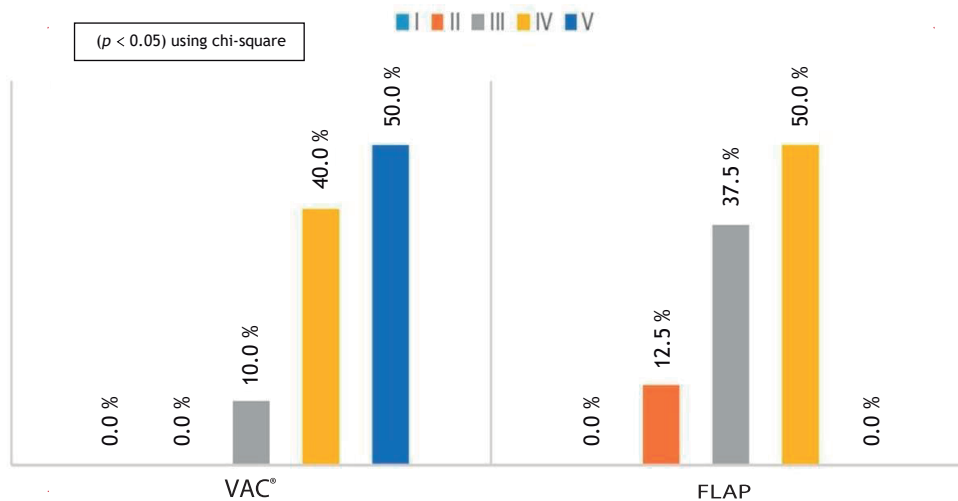


Figure 3. Percent distribution of FAC scale functional measurement by technique

DISCUSSION

Regarding the functional grade, the research showed a positive relationship between the coverage of lower limb injuries with exposed bone and the VAC® system technique, which was effective compared with the medial calf muscle flap technique in patients treated at Clínica Stella Maris during 2019⁽¹⁷⁻¹⁹⁾. The results showed the significance of the functional measurement, with higher FAC scale scores, in patients who underwent the VAC® technique.

Our study agrees with the one conducted by Bernal-Martínez et al.⁽¹⁷⁾ (Mexico), who treated with surgical debridement cases of full-thickness burns with exposed bone that caused coverage defects because of the limited availability of tissues to reconstruct these defects. The results stood out the complete wound closure after the total bone coverage with granulation tissue and subsequent skin graft. Therefore, it is concluded that the vacuum therapy is a useful and safe option that stimulates wound closure and minimizes the need for surgical treatment for full-thickness burns with exposed bone⁽¹⁷⁻¹⁹⁾.

Additionally, De Juan Pérez⁽¹⁾ (Spain) conducted an analytic observational study in order to use the VAC® therapy in case of a serious left leg trauma. The results of NPWT with this system demonstrated that it reduced the risk of infection of serious fractures, which notably accelerated wound granulation. After admission to the hospital, a good granulation tissue over a large part of the surface could

be observed since the first VAC® dressing change. This fact significantly improved the appearance and prognosis of risk of leg amputation. If compared with the results of this research, the VAC® system poses a milestone for acute or chronic complex injury treatment since it is an important therapeutic tool to treat serious open fractures of lower limbs. The relationship between the time to closure or coverage and the results shows that the VAC® system technique is effective⁽²⁰⁻²²⁾.

In 2018, Maitret-Velázquez et al.⁽²⁹⁾ (Mexico) claimed that NPWT accelerated wound healing, which facilitated intrahospital treatment: pain and function of lower limb injuries were controlled and infections were prevented, which helped wound closure in medically compromised patients. This agrees with the present study on the evaluation of the functional grade using the VAC® system technique. Their study analyzed 93 patients who underwent NPWT. Surgical wound infection and vascular exposure were observed in 40.9% and 22.6% of the patients, respectively. NPWT or VAC® system accelerated wound healing, thereby facilitating the intrahospital treatment and controlling pain and infection; such results also agree with the present study and the difference was statistically significant.

In 2020, Goyo et al.⁽¹⁴⁾ (Venezuela) observed the complete clinical improvement of all the characteristics of the wound. Moreover, their analysis also showed acceleration of the healing process, infection control and reduction of hospital stay. This demonstrated that no complications

were found with the use of the VAC® system, which agrees with our results.

According to different research studies reviewed and the results of this study, it was possible to analyze and determine that NPWT is a non-invasive treatment that nowadays is included in general surgery. It is used to treat chronic, acute and complex wounds, in order to reduce the number of wound healing procedures and the time required to perform them, as well as avoid surgeries involving an elevated morbidity for the patient. The VAC® system allows reducing the number of weekly wound healing procedures and the time required to perform them, so patients recover their functionality and are able to walk independently during their rehabilitation (23-25).

In conclusion, according to the FAC scale, patients who underwent the VAC® technique showed a better recovery than those who underwent the medial calf muscle flap coverage technique since 50 % of the VAC® group got grade V functionality and 50 % of the flap group got grade IV functionality. The differences were statistically significant in the overall results (26-27). Also, the main immediate complications from the two techniques—i.e., bleeding and infection—were determined, finding more complications in the patients treated with the flap technique compared to those treated with the VAC® technique (37.5 % and 10 %, respectively); such differences were statistically significant (28-29).

On the other hand, the difference in the postoperative pain intensity between the two techniques was evident, being moderate to severe in patients who underwent the flap technique and mostly mild among those who underwent the VAC® technique. The difference was statistically significant ($p < 0.05$).

Regarding the vacuum therapy, this is a useful and safe option that stimulates wound closure and minimizes the need for wide surgical treatment in wounds with exposed bone. This has a positive impact on patients' financial situation because it avoids expensive treatments. Moreover, it helps workers to resume their daily and social activities.

The VAC® technique or NPWT is an alternative that should be preferred over the flap technique since the principles of reconstructive surgery include protecting limb motor function, which is one of the most important objectives.

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Corresponding author:


Enrique Antonio Chau Ramos

Address: Av. Javier Prado Oeste 1351, dpto.1304 - San Isidro. Lima, Perú.

Telephone: +51 948029959

E-mail: eachaur@gmail.com

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ORCID iD

Enrique Antonio Chau Ramos PhD  <https://orcid.org/0000-0003-1482-2614>