

Evidence for the benefits of negative pressure therapy in the treatment of diabetic foot in adults: a comprehensive approach to improved health

Abstract

Diabetic foot ulcers represent an increase in recent years in the cures to be carried out by nursing staff. For this reason, the new negative pressure therapy has been chosen, which involves an increase in granulation tissue, leading to complete healing in a minimum time, highlighting the few complications derived from said therapy.

Objective: To demonstrate the effectiveness of negative pressure therapy in patients with diabetic foot.

Methodology: A narrative review was carried out between December 2022 and November 2023 in the databases of Pubmed, Dialnet, Google Scholar, WOS, Scopus and Cochrane, following a search string, which combines keywords derived from the thesauri “Health Sciences Descriptors” (DeCS) and “Medical Subject Headings” (MeSH), being combined with the Boolean operators “NOT”, “OR” and “AND”.

Results: Negative pressure therapy offers a number of significant benefits for adult patients with diabetic foot, improving wound healing, reducing the risk of serious complications and contributing to a better quality of life. It is important to highlight that the implementation of this therapy must be guided by health professionals and adapted to the specific needs of each patient.

Conclusion: After comparing the different selected articles, it was determined that the application of negative pressure therapy in diabetic foot ulcers is beneficial in relation to the reduction in healing time compared to conventional wound healing dressings. The associated complications being minimal. Furthermore, treatment with this therapy turns out to be cost-effective by reducing patients’ hospital stays, leading to an increase in quality of life.

Keywords: negative pressure therapy, diabetic foot, diabetic foot ulcer, conventional dressings, quality of life

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Abbreviations: PAE, nursing care process; NPT, negative pressure therapy; VAC, vacuum assisted closing; DeCS, descriptors in health sciences; MeSH, medical subject headings; SJR, Scimago journal & country rank; WOS, web of science; NPWT, negative pressure wound therapy; TWC, traditional wound care; MWC, moist wound care

Introduction

Diabetic foot wounds or ulcers are increasingly common among the treatments to be carried out by nursing, their complete healing being very complex due to the difficulty in healing that diabetic patients have. Negative pressure therapy is a novel alternative in carrying out these cures, since due to the subatmospheric pressure it exerts on the wound bed, it facilitates healing through a multimodal action.¹

Negative pressure therapy is the choice in DFU due to its few complications and the duration of treatment is variable and will always depend on the therapeutic objective and the size of the wound.¹ The application of this therapy offers numerous clinically proven benefits, among which macrotension stands out, which allows the approximation of the edges, cellular microtension, favoring the formation of granulation tissue and the elimination of fluids in the wound bed.² However, it is important to keep in mind that all patients require individualized care focused on them and their injury. To do this, it is necessary to correctly apply the nursing care process (PAE),

which allows the development of a specific and individualized care plan for each patient, guaranteeing the quality and continuity of the care offered.²

Negative pressure therapy concept

Negative Pressure Therapy (NPT) or also called Vacuum Assisted Closure Therapy (VAC), is a non-invasive system, which consists of the use of direct subatmospheric pressure to the bed of a wound. The objective of the therapy is to facilitate healing after the application of localized and controlled negative pressure on the wound, stimulating its healing.^{1,2} Therefore, this type of systems are an alternative treatment for complex open wounds. With this therapy, healing times are reduced as well as additional costs. They also reduce hospital stays and provide a lower incidence of complications associated with the type of injury without affecting the patient’s quality of life.^{1,2}

History of negative pressure therapy

The clinical application of negative pressure therapy dates back to the past, where it was used as an adjuvant in acupuncture techniques in Chinese medicine due to its ability to produce local hyperemia. It was in the 19th century when it was introduced into Western medicine in order to stimulate circulation locally in healthy skin. However, negative pressure therapy was not applied to open wounds until the 1990s.^{1,3}

In 1993, traumatologist Wilhelm Fleischmann reported effective wound cleaning and conditioning by applying subatmospheric pressure in 15 patients with open fractures. Simultaneously, doctors Louis Argenta and Michael Morykwas experienced a similar experience, thus patenting a device called “V.A.C therapy” or vacuum-mediated wound closure. From that moment on, the use of V.A.C therapy became widespread while the devices for its application improved.^{1,3} It was in 2013 that the first meeting of experts on Negative Pressure Therapy took place with the aim of establishing agreed guidelines for its use. Therefore, although it was discovered in the 90s, it is in this last decade that there has been a notable growth in the number of research and publications on the use of said therapy. Thus, gradually, Negative Pressure Therapy has been established as a therapeutic modality in the management of wounds.¹

Pathophysiological effect of negative pressure therapy

Negative Pressure therapy promotes the evolution of the wound, from the inflammatory phase to the proliferative phase.⁴ The mechanism of action is based on the reduction of excess fluid, that is, reducing both edema and exudate and, therefore, inflammation. Furthermore, with this technique the bacterial load is controlled, improving blood flow and therefore increasing the formation of vascularization, increasing the supply of nutrients and oxygen to the injury. In the same way, with this therapy a mechanical effect is produced in the cells, which favors the approximation of the edges. This fact prepares the wound bed with the increase in the formation of granulation tissue and the action of growth factors.³

Indications and contraindications of negative pressure therapy

Negative Pressure Therapy is designed and intended as a complementary treatment for wound healing, specifically for those that do not respond to conventional treatment. It is true that not all wounds that do not respond to treatment can be treated with this type of therapy.⁵ Below are the indications and contraindications of Negative Pressure Therapy (NPT) (Table 1).^{4,5}

Table 1 Indications and contraindications of negative pressure therapy

Indications	Contraindications
Acute wounds:	Untreated osteomyelitis.
- Surgical resections.	Tumor wounds.
- Non-suturable traumatic wound.	Undebrided necrotic tissue. Anastomosis.
- Dehiscences.	Untreated infected ulcers.
- Burns or grafts.	Acute hemorrhage.
- Postoperative complications.	Exposed bone, nerves and organs.
Chronic wounds:	
- Venous or arterial ulcers.	
- Pressure ulcers (grade III or IV).	
- Diabetic foot.	

Complications associated with negative pressure therapy

Among the complications associated with TPN, according to scientific evidence, the complications associated with said therapy are few and are mostly related to the manipulation and control of the pressure pump.

The most common complications related to TPN are perilesional maceration due to exposure to foam and pressure, bleeding, tissue

necrosis, local wound infection, and pain on removal of the dressing or at the beginning of therapy. Therefore, the most important prophylactic measure is to raise the pressure progressively and slowly, allowing the patient to get used to the sensations of negative pressure.^{6,7}

Components of negative pressure therapy

In relation to the components of the TPN, they all have the same, since regardless of the system manufacturer, they have similar characteristics. Within the components of the system are the following.^{3,4}

Foam dressing: this is the part that is in direct contact with the wound, since it is introduced into the wound bed. Its structure consists of pores of different sizes, through which fluids flow from the wound to the system. The vacuum system causes the foams to contract, adhering to the transparent dressing with which they are covered, thus generating an airtight and isolated environment. When choosing one form or another, the characteristics of the wound and the objectives to be achieved are taken into account. Among the foam options are polyurethane foam, black in color. This is recommended when the established objective is to stimulate granulation tissue. On the other hand, there are polyvinyl alcohol foams, with white color, whose function is to retain moisture. They are used when granulation tissue in the wound is scarce.

Transparent film: This is a transparent, adhesive and semi-occlusive covering, which covers the wound and the foam. This transparent film must be glued without any leakage, since its purpose is to isolate the injury, protecting it from particles and substances in the environment, while allowing gas and water vapor exchange between both media.

Reservoir: this is the part of the device which collects the fluids extracted from the wound. The main function is to store the excretions from the wound in an airtight manner, avoiding the bad smell they give off through active carbon filters.

Suction cup and tube: consists of a pad, which, attached to a drainage tube, connects the foam with the reservoir and the pump. Through the suction cup and tube, the wound exudate reaches the reservoir and suction occurs on the wound through the pump.

Suction pump: this is a digital system, which consists of a microprocessor. This part is responsible for generating negative pressure, by transferring gas molecules from the wound itself to the outside. Likewise, the microprocessor is capable of collecting different signals from the system and issuing alarms if there are problems, such as incorrect pressure or air leaks.

The negative pressure exerted on the wound by the suction pump can be⁸ continuous: the effective negative pressure figure at the time of granulation tissue formation is 125 mmHg.⁹ This can be increased or decreased in intervals of 25 mmHg depending on the patient's tolerance and the evolution of the wound. This continuous pressure is applied in the first 48 hours and as the exudate decreases, as well as its bacterial load, the pressure becomes intermittent.¹⁰

Intermittent: applied in interspersed periods of 5 minutes with aspiration and 2 minutes without.¹¹ Intermittent negative pressure has been shown¹² to accelerate the formation of granulation tissue more efficiently than if negative pressure is applied continuously.¹³

Negative pressure therapy precautions

In the practical application of Negative Pressure Therapy it is necessary to take into account different aspects. Among the precautions for this technique are the following.^{3,11} In patients with a high risk

of bleeding, this technique should be performed in a healthcare environment, where they can have greater control and surveillance. The size and weight of the patient must be taken into account, since in patients who are not able to tolerate a large loss of fluids it can lead to dehydration.

Foam dressings are radiolucent, that is, they are not detected by X-rays. However, the device is not compatible with magnetic resonance imaging, so before performing this test the patient must be disconnected from the device. V.A.C therapy should not be disconnected for more than two hours. In this case, the dressing must be removed and the wound irrigated. If the application of a defibrillator is necessary, it must be taken into account that the transmission of energy can be inhibited if the dressing is not previously removed.

The objective of this study is to demonstrate the effectiveness of Negative Pressure Therapy in adult patients with diabetic foot. Likewise, this work will estimate the quality of life of patients with diabetic foot who undergo Negative Pressure Therapy. It will also attempt to evaluate the effectiveness of Negative Pressure Therapy on the diabetic foot in combination and comparison with other conventional wound healing treatments. Also collect the complications of the diabetic patient undergoing Negative Pressure Therapy.

Materials and methods

The preparation of this work was carried out through a systematic bibliographic review of the articles found by searching the following databases: Pubmed, Dialnet, Google Scholar, WOS, Scopus and Cochrane. To find the best possible scientific evidence, a series of inclusion and exclusion criteria were applied.

The keywords for this review are: Negative pressure therapy; diabetic foot; diabetic foot ulcer; conventional dressings; quality of life. To carry out the bibliographic search, different keywords in English were used, such as: “nursing”, “diabetic foot”, “Negative-Pressure Wound Therapy”, “treatment outcomes”. These have been validated by the DeCS and MeSH. Once selected, the corresponding Boolean operators were used: AND/OR, as well as the necessary parentheses and quotation marks. The final search string is as follows: (Negative-Pressure Wound Therapy OR Vaccum Assisted Closure) OR (Conventional Therapy) AND (Diabetic foot) AND (Quality of life).

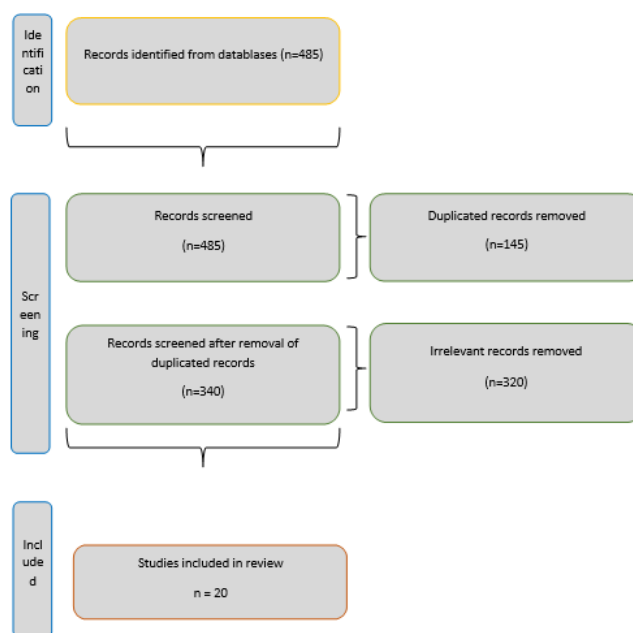
The criteria that were taken into account for the selection of the relevant studies were the following. Inclusion criteria: the period between 2015 and 2023; article type: article review and article research; field: medicine; English language; sample in adult population; and studies that provide scientific evidence justified by the level of indexing of articles in journals according to the latest certainties. Exclusion criteria: articles prior to 2015; language: not English; studies in which the population was minors; studies that do not provide scientific evidence justified by the level of indexing of articles in journals according to the latest certainties.

The research question was constructed following the PICO format (Population/patient, Intervention, Comparator, and Outcomes/Outcomes). Detailed as P (Patients): Adults of both sexes, of any age with diabetic foot. I (Intervention): Negative pressure therapy (NPT) or vacuum assisted closure (VAC), C (Comparison): system conventional wound healing technique, O (Outcomes, Results): Effectiveness, quality of life and complications.

Results

Below is a scheme that shows the search strategy used to select

the 20 articles selected from the 6 databases, following the criteria of identified studies, duplicate studies, title, abstract, full text, and valid studies of a definitive nature (Scheme).



Scientific evidence of the most relevant selected studies

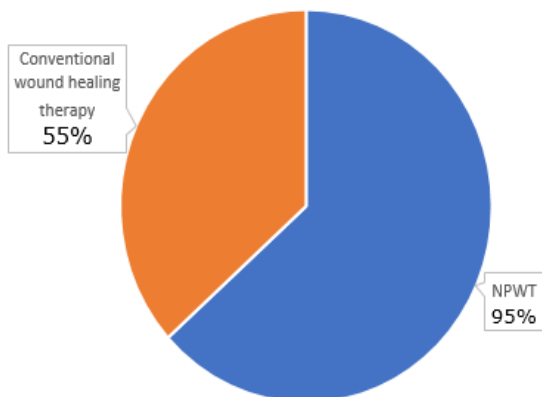
In this bibliographic review, the most relevant data from the 20 selected articles on treatment with negative pressure therapy in diabetic foot wounds have been included. Annex shows the information on each of the selected articles, explaining their authors, the type of study, the sample included in the study and summary of the article.

In the studies of Seidel D, et al.,¹⁴ Wang N, et al.,¹⁵ Nathaniel Chiang, et al.,²⁰ Borys S, et al.,¹⁹ Maranna H, et al.,²⁶ Liu Z, et al.,²⁹ Sukur E, et al.,³⁰ and Rys P, et al.,³² is shown in reference to the comparison of the use of NPWT with conventional wound healing therapies in the diabetic foot. In these studies the average number of days in outpatient treatment with NPWT is 36 days compared to 56 days of outpatient treatment with conventional cures.

NPT promotes wound healing by promoting blood flow and reducing edema. This is particularly relevant in patients with diabetic foot, as slow ulcer healing is a common concern.¹⁴ Applying negative pressure helps remove excess fluid from the affected area, thereby reducing the swelling and inflammation associated with diabetic foot. This contributes to a more conducive healing environment. Negative pressure therapy can help control infections by removing exudate and reducing the bacterial load in the wound. This is crucial, since infections are a serious complication in patients with diabetes.¹⁵ Negative pressure promotes the formation of granulation tissue, a new connective tissue that is essential for wound healing. This helps fill the wound space and promote a more complete recovery.¹⁶ By improving wound healing, controlling infections, and promoting a healthy healing environment, negative pressure therapy may help reduce the risk of amputation in patients with diabetic foot, a serious complication of the disease.¹⁷ By relieving pain associated with ulcers and wounds, negative pressure therapy can also improve a patient's overall comfort, which is crucial to quality of life in those facing the challenges of diabetic foot.¹⁸

The previous studies, together with the study by Wynn M, et al.,¹⁸ observed that granulation tissue on day 14 of treatment is 95% in patients treated with NPWT compared to 55% with conventional cure therapy of wounds (Graph 1).

Granulation tissue. Day 14 of treatment

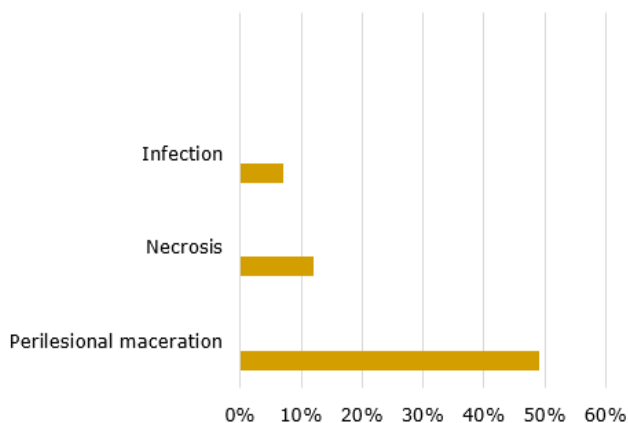


Graph 1 Granulation tissue. Day 14 of treatment.

Source: self-made

In the article by Vasallo IM and Formosa C,²³ it was observed that, after the application of negative pressure therapy in 15 patients, it was 3.2 times more effective in reducing the surface area and 3.78 times more effective to decrease wound depth compared to patients treated with calcium alginate. In the studies by Llamas Fernández,¹⁶ and García Oreja et al.,⁶ it was observed that of the 82 patients who presented some complication associated with negative pressure therapy, the most frequent was maceration of the perilesional skin in 49% of cases, compared to 12% for necrosis and 7% for infection (Graph 2).

Complications of TPN



Graph 2 Complications of TPN.

Source: self-made

Amputation data

In the studies carried out by Wynn M, et al.,¹⁸ and Yafeng Yan, et al.,²⁸ it was observed that after the use of negative pressure therapy in diabetic foot ulcers the incidence of amputations was very close to 2% compared to with a significantly higher incidence in diabetic foot treated with conventional cures.

Negative pressure therapy in combination with other treatments:

In the study carried out by Jun Wu Y, et al.,¹⁷ the application of simple skin tightening system and wound margin conditioning was evaluated together with the application of negative pressure therapy. In the study, it was observed that the average closure time of complex diabetic foot wounds was 10.5 days. Presenting a range of 8 to 14 days on the side of the foot and an average of 14.5 days in wounds on the dorsum of the foot.

As well, in the article by Ho Park J. and Ung Park J.²⁴ looked at patients previously undergoing negative pressure therapy upon flap insertion. The study observed that the mean operative time was 284.9 minutes compared to 303.8 minutes in those patients who did not receive combination negative pressure therapy. Similarly, it was observed that of the 14 patients with negative pressure therapy there was only one case of complication and none of infection. Furthermore, the mean flap monitoring time was significantly shorter in patients with negative pressure therapy, this time being 86.4 minutes compared to 225.1 minutes in patients without this therapy.

In the study by Lehrman,²⁷ based on a case, it was observed that after the application of negative pressure therapy at a pressure of -125 mmHg, together with collagen matrix applied to the wound bed, on day 35 The foot wound area decreased by 91%, measuring 3.2 mm X 1.2 mm X 1 mm, compared to the initial measurements 3.8 cm X 3.7 cm X 3 mm. Likewise, it was observed that on day 63 of combined treatment, complete closure of the wound had been achieved, remaining healed during the subsequent 18 months of follow-up.

Cost-benefit of negative pressure therapy:

In the studies carried out by González-Ruiz M, et al.,²² Barreiro García L, et al.,²¹ and Alipur V, et al.,²⁵ it was observed that the application of negative pressure therapy reduced the days necessary to achieve complete healing of the wound. A reduction in the number of daily dressing changes was also observed, which favors a reduction in hospitalization time and successive outpatient visits, considering this novel therapy as profitable and cost-effective.

Discussion

Reviewing the scientific evidence studied, several authors state that negative pressure therapy, applied to diabetic foot ulcers, is more effective than conventional wound healing techniques. According to Seidel D. et al.,¹⁴ treatment duration was significantly shorter in those patients, who underwent NPWT than in those treated with conventional wound healing therapies. However, Wang, et al.,¹⁵ concluded that there is still a lack of research related to said therapy and its clinical effectiveness, although they determined that patients to whom negative pressure therapy was applied showed positively better results in relation to the duration of treatment compared to with conventional wound healing therapy. Similarly, Borys S et al.,¹⁹ confirmed the effectiveness of TPN, carried out in two trials, where superiority was shown compared to standard wound healing therapy with the measure of closure rate, which was higher in patients treated with TPN.

According to Nathaniel Chiang, et al.,²⁰ there is no significant improvement in ulcer volume reduction with negative pressure therapy compared to conventional therapies. However, he stated that there is a reduction in wound depth of 36% on day 14 of treatment, compared to 18% with traditional dressings. In contrast, Liu, et al.,²⁹ state that TPN can be effective in achieving healing of DFUs compared to traditional dressings, but the effectiveness of this therapy currently requires further investigation.

Along the same lines, Sukur, et al.,³⁰ evaluated the effectiveness of VAC therapy compared to conventional wet dressings in DFU after partial amputation, stating that the use of VAC therapy is a well-tolerated technique, which generates large granulation tissue in a short time. shorter than conventional wet dressings, with the average treatment duration being 22.8 days with VAC therapy and 42.8 days with dressings. In contrast, Rys, et al.,³² assessed the need to continue researching conventional wet dressings and negative pressure therapy in diabetic foot wounds, although they highlight that, after several reviews, the application of NPWT is an effective and safe therapy in DFU due to its great healing capacity by generating greater granulation tissue. Similarly, Wynn and Freeman,¹⁸ stated that the use of NPWT in DFU increases the development of granulation tissue more rapidly than in ulcers not treated with NPWT.

Regarding wound size reduction, Vasallo and Formosa state that the use of vacuum-assisted closure therapy results in a significant reduction in wound surface area and depth compared to conventional alginate dressings. calcium, as long as patients adhere strictly to treatment.

Related to the complications of negative pressure therapy, according to Llamas Fernández, this novel vacuum-assisted closure therapy can cause slight complications, notably maceration of the perilesional skin. In the same way, García Oreja,⁶ like Llamas Fernández,¹⁶ states that the most frequent complication is perilesional maceration with a significantly higher percentage than other complications such as infection or necrosis. On the other hand, according to Wynn, et al.,¹⁸ the application of this therapy reduces the incidence of amputation significantly compared to those patients treated with conventional wound healing therapies.

Negative pressure therapy in combination with other therapies has been quite effective in terms of healing time and increase in granulation tissue. According to Jun Wu Y, et al.,¹⁷ the application of a simple skin tightening system together with TPN is an effective method that accelerates healing due to the skin's own biomechanical properties, compared to traditional surgeries. However, this application is still limited by its high cost. Similarly, Jun Ho Park, et al.,²⁴ demonstrated that the use of negative pressure therapy prior to flap insertion, the mean operative time was significantly shorter than in patients who had not received this therapy. Furthermore, they highlighted that of 14 patients treated with NPWT there was only one case of complication and none of infection. Along the same lines, Lehrman²⁷ states that the use of a layer of collagen, applied to the wound bed together with negative pressure therapy, is effective in curing chronic DFUs, since this combination eliminates large amounts of exudate, thus increasing granulation tissue, which leads to healing. However, he points out the need for more research related to this therapeutic combination.

Related to the cost-benefit of this novel therapy, González-Ruiz, et al.,²² Barreiro García, et al.,²¹ and Vahid Alipur, et al.,²⁵ concluded that its use in DFU reduced the days necessary for total healing of the wound. Furthermore, they agreed that this therapy reduces the number of daily dressing changes, favoring a reduction in hospitalization time, as well as outpatient visits, which is why they consider TPN as profitable and cost-effective.

After completing the scientific review, evaluating the results obtained and comparing the information from each of the articles studied, the following can be concluded: In relation to the main objective "To demonstrate the effectiveness of Negative Pressure Therapy in patients with diabetic foot" it has been proven that the use of this therapy in diabetic foot ulcers is promising, since it increases the rate of granulation tissue and reduces the area and depth of the

wound, resulting in complete healing in a minimum time. In reference to the objective "Estimate the quality of life of patients with diabetic foot who undergo Negative Pressure Therapy" it has been shown that the application of this therapy contributes to an improvement in the quality of life of these patients, due to the reduction of hospital stay and successive outpatient visits, as well as a reduction in daily dressing changes, allowing them greater independence and autonomy. Regarding the objective "Evaluate the effectiveness of Negative Pressure Therapy in the diabetic foot in combination and comparison with other conventional wound healing treatments", promising results have been obtained. The use of this novel therapy together with other treatments such as simple cutaneous tightening of the skin, the insertion of flaps or the application of collagen matrix to the wound bed, represents a reduction of this in all aspects, as well as a reduction in healing and complete healing time. Finally, in relation to the objective "To collect the complications of diabetic patients subjected to Negative Pressure Therapy", it is concluded that the use of vacuum-assisted closure therapy in patients with diabetic foot ulcers is highly safe, since the evidence shows minimal complications that arise from its use, the biggest problem being maceration of the perilesional skin, which decreases with the application of non-irritant barrier films.

Conclusion

In conclusion, negative pressure therapy proves to be an effective and beneficial tool in the treatment of adult patients with diabetic foot. The results of various research and clinical studies support the effectiveness of this therapeutic modality in several key aspects of the management of this complicated medical condition. The ability of negative pressure therapy to improve wound healing, reduce edema and inflammation, control infections, stimulate the formation of granulation tissue and, ultimately, reduce the risk of amputation, highlights its relevance in the comprehensive approach. of diabetic foot. Furthermore, it is not only limited to the physical aspects of recovery, but also contributes to the patient's overall well-being by relieving the pain associated with ulcers and improving their comfort. Although negative pressure therapy offers substantial benefits, it is essential to emphasize the importance of supervision and guidance from health professionals in the implementation of this therapy. Each patient is unique, and a personalized approach will ensure the optimal application of the therapy, maximizing its benefits and contributing to a better quality of life for those affected by diabetic foot.

Author contributions

Conceptualization, B.G.-M. and C.A.-M.; methodology, Á.A.-P.; software, B.G.-M. and M.d.C.Z.-B.; validation, B.G.-M., P.C.-M. and Á.A.-P. formal analysis, Á.A.-P. investigation, C.A.-M. and Á.A.-P.; resources, P.C.-M.; data curation, B.G.-M.; writing—original draft preparation, Á.A.-P.; writing—review and editing, Á.A.-P.; visualization, B.G.-M. supervision, Á.A.-P.; project administration, Á.A.-P. All authors have read and agreed to the published version of the manuscript.

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