STUDY ON

THE EFFECTS OF NEGATIVE PRESSURE WOUND THERAPY (N.P.W.T.) ON WOUND HEALING

At

TRIAGE MEDITECH PRIVATE LIMITED, DELHI

Dissertation Submitted

To

IIHMR University, Jaipur

For the partial fulfilment for the award of the degree of

Master of Business Administration (MBA)

In

Hospital and Health Management

(2020-2022)

By

Neha Tokas

Under the Guidance of

Alok Mathur

DECLARATION BY STUDENT

I hereby declare that this dissertation titled “the effects of negative pressure wound therapy (N.P.W.T.) on wound healing at the Triage Meditech Pvt. Limited” is the bonafide record of my original research work. I declare that it has not been submitted to any other university or institution for the award of any degree or diploma. Information derived from the published or unpublished work of others has been duly acknowledged in the text.

(Signature)

Dr. Neha Tokas

Date :-

CERTIFICATE

CERTIFICATE

This is to certify that dissertation titled Study on The effects of Negative Pressure Wound Therapy (N.P.W.T.) on wound healing is a record of the research work undertaken by Neha Tokas in partial fulfillment of the requirements for the award of the degree of MBA (Hospital and Health Management) from the IIHMR University, Jaipur under my guidance and supervision and her approach to the research study has been sincere, scientific, and analytical.

Faculty Guide

IIHMR University, Jaipur

Date: 20th June 2022

School Dean

IIHMR University, Jaipur

Date: 20th June 2022

ACKNOWLEDGEMENTS

I would like to begin this report by expressing my honest and sincere gratitude to all the respectable individuals who have assisted me in this quest. I would not have advanced with the report without their active direction, assistance, cooperation, and encouragement. It is a privilege to have a wonderful internship in one of the renowned Medical Devices Organization. The internship opportunity I had with the **Triage Meditech Pvt. Ltd.** was a great chance for learning and professional development. I'm appreciative for this chance and for getting an opportunity to meet such countless brilliant individuals and experts who directed me through this internship.

I would also like to take this opportunity to express my deepest gratitude and special thanks to the Product Manager, **Ms. Kamini Bharti,** who despite being extraordinary busy with her duties, took time to hear, guide and keep me on the correct path and allowing me to carry my internship at their esteemed organization and guiding throughout the internship.

It is my radiant sentiment to place on record my best regards, deepest sense of gratitude to **Mr. Siddharth Mandal (CEO)** for their careful and precious guidance which was extremely valuable for my study both theoretically and practically.

I would like to express sincere thanks to **Dr. P.R. Sodani** (president, IIHMR university, Jaipur) for giving me a chance to do this internship. Now, I would like to express my gratitude towards my mentor at IIHMR University, **Dr. Alok Mathur** for his extraordinary cooperation, invaluable guidance and supervision. This report is the result of his painstaking and generous attitude.

I would also like to express a deep sense of gratitude to the Placement Cell of my esteemed university for guiding me throughout the internship process and for providing time to time internship guidelines.

I view this chance as a significant turning point in my professional progress. I'll do my best to make the best use of the knowledge and abilities I've acquired, and I'll keep working to make improvements, in order to achieve my career goals.

INDEX

Contents

LIST OF ABBREVIATIONS:

D.F.U – Diabetic Foot Ulcer

DM – Diabetes Mellitus

F.D.A - Food and Drug Administration

N.P.W.T. - Negative-pressure wound therapy

PVD - Peripheral vascular disease

SSI - Surgical Site Infection

T.N.P. - Topical Negative pressure

V.A.C. – V.A.C.uum - Assisted closure

LIST OF FIGURES:

ABSTRACT

Background

A form of therapy called TNP (Topical Negative Pressure) improves the healing of wounds. For chronic or serious wounds, it can serve as the primary treatment or as an addition to surgery. Based on available data, it is currently unknown if Negative Pressure therapy is clinically helpful. Despite case reports and retrospective studies showing improved wound healing in acute/traumatic wounds, chronic wounds, infected wounds, wounds caused by diabetes mellitus, sternal wounds, and lower limb wounds, there are only a small number of randomised controlled trials with contradictory results. Other applications of TNP therapy to boost wound healing, such as in persons with diabetes, peripheral vascular disease, decubitus ulcers, and to improve skin transplant acceptance, are not supported by sufficient data. Studies on the quality of life have not yet been conducted on negative pressure therapy. TNP use is rising in spite of this. This study gives future research opportunities to clarify the precise mechanism of TNP and provides an overview of clinical studies utilising TNP in addition to substantial randomised controlled clinical trials of patients receiving this medication.

RESEARCH QUESTION

What is the effectiveness of N.P.W.T. in wound healing?

OBJECTIVES:

1. To study the mechanism of N.P.W.T..
2. To evaluate effectiveness of N.P.W.T. over traditional wound healing.
3. To study the role of N.P.W.T. in different types of wounds.
4. To analyze the future perspective of N.P.W.T. in Plastic Surgeries.

Method

The literature was searched in the Medline, PubMed, and Cochrane databases, and reference lists of pertinent systematic reviews and health technology assessments were inspected. At least one patient-relevant outcome was examined in studies that were eligible (e.g. wound closure). We looked for publication bias and, where possible, conducted meta-analyses, categorizing the data.

Conclusion

The wound healing technique known as N.P.W.T. has been utilised frequently to hasten healing, improve wound healing rates, and ready the wound bed for surgery. Negative-pressure therapy's clinical efficacy is yet undetermined based on the research that is currently available. Despite case studies and retrospective research indicating that lower limb and sternal wounds, chronic wounds, infections, wounds brought on by diabetes, and acute/traumatic wounds all heal more quickly, there are few randomised controlled trials with conclusive findings.

INTRODUCTION

Negative-pressure wound therapy (N.P.W.T.) is a wound-care approach that is used to treat big chronic persistent wounds as well as acute difficult wounds. An electronically controlled pump and a foam dressing that drains the wound make up the system. An airtight adhesive film covers the wound and applies adjustable negative pressure. N.P.W.T. removes wound exudate and is supposed to aid healing by improving blood circulation.

A specific dressing (bandage), tubing, a negative pressure device, and a canister to collect fluids are all used in this therapy.

Layers of foam dressing will be fitted to the form of the wound by the healthcare experts. After that, the dressing will be sealed with a film.

An opening in the film is connected to a tube. The tube attaches to a fluid collection canister and a V.A.C.uum pump. It is possible to programme the V.A.C.uum pump to run continuously or to start and stop at irregular intervals.

The V.A.C.uum pump clears the incision of fluid and infection. This helps the edges of the wound to heal. Additionally, it encourages the growth of new tissue, which helps the wound heal.

Saline and antibiotics can be injected into the wound as necessary.

TECHNIQUE

The following is a general N.P.W.T. technique: To protect the periwound, a dressing or filler material is applied to the contour of the wound, and the foam or gauze that is then applied on top is coated with a clear film. The dressing is then connected to a drainage tube using a hole in the transparent covering. Tubing is linked to a canister on the side of a V.A.C.uum pump through a hole in the film drape. In order to improve circulation and drain wound fluids, it also eliminates surplus fluid from the wound bed. By doing this, an open wound is closed under control and sealed airtight. Oedema is reduced, and a moist healing environment is provided.

The four different types of dressings put on the wound surface include foam or gauze, a transparent film, and, if required, a non-adherent contact layer. Wounds with open cavities are covered with woven gauze or foam dressings. Foam can be trimmed to fit wounds. A transparent film is placed on top of the dressing after the wound has been filled to seal the dressing. The tubing is then connected and connected to the pump.

After the dressing has been sealed, the V.A.C.uum pump can be configured to deliver continuous or intermittent pressures, with pressure levels ranging between 220 and 20 mmHg depending on the material and patient tolerance. Pressure might be provided continuously or just when it's required.

How it is applied depends on the type of wound, the patient's clinical goals, and the dressing selected. While gauze can be used for pain-sensitive patients with shallow or irregular wounds, wounds with undermining, or wounds with explored tracts or tunnels, foam can be easily cut to fit a patient's wound with a regular contour and performs better when aggressive granulation formation and wound contraction are desired.

MECHANISM OF ACTION

N.P.W.T. improves healing of wounds by a variety of processes at both the macroscopic and microscopic levels. The following are the primary mechanisms of action:

N.P.W.T. provides a moist wound environment suited for the procedure as an occlusive wound dressing. Reepithelialisation, growth factor action, angiogenesis, and granulation promotion are all aided by a moist wound bed. A wet wound, on the other hand, lowers local discomfort while protecting nerve endings and enhancing quality of life.

Macro deformation of the wound occurs when the suction spread through the foam sponge brings the wound edges closer together, depending on the deformability of the surrounding tissues. This cuts down on the amount of area that needs to be healed through primary closure or secondary granulation.

At the microscopic level, the wound surface micro deforms. N.P.W.T. causes 5-20% strain across the healing tissues, which increases cell division and proliferation, growth factor production, and angiogenesis, according to finite element computer models.

Extraction of oedematous fluid and exudate from the extracellular space, as well as inflammatory mediators and cytokines, which might impede the microcirculation's ability to maintain damaged tissue if left untreated. This can result in further tissue necrosis, which is commonly seen after more debridement.

A warm, wet environment that keeps the wound from drying up and promotes the growth of granulation tissue.

EFFECTIVENESS

Chronic wounds or wounds that are thought to be difficult to heal are the two conditions for which negative pressure wound therapy is most frequently utilised (such as those associated with diabetes). Although the FDA has approved negative pressure wound therapy, and Although the technique has been the subject of numerous randomised controlled trials, it is unclear from the data if N.P.W.T. is more effective than conventional wound care dressings. Low-level evidence suggests that there may not be a difference in the risk of wound reopening between N.P.W.T. and conventional dressing care. The risk of death may be lower and there may be fewer surgical site infections with N.P.W.T., nevertheless. If N.P.W.T. is used instead of conventional wound care, skin blistering may be more likely to occur. In obese women, N.P.W.T. might become a more affordable technique to repair wounds after caesarean sections, but it is unlikely to be as affordable for wounds from fracture surgeries. It's unclear whether N.P.W.T. is cost-effective in sealing wounds from other forms of surgery.

"Consistent evidence of the usefulness of N.P.W.T. in the treatment of diabetic ulcers of the feet" has been reported in the treatment of foot ulcers caused by diabetes. The results for bedsores were conflicting, whereas the research on mixed wounds was sloppy but promising. There was no evidence of a rise in serious effects, according to the report. "There is currently sufficient evidence to establish that N.P.W.T. is safe and accelerates healing to justify its usage in the treatment of diabetes-related chronic leg wounds," the evaluation found. Other, less reliable data indicates that other wounds might also heal more quickly.

By eliminating extracellular fluid and lowering tissue oedema, which increases blood flow and stabilises the wound environment, N.P.W.T. is utilised to enhance wound healing. Matrix metalloproteinase activity and bacterial load have decreased in clinical research, and both systemic (like interleukins and monocytes) and local mediators of inflammation have decreased in experimental settings. N.P.W.T. has been demonstrated to improve wound healing by encouraging fibroblast migration and proliferation, collagen organisation, and the expression of vascular endothelial growth factor and fibroblast growth factor-2 in vivo.

INDICATIONS:

- Wound types:
    - Diabetic foot ulcers
    - Pressure injuries
    - Surgical wounds
    - Grafts and flaps
    - Traumatic wounds
    - Partial-thickness burns
    - Necrotizing fasciitis
- To accelerate the formation of granulation tissue
- To improve perfusion through removal of excess interstitial fluid
- To reduce bacterial colonization
- To enhance epithelial migration

CONTRAINDICATIONS:

- Presence of necrotic and fibrotic tissue
- Untreated osteomyelitis
- Malignant wounds
- Localized ischemia
- High output, non-enteric and unexplored fistulas
- In the absence of appropriate blood supply
- Severe excoriation of peri wound.
- Do not place dressings in direct contact with exposed blood vessels, anastomotic sites, organs or nerves
- Do not place dressings into blind/unexplored tunnels
- Stop therapy if person experiences autonomic dysreflexia
- Do not place therapy in proximity to the vagus nerve
- Do not over fill the wound with dressing material

PRECAUTIONS:

- People with weakened or friable blood vessels or organs in or around the wound as a result of suturing of the blood vessel/organ, infection, trauma, or radiation
- People without adequate wound haemostasis or where achieving haemostasis was difficult
- In those with active bleeding

- Anticoagulant and/or platelet aggregation inhibitor use
- People who do not have adequate tissue coverage over vascular structures
- In those with immunodeficient disease, i.e. leukaemia, HIV
- Protect exposed or superficial vessels and organs prior to the application of negative pressure
- Infected blood vessels
- Haemostatic agents applied at the wound site, i.e. bone wax, absorbable gelatin sponge, or spray wound sealant
- Sharp edges, i.e. bone fragments or sharp bone edges
- Infected wounds
- Inflammatory wounds
- Caution in those with adhesive allergies
- Avoid a circumferential dressing
- Inspect the wound thoroughly to ensure all dressing components are accounted for/removed
- Post-surgical excision of malignancy

CLASSIFICATION OF WOUND

DIABETIC FOOT ULCER

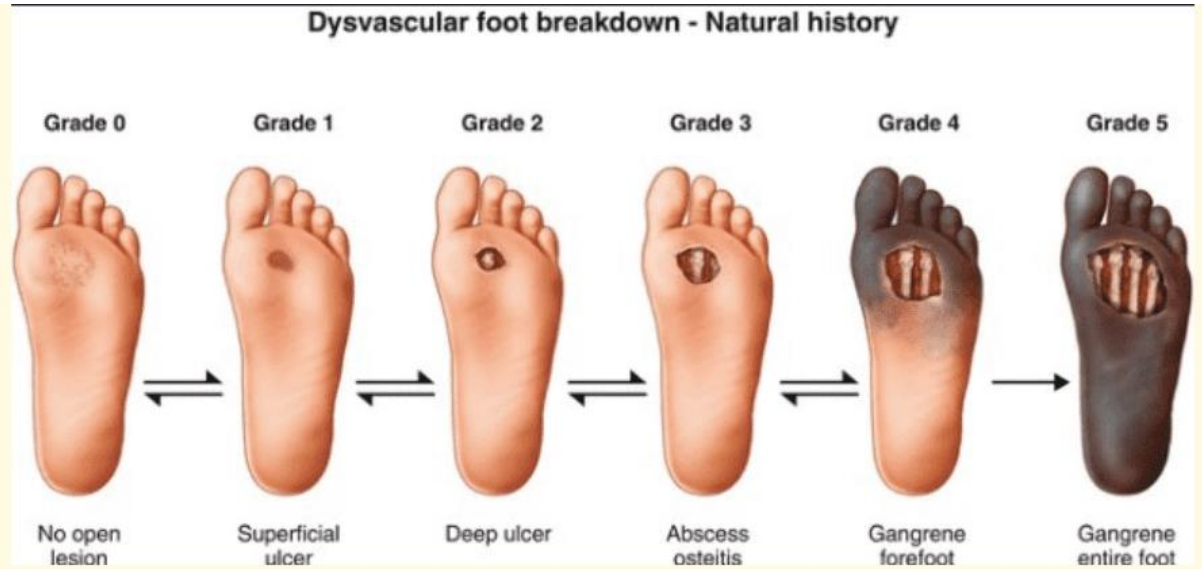

Figure 1: Diabetic Foot Ulcer

Concerns among medical professionals are raised by the sharp increase in the prevalence of the deadly, lifelong disease diabetes. By 2025, the illness would be present in more than 325 million people worldwide, according to latest data from the World Health Organization. One of the most common complications of diabetes is diabetic foot ulceration, which is well-known for its intricacy and challenging recovery. People with diabetes mellitus have a higher risk of developing foot ulcers, ranging from 4% to 10%. This equates to a population-based annual incidence of 1percent–4.1 percent, with a lifelong incidence of up to 25%. Infected diabetic foot ulcers are a leading cause of hospitalisation. In this patient population, they are also responsible for the majority of non-traumatic lower limb amputations. Diabetic foot ulcers wreak havoc on our health-care system in terms of both medical and financial costs. For two reasons, foot ulcers are critical events in the progression of limb loss. In the context of critical ischaemia, they provide an entry point for infection and can result in increasing necrosed tissue and poor wound healing. Over time, 56 percent of diabetic foot wounds get infected, and in 20% of these patients, severe debridement of soft tissue and bone is necessary, leading to lower extremity amputation. Such wounds typically require significant preparation prior to delayed primary closure or healing by secondary purpose due to their depth, size, and presence of pre-existing infection. The significant wound deficit that occurs typically needs lengthy hospital stays and healing times, raising the

possibility of reinfection. Additionally, this drawn-out and occasionally halted healing process decreases patient mobility, causes significant lost productivity, diminishes quality of life, has severe medical, psychosocial, and financial repercussions, and poses a significant management challenge for healthcare professionals.

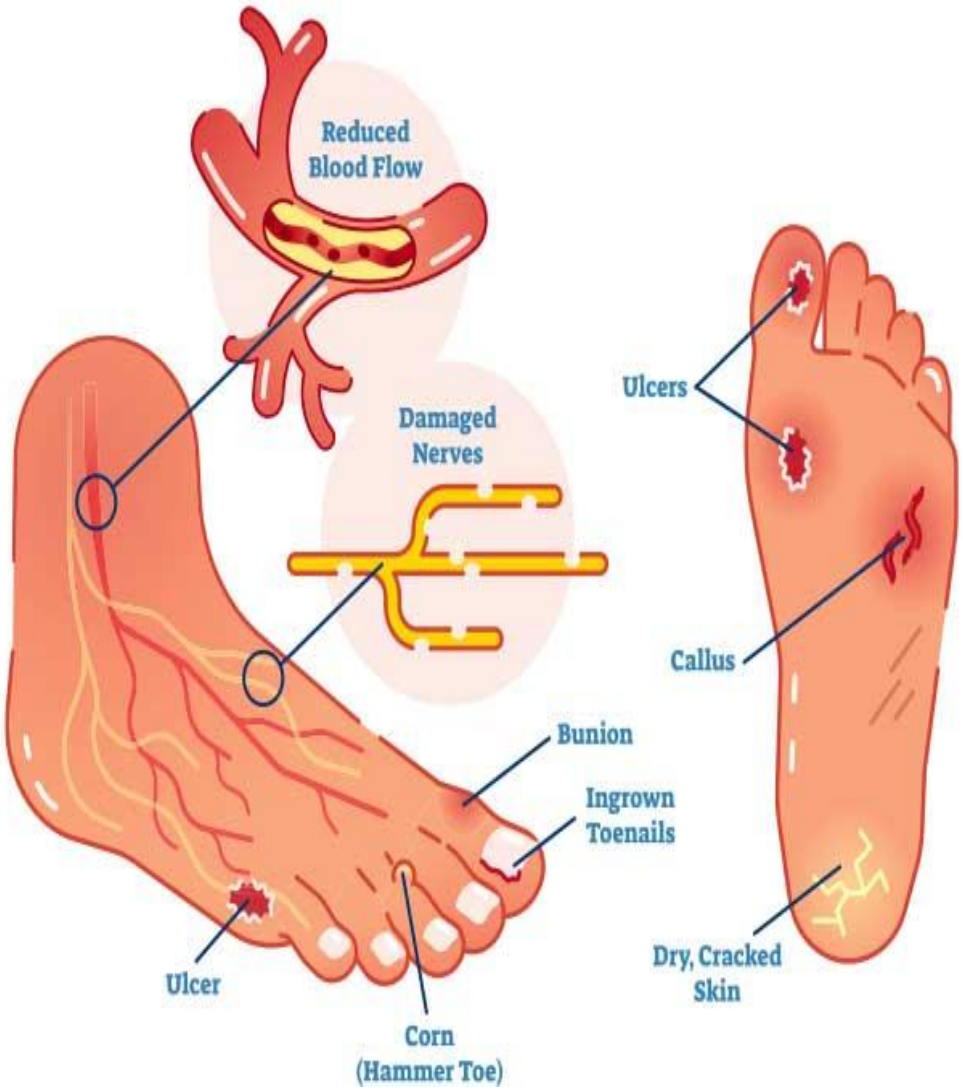

Figure 2: Diabetic Foot Ulcer Mechanism

BURNS

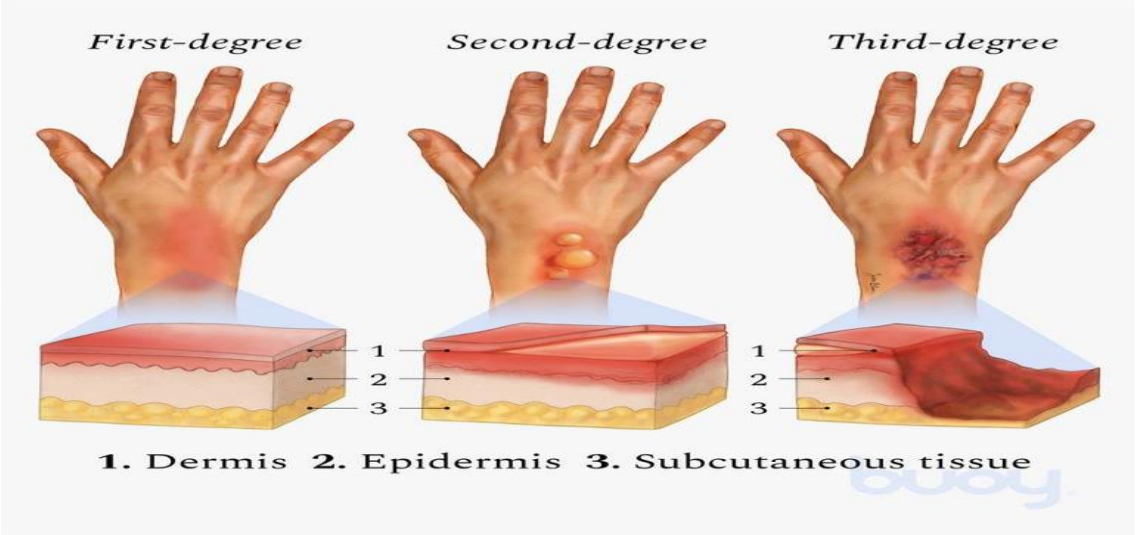

Figure 3: Degree of Burns

Burns is one of the main causes of death in terms of disability-adjusted life years, with an estimated 180000 fatalities occurring each year in low- and middle-income countries. Burn survivors may face physical and emotional issues for the rest of their lives, putting a significant financial strain on society. Although burn wounds are classified in a variety of ways, the fundamentals of wound healing and management are the same. The healing potential and the requirement for surgical grafting are determined by the depth to which a burn has harmed tissue. Even if there is no infection, deep partial-thickness burns take more than 3 weeks to heal. Scar development and contracture are caused by delayed wound closure, which can be avoided by performing excision and grafting during the first few days after an accident. Various strategies have been employed to improve skin graft take, and much ground-breaking research has been done to improve grafting outcomes. Surgical procedures involving split- and full-thickness skin grafting have been shown to be beneficial treating burn wounds since 1817, according to the literature.

The formation of oedema, strong white cell and platelet activity, and microvascular alterations all contribute to the burn wound's propensity to spread locally during the acute (first) phase of the injury (build up of fluid). When heated, many tiny arteries clot, but eventually thrombose (block) and cause tissue dryness (Boykin 1980). Interstitial oedema in distant organs is a characteristic of the systemic response to burning and is

triggered by a combination of wound-produced mediators and hypoproteinaemia. It is defined as the swelling of any organ or tissue as a result of the accumulation of excess lymph fluid (between cells) (abnormally small amounts of protein in the circulating blood plasma). According to their depth, burn wounds can be categorised as superficial (first degree burn), partial thickness (second degree burn), and entire thickness (third degree burn) (third degree burn). The epidermis, the outermost thin layer of skin, the stratum corneum, and the dermis, the deepest layer of skin, are usually used to gauge the depth of injury. This information is based on clinical observation, objective measurement, or both. Blanching, capillary return, the presence and degree of fixed capillary staining, and evaluation of residual light touch and pinprick sensation are all aspects of the burn wound's appearance that are frequently used in clinical evaluation. It is feasible to evaluate blood flow into the tissue and consequently the depth of burn injuries using objective evaluation techniques such laser doppler flowmetry, laser doppler imaging, or indocyanine green video angiography. Burns of the first degree, also known as superficial burns, affect only the epidermis, or outside layer of the skin, and are usually minor injuries that heal quickly and spontaneously. Burns of the second degree, also known as partial thickness burns, affect variable percentages of dermis. The severity of the scarring, which is influenced in part by the depth of the burn, may worsen and heal with these. Burns of the first degree, also known as superficial burns, affect only the epidermis, or outside layer of the skin, and are usually minor injuries that heal Within minutes of the damage, thin-walled, fluid-filled blisters appear. These lesions are extremely painful because the exposed nerve ends transmit light touch, warmth, and superficial pain when the blisters rupture. Damage to the epidermis' waterproofing allows bodily fluid to seep onto the wound's surface, making the wound moist. Significant oedema typically manifests promptly and spontaneously in this type of injury due to the involvement of the cutaneous blood vessels. Variable amounts of dermis are impacted by second-degree burns, commonly known as partial thickness burns. The severity of the scarring, which is influenced in part by the depth of the burn, may worsen and heal with these. A subset of partial thickness burns is a superficial partial thickness burn, which is one of the different types of partial thickness burns. This type of burn enters the papillary (superficial) layer of the dermis from the epidermis. Because the dermal tissue has become inflamed, these wounds become erythematous, which means the skin reddens. One of the characteristics of the superficial partial thickness burn is blanching followed by a rapid capillary refill when pressure is applied to the reddish area and subsequently removed. Deep partial-thickness burns reach the

reticular (deeper) layer of the dermis and present as mixed red or waxy white burns. Capillary refill may be absent or sluggish when pressure is applied to areas of redness, but it may also be absent or sluggish when pressure is released. Blisters are frequently missing, but the wound's exposed surface is damp or moist, comparable to superficial partial-thickness burns. In places of a deep partial thickness burn, oedema is noticeable, and feeling is changed.

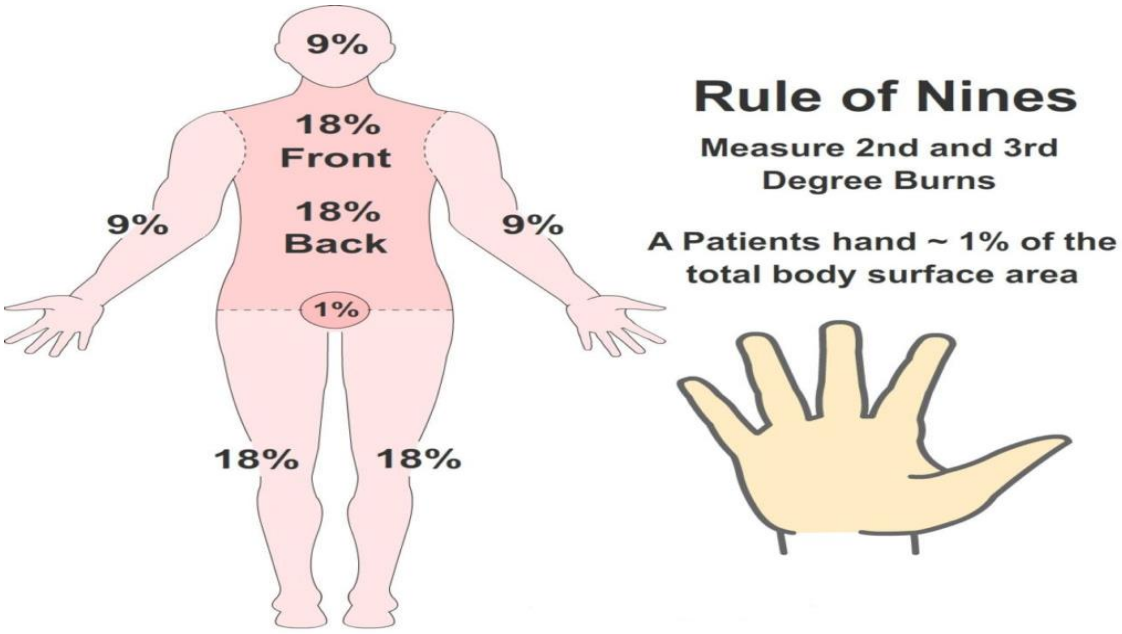

Figure 4: Rule of Nine

WOUND INFECTION

Wound infection occurs when bacteria infiltrate the wound and surrounding tissue as a result of contamination and colonisation. It can cause serious consequences that delay wound healing and even prove lethal. A wound infection occurs when germs, such as bacteria, grow within the damaged skin of a wound. Symptoms can include increasing pain, swelling, and redness. More severe infections may cause nausea, chills, or fever. There are a number of ways microorganisms can get into wounds.

- Direct contact – transfer from surgical equipment or the hands of the surgeons or nurses
- Airborne dispersal – surrounding air contaminated with micro-organisms that deposit onto the wound

- Self-contamination – physical migration of the patient's own endogenous flora which is present on the skin, mucous membranes or gastrointestinal tract to the surgical site.

SURGICAL SITE INFECTION

The following parameters define a surgical wound/site infection. Within 30 days of the surgical procedure, infection must arise, & at least one of the following should occur:

- The Surgical Site is producing a foul-smelling discharge.
- Purulent-discharge from a wound, or a drain that has been inserted into the wound
- Organisms isolated from wound cultures obtained in an aseptic manner
- Either pain or discomfort, any localised swelling, or the redness/heat must all be present as signs and symptoms of infection.

The following are some other indicators of a wound infection:

- Healing that was not expected to take as long as it did.
- Tissue discoloration within and around the wound edges.
- A strange odour emanates from the incision site.
- Despite proper care and control, granulation tissue is brittle and bleeding.

Infection at the Surgical Site (SSI). This is defined as follows:

- Superficial Incisional SSI – Infection that involves only skin and the subcutaneous tissue of incision.
- Deep Incisional SSI — Infection that involves deep tissues, such as facial and the muscle layers.
- Organ/Space SSI — Infection that involves any part of anatomy in organs and spaces other than incision, which is opened or was manipulated during the operation.

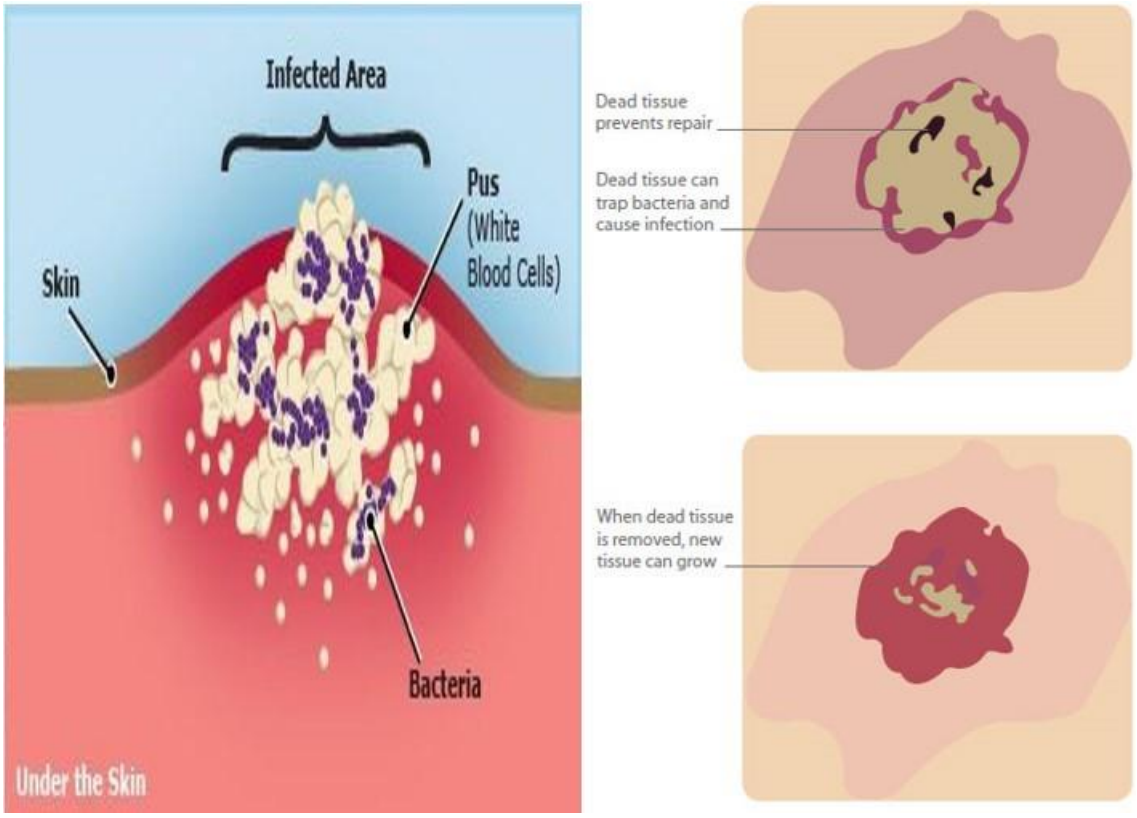

Figure 5: Surgical Site Infection

PRESSURE ULCERS

Pressure ulcers (sometimes called pressure sores or bedsores) are skin and underlying tissue lesions produced by continuous pressure on the skin. Bedsores can form when a person is confined to their bed, immobile in another way, asleep, or incapable of feeling discomfort. Bedsores are skin ulcers that develop on pressure-sensitive areas of the skin as a result of protracted bed rest, wheelchair use, or cast usage. Bedsores are also known as pressure injuries, pressure sores, pressure ulcers, and decubitus ulcers. For senior persons, bedsores can be a serious issue. They might be connected to the calibre of care a person gets. If an immobile or bedridden individual is not moved, positioned correctly, and provided the right nutrition and skin care, bedsores may develop. People are more susceptible to diabetes, cardiovascular problems, and poor nutrition.

Bedsores are common on the following areas:

- Area of the buttocks (on the tailbone or hips)
- Shoulder blades
- Heels of the feet
- Backs of the head, as well as the sides and backs of the knees.

Figure 6: Pressure Sore Areas

From mild to severe, bedsores are divided into four categories. These are listed below:

- Stage 1: The affected area feels warm to the touch and appears red. If you have darker skin, the area could seem blue or purple. Additionally, it could irritate, sting, or burn the sufferer.
- Stage 2: An open sore, scrape, or blister is present, and the affected area looks to be more severely wounded. The skin around the wound may be discoloured, and the sufferer is in great pain.
- Stage 3: Due to damage beneath the skin's surface, the area has a crater-like look.
- Stage 4: There is a significant wound and the area has suffered considerable damage. Targets could include bones, joints, muscles, tendons, and ligaments. Infection is now a significant worry.

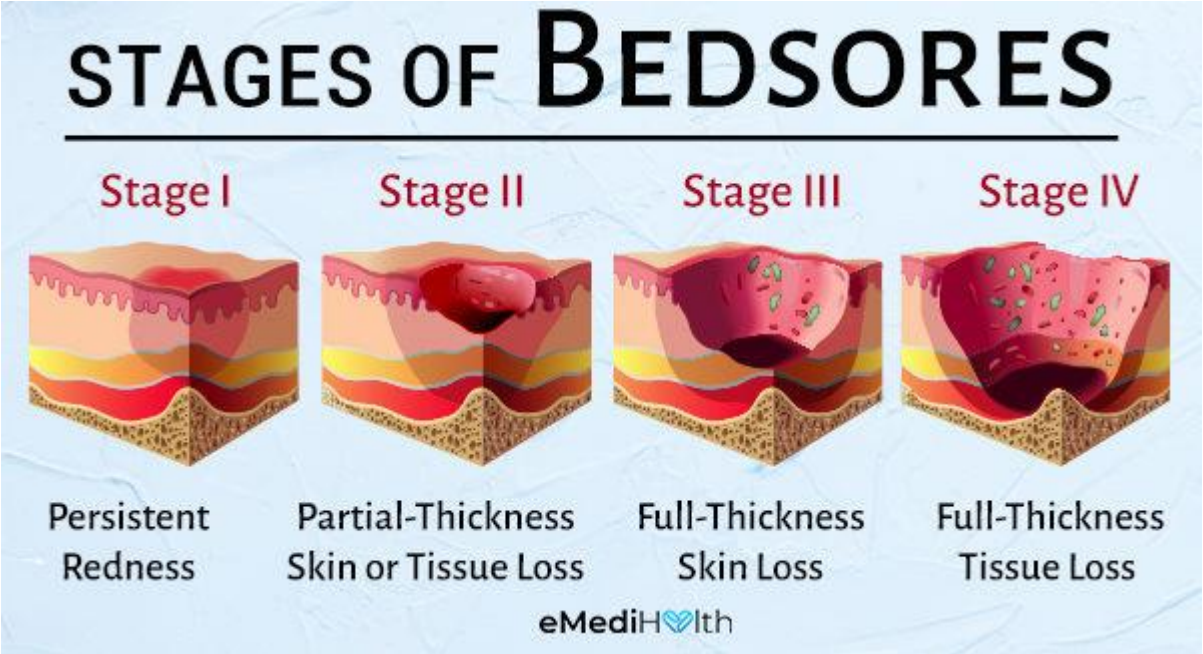

Figure 7: Stages of Bedsores

SYSTEMATIC REVIEW

N.P.W.T. and pressure ulcers

N.P.W.T. was compared to conventional wound care methods such as gel products or moist bandages in two trials that dealt with treatment of the deep pressure wounds. The results of a research by Wanner et al. with 22 patients showed no discernible difference. To halve the wound volume, the N.P.W.T. group required mean (SD) of the 27 (10) days, whereas moist bandage groups required 28 (7) days. There was no statistically significant change in results in another 28-patient research by Ford et al. Within the 6 week research period, complete recovery occurred in 4 patients (2 vs. 2). With gel products, the average percentage reduction in ulcer volume was 42 percent, but with N.P.W.T., it was 52 percent.

N.P.W.T. and post - traumatic wounds

In two separate 44-patient studies that were combined into a single publication, Stannard et al evaluated impact of N.P.W.T. on the quantity of the wound exudate that developed after a surgery. Exudation of the wound stopped sooner in the N.P.W.T. group than the pressure dressing group (0–5 vs. 0–11 days) after excision of traumatic haematomas (part A). In this investigation, there were no differences in wound infection or breakdown rates. In the study with surgical complicated fractures at the lower extremities (part B), the N.P.W.T. showed a faster reduction in wound exudate than patients treated with standard dressing (0–6 vs. 0–28 days). On the other hand, there were no significant variations in the number of people who needed repeat surgery or had wound infections.

Llanos et al. randomised 60 patients who needed skin grafting due to Acute Trauma injuries and skin loss. The randomization was carried out following split thickness skin grafting and wound dressing. The wounds were photographed after four days, and a blinded observer completed the final analysis based on the images. The treatment group's major outcome measure, skin grafts loss in cm^2, was considerably lower. In therapy groups, the need for a second covering surgery was less common. The period from the start procedure to the discharge from unit was shortened by days once the suction was installed.

N.P.W.T. and diabetic foot ulcers

Armstrong et al compared N.P.W.T. to contemporary moist wound care in 162 patients with trans metatarsal amputation wounds. Transcutaneous oximetry (tcpO2 30 mm Hg) or the toe pressure measurement (30 mm Hg) were used to check whether the foot had adequate blood circulation. More patients experienced complete re-epithelialization. in the N.P.W.T. group than in the control group, with or without additional surgical intervention. Patients who had achieved full closure experienced faster wound healing in the N.P.W.T. group (56 vs. 77 days). 2 (3%) patients in the N.P.W.T. group required subsequent surgery revision or amputation, compared to 9 in the control group (11 percent). Five (6%) of the patients in the control group had amputations above the ankle, but none of the therapy group's patients had a high amputation. However, these variations in revisions and amputations could not be connected to the N.P.W.T. treatment since they were not statistically significant. In a 24-patient trial on diabetic foot ulcers, Etöz et al. found that the formation of the granulation tissue in the N.P.W.T. was faster and the ulcer surface area decreased more than in patients treated with saline bandages. Eginton et al. compared N.P.W.T. to moist wound care in a cross-over experiment of ten patients. Although there was no discernible reduction in surface area throughout the follow-up period of one month, the volume of ulcer shrank more in the N.P.W.T. groups. After a 6-week follow-up, McCallon et al 10-patient's experiment observed no difference between patients treated with N.P.W.T. or wet bandages in the amount of time required to heal the ulcer or the change in the ulcer surface area.

The Consistent Delivery of Negative Pressure to Wounds Using Reticulated, Open Cell Foam and Regulated Pressure Feedback

According to the study, macrostrain is significantly influenced by the material utilised as the contact to transfer negative pressure to tissue. Gauze was unable to produce as much macrostrain as ROCF could. The consistent supply of negative pressure to the surrogate wound was demonstrated to depend on both the interface material and the application of RPFT. Gauze was less effective at horizontal pressure transmission than ROCF. When V.A.C.uum pumps were positioned above the surrogate wounds without the use of RPFT, a comparable level of pressure reduction was seen for both ROCF and gauze. Significantly less pressure decrease occurred under ROCF when RPFT was used compared to gauze. With V.A.C. Therapy, the wound receives a transfer of negative pressure, which generates macrostrain and microstrain. It has been demonstrated that the entire V.A.C. Therapy System, which combines T.R.A.C. Technology and ROCF, reliably delivers negative pressure when compared to gauze under suction or when

utilising ROCF without T.R.A.C. Technology. To obtain the intended clinical effects associated with V.A.C. Therapy, it is crucial to be able to administer persistent negative pressure to the wound site.

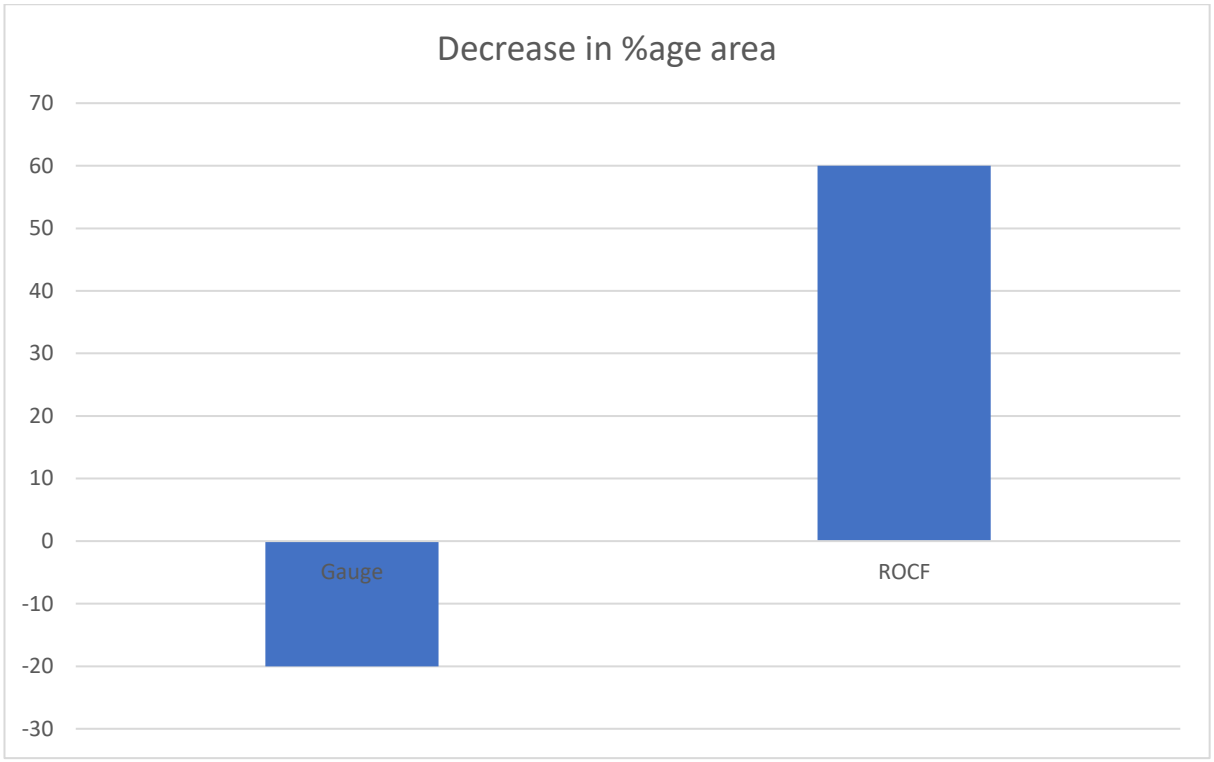

Figure 8: Decrease in the wound Area

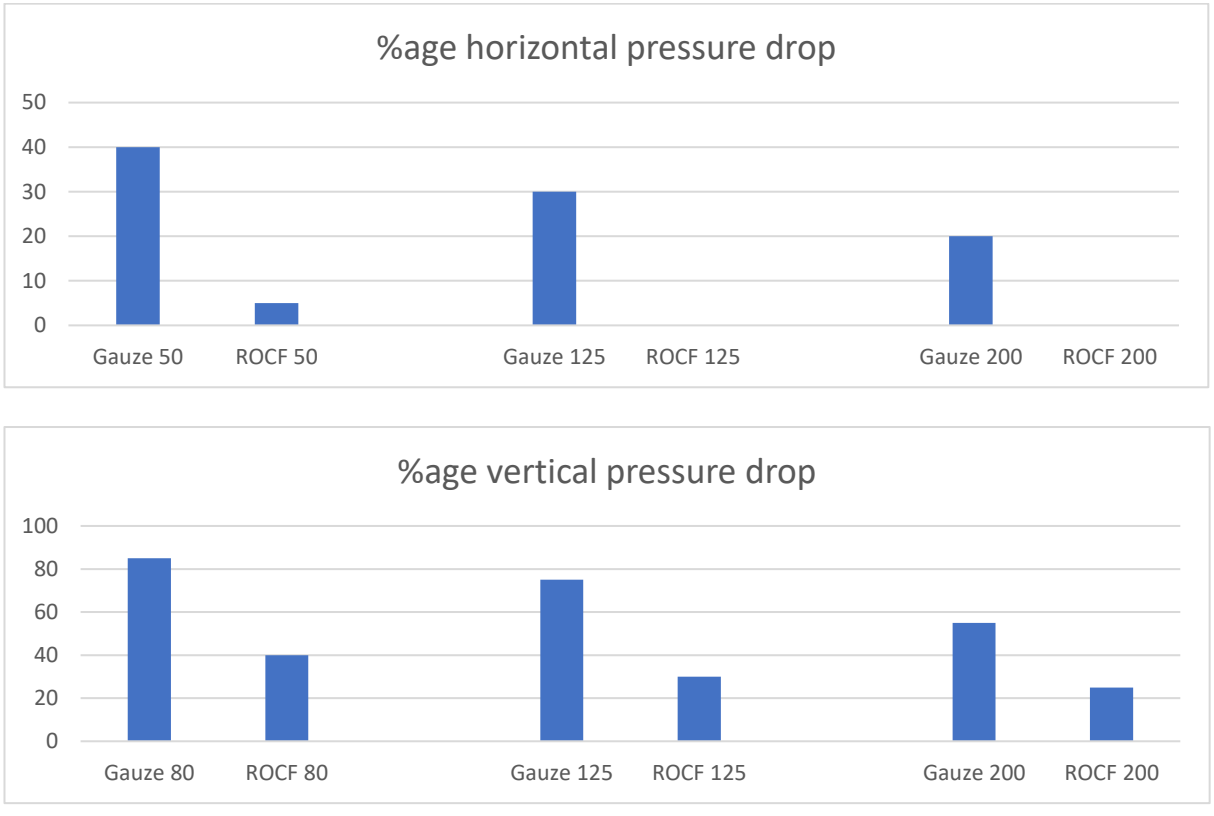

Figure 9: Horizontal and Vertical Pressure Drop

PICO ANALYSIS

Table 1. Clinical studies of negative pressure wound treatment for different clinical conditions: An Overview

STUDY	DESIGN	NO. OF PATIENTS	INCLUSION CRITERIA	OUTCOME	COMMENTS
Traumatic Wound					
Hersovici et al (2003)	Consecutive non-randomised	21 patients	A V.A.C.uum-assisted closure device was used to treat 21 high-energy soft tissue wounds at a Level 1 trauma centre, including 6 tibial, 10 ankle, 5 with lesions of the forearm, elbow, femur, pelvis, and a below-knee stump.	Twelve wounds required less invasive operations; nine patients (43%) required free tissue transfer (57 percent)	Sponge changes were conducted at the bedside for 77% of patients, indicating that this could be done there might lessen the requirement for substantial reconstruction
Defranzo et al. (2001)	Retrospective	75 patients	cuts to the lower extremities that reveal bone and metal	Skin graft/local flaps successfully covered 71/75 wounds; in 3 to 5 days, the area of the wounds decreased; and no free tissue transfers were necessary.	Hence, it was determined that massive, superficially visible plates and vast sections with the exposed bone were not suitable for V.A.C..
Pressure Ulcer					
Mullner et al (1997)	"Prospective Study"	"17 patients	"Sacral pressure"	With a favourable	V.A.C. made it easier to

		”	injuries that are resistant to conventional therapy	response rate of 12/17 (80%), 3/2 local flaps and 9/12 skin grafts were used.	apply skin grafts early; nevertheless, there is no proof to back up this assertion; not using a control
Ford et al. (2002)	“Randomised Controlled Study”	“28 patients with 41 wounds ”	Pressure Ulcer randomly assigned to N.P.W.T. and gel products	Gel therapy reduced wound dimensions by 42%, V.A.C. therapy by 52%; V.A.C. therapy also reduced polymorphonuclear cells, lymphocytes, and capillary mean number.	In comparison to gel treatments, V.A.C. accelerates wound healing and favourably alters the histology of soft tissue and bone.
“Wanner et al (2001)”	“Consecutive study, randomised into two groups: V.A.C. and saline dressing”	22 patients	Paralysis-related pressure ulcers that are resistant to conventional therapy	Average time 50% of the initial volume: There was no discernible difference between the two groups' days to healing (N.P.W.T., 27 days; saline dressings, 28 days)	N.P.W.T. is not more beneficial than regular group therapy, according to the study's findings.
“Chronic wounds”					
“Joseph et al (2000)”	“Prospective randomised controlled trial”	“24 patients, 36 wounds ”	“Chronic wounds that had been present for more than a month; half were treated with V.A.C., the other half with saline dressings.”	“At six weeks, there was a significant difference favouring V.A.C. in the percentage change in wound volume (78 vs 30 percent)”	Blinded investigation came to the conclusion that N.P.W.T. improves the rate of wound healing.
“Page et al (2005)”	“Retrospective analysis of patients undergoing		Infected wound and post-amputation	76 percent less need for additional surgery, 80	N.P.W.T. improved wound filling early on in the

	V.A.C. therapy and traditional treatment"		stumps	percent less readmission, and 83 percent less complications; median time to wound filling with V.A.C. 38 days (26 to70), conventional 80 days (55–98).	treatment, it was concluded.
Anthony and Terrazas (2004)	"Retrospecti ve review"	"42 patients "	"12 sternal, 16 spinal, and 14 lower-limb wounds that were unresponsive to conventional treatment"	fewer exudates, more granulation tissue, shorter healing times, and shorter hospital stays	bleeding from the sponge if the dressing is left on for more than 48–72 hours
Argenta and Morykwas (1997)	"Prospective study"	"300 patients "	"31 acute wounds, 94 subacute wounds, and 175 chronic wounds"	296/300 (98%) patients responded favourably to treatment; this resulted in enhanced granulation tissue and the healing of 32% of decubitus ulcers.	The 1st and the largest clinical study, a standard for subsequent studies.
"Loree et al. (2004)"	"Prospective, controlled, open, non comparative study"	"15 patients "	Any persistent ulcer that has not responded to prior therapy	"Reduced fibrinous tissue by 28% on day 3, and by 40% on day 6, proving the effectiveness of V.A.C. for wound debridement."	Uncertain what constitutes debridement: surgery or cleaning; no wound dimension described
"Clare et al (2002)"	"Retrospecti ve study"	"17 patients with 17 wounds on lower extremi ty"	All patients had previously failed treatment for chronic and non-healing wounds on	"3/17 (18%) failed treatment; these three had diabetes, and two of them had PVD. Of the 14/17	Recommend that individuals with minor wound may not get benefited from N.P.W.T. and

			the lower extremities.	wounds that did heal, 82% required skin grafts, 4% growth factors, and 6% more dressings."	those with PVD may also not be acceptable candidates.
"Mendonca et al (2005)"	Retrospective study	"15 patients with 18 wounds"	"All of the chronic, complicated wounds were surgically debrided prior to V.A.C. treatment."	"Five of eight wounds failed therapy, three of which required amputations, and three of which had DM and PVD. The wound area shrank from 7 cm^2 to 1 cm^2, healing 13 of the 18 wounds."	Considering possibility that N.P.W.T. could fail in both D.M. and P.V.D.
"Negative pressure and skin grafts"					
"Scherer et al (2002)"	Prospective study	"61 patients"	Traumatic wounds in "level 1 trauma centre include burns (32) and soft tissue (27), as well as fasciotomies (2)"	Compared to traditional bolster dressings, V.A.C. reduced the requirement for subsequent skin transplants.	Skin grafts could be securely fastened by V.A.C., but there isn't any evidence to prove that V.A.C. evenly distributes pressure or apposition.
"Moisidis et al. (2004)"	"Prospective randomised blinded trial"	"22 patients"	It is possible for V.A.C. to firmly fasten skin grafts, but there is no proof that V.A.C. equally distributes pressure or apposition.	V.A.C. stimulates epithelialization by 30%, with no change in epithelialization at 45%, and a 25% reduction at 80%; the standard of skin grafts rose by 50%, stayed the same at 35%, and fell by 15%.	Although it is unclear how the quality is better, it was found that in 85% of cases, V.A.C. results in epithelialization that is at least as good as the control.

Infected wounds					
Wongworawat et al. (2003)	Prospective	14 patients	Lower limbs with orthopaedic infected wounds larger than 20 cm	In just 10 days, the average wound shrank by 43%.	N.P.W.T. promotes wound healing and has the advantage of limiting staff exposure to infected wounds.
"Diabetic wounds"					
Mc Callon et al (2000)	"Randomised controlled study"	"10 patients"	Randomized use of N.P.W.T. and moist-gauze dressings to diabetic foot wounds	Reduce the time needed for healing to be sufficient while favouring V.A.C.. Gauze: 42.08 days to 32.05 days; shift in percent surface area in favour of the V.A.C.: 22.08 days to 17.4 days.	Despite the lack of blinding, it was determined that N.P.W.T. promotes quicker healing & a decrease in the wound surface area than the saline dressing.
Eginton et al. 2003	Prospective randomised cross-over design	7 patients	wound measurements were calculated for diabetic wounds.	With V.A.C., all wound dimensions shrank; the depth of the wound shrank more quickly.	Determined that the first two weeks of treatment are when V.A.C. is most effective.
"Sternal wounds"					
"Fleck et al (2002)"	Retrospective cases	11 patients	Infection of the sternum following heart surgery	Five patients received sternum rewiring; six patients underwent N.P.W.T. as an adjuvant to the reconstructive surgery using a pectoralis major flap.	N.P.W.T. is beneficial complement to traditional treatments for sternal wound infections, it was determined.
"Song et al(2003)"	Retrospective study	35 patients	problems with sternal wounds	The V.A.C. group had a shorter (6 days) time between	Hence, it was determined that V.A.C. might make

				debridement and closure, less soft tissue flaps, and simpler flaps.	rebuilding less complex.
Cost analysis					
"Hersovici et al (2003)"	Retrospective study	"21 patients"	"Cost analysis for patients with V.A.C. and high-energy wounds"	$100/day for dressings and $103/day for V.A.C.	V.A.C. has a greater overall cost, but this is justified because it prepare the wound bed and removes necrotised tissue, resulting in fewer extensive operations and a longer-term cost savings.
Microbiology					
Argenta and Morykwas (1997)	Prospective	300 patients	V.A.C. therapy is used to treat both acute and chronic wounds, and bacterial levels are examined.	After 3–4 days, there is a noticeable drop in bacterial count	Suction impact reduces the bacterial burden
Weed et al. (2004)	Retrospective	25 patient	"Acute and chronic wound patients receiving V.A.C. therapy"	An increase in bacterial colonisation and a bioburden rise of 43%	In both acute and chronic wounds, N.P.W.T. actively raised bacterial numbers; there was no association between this and the pace at which the therapy failed.
"Moues et al (2004)"	"Prospective randomised controlled trial"	54 patient	Chronic wounds & wound unfit for wound closure;	Staphylococcus aureus increased following treatment,	A same bacterial load was found, and it was hypothesized

			randomly assigned to moist gauze and N.P.W.T.; wound biopsies for culture	while anaerobes remained unaffected and wounds were reduced on average by 3.8% per day for N.P.W.T. and 1.7% per day for the gauze.	that more S. aureus might have caused healing.

DISCUSSION

Trials have demonstrated that negative pressure therapy enhances angiogenesis and granulation tissue formation. Distraction forces are produced by micromechanical forces that draw the margins of the wound together. It has been demonstrated that suction pressure changes bacterial counts and reduces wound exudate. Negative pressure enhances wound healing, although the precise mechanism by which this occurs is still a mystery. Negative pressure does not appear to affect cell growth, and the growth factors and cytokines that start the processes of cell migration and angiogenesis have not been discovered. Although negative-pressure therapy models have been developed, the relationship between traction pressures on the wound surface and physiologic changes in the wound environment has yet to be shown in vitro or in vivo. Also absent in study is information on the optimal negative-pressure settings' biomechanics and the delivery method (intermittent vs. continuous). These information gaps about the biological process underlying negative-pressure therapy may be filled by future research.

There were no randomised controlled studies that compared the efficacy of various TNP regimes. The assignment schedule appeared to have been created using true randomization in the trial by Joseph et al., however it is questionable whether allocation concealment was effective because it was absent from the study by McCallon et al. The assertion that trials with opaque or insufficient concealment lead to greater treatment effect estimates is supported by some data. Because the experimental groups in the investigations by Joseph et al. and McCallon et al. received TNP given via foam dressings while the control groups received saline-moistened dressings, it was difficult to blind those providing and receiving therapy. The outcome assessors in the trial by Joseph et al. were blinded to treatment allocation, however this was not made explicit in the study by McCallon et al. putting the latter study at risk of detection bias. Joseph et al. study was single-blinded, whereas McCallon et al. study was not. There's additional evidence that trials that aren't double-blinded have higher treatment effect estimates. Because both studies were tiny, there's a good chance that the samples weren't totally typical of the people studied. It has been demonstrated that negative pressure therapy can lessen the need for free tissue transfer in acute traumatic wounds with exposed bone, metal, and tendon. The wound bed is prepped for a local muscle/cutaneous flap or a final skin graft. Although Song et al. observed that it may lead to fewer treatments, it

may reduce the need for free tissue transfer in large wounds with exposed bone or metal. The long-term consequences of reconstruction on tissue mass, wound healing, scar assessment, functional result, and quality of life must also be researched.

Negative Pressure therapy been demonstrated to speed up the healing process, reduce exudate, and lower bacterial counts in chronic wounds. For those who have diabetes mellitus and peripheral vascular disease, the results are still pending. The need for less intrusive surgery has been proven in patients getting negative-pressure therapy, as have the rates of readmission after recovery. Negative-pressure therapy for chronic wounds is currently only the subject of a small number of randomised controlled trials. Due to the tiny sample sizes in the two trials that were given, it is difficult to compare data effectively. Future randomised controlled studies of negative-pressure therapy must use rigorous methods, blinding, and a methodical approach to measuring wound size.

There is no conclusive evidence that using TNP to treat pressure ulcers improves wound healing. Numerous studies have failed to establish whether TNP therapy was started with or without surgical debridement. This is significant because a chronic wound becomes acute in the first scenario. The information that is currently available about the long-term effects of TNP therapy for pressure wounds is not complete. The frequency of pressure wound recurrence after healing has not been studied. Additionally, it's not obvious if tissue transfer is necessary less often when TNP is used, as was demonstrated in acute traumatic wounds. Additionally, it is unclear why negative pressure therapy tends to plateau after the first two weeks but is most effective during that time. There are no randomised, blinded, controlled studies of negative-pressure therapy for pressure ulcers, despite possible future study in this area.

There are major differences in the studies on diabetic wounds by Eginton et al. and McCallon et al. The repeated measures research approach adopted by Eginton et al. prevents a potential bias in the McCallon et al. study by having each wound act as its own control. The McCallon et al. study only looked at surface area, which might not be a good representation of how well larger, deeper foot wounds heal. Not to mention, the McCallon et al. trial's measurement timing was erratic, which might have resulted in erroneous results at various times. The study by Eginton et al., on the other hand, is limited and might be biassed. Eginton et al. asserted that by promoting granulation tissue, microcirculation, and bacterial clearance, V.A.C. therapy is best suited to diabetes wounds. To prove this, however, more laboratory studies focusing on diabetes patients are necessary.

Three of the 13 diabetic patients in Clare et alstudy .'s who had significant foot sores and required repeated amputations after failing V.A.C. treatment. Two of the three were affected by peripheral vascular disease, and both had previously tried revascularization but had failed. Patients with diabetes mellitus and peripheral vascular disease may not be suitable candidates for V.A.C. therapy and should be treated in other methods, as suggested by Clare et al., which was validated by Mendonca et al. Negative-pressure therapy, in conclusion, clearly helps diabetic wounds by accelerating the healing process and may even help preserve limbs. The cellular impact of negative pressure on diabetic lesions is unknown.

It has been proven that negative pressure therapy speeds up the healing of skin grafts. Although the exact mechanisms are uncertain, it is believed that negative pressure increases graft apposition with the wound bed, suction of haemorrhages, and reduced shearing effect, all of which have an impact on graft take. It is still unclear, though, why negative pressure makes grafts more likely to succeed. Additionally, the standards employed to gauge graft take quality are arbitrary.

COMPLICATIONS

The V.A.C. method is known to have issues with granulation tissue overgrowth into the sponge, bleeding following dressing changes, recurrent infections, and maceration of nearby skin. Because only intermittent reports of issues have been made public, it is unknown how widespread these worries are. About 20 minutes after the foam dressing was first compressed, pain associated with subatmospheric pressure therapy in some patients vanished. To estimate the number of patients who experience pain while receiving V.A.C. therapy, more thorough research is once again required. The V.A.C. approach has drawbacks related to machine maintenance and monitoring. To guarantee a good seal around the wound and proper machine operation, the device must be periodically evaluated. Patients describe upsetting incidents when a series of alarms went off when the battery ran out, which can be upsetting. The machine's more recent models address these issues.

RESEARCH IMPLICATIONS:

This systematic study emphasises the need for high calibre studies on the security and efficiency of N.P.W.T..

1. Multicentre, well-designed, sufficiently powered randomised controlled trials to assess the role of N.P.W.T. in wound healing

2. Randomized Control Trials of N.P.W.T. in which the comparator intervention corresponds to the most recent accepted standard of care for wound healing.

3. Randomized control trials to assess how N.P.W.T. affects recovery times, costs, quality of life, pain, and comfort, and to ascertain whether there is an ideal N.P.W.T. regimen for wound healing.

4. Economic analyses to ascertain whether the expenses of N.P.W.T. outweigh its possible advantages.

CONCLUSION

A wound healing technique called N.P.W.T. is widely applied to hasten healing, prepare the wound bed for surgery, and boost wound healing rates. The clinical value of negative-pressure therapy is still uncertain based on the information currently available. There are few randomised controlled trials with contradictory findings, despite case studies and retrospective research showing that sternal wounds, chronic wounds, infected wounds, wounds brought on by diabetes mellitus, wounds on the lower limb, and acute/traumatic wounds heal more quickly. There isn't much evidence that TNP therapy hastens the healing of wounds and the acceptance of skin grafts in patients with decubitus ulcers, diabetes, and peripheral vascular disease.

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