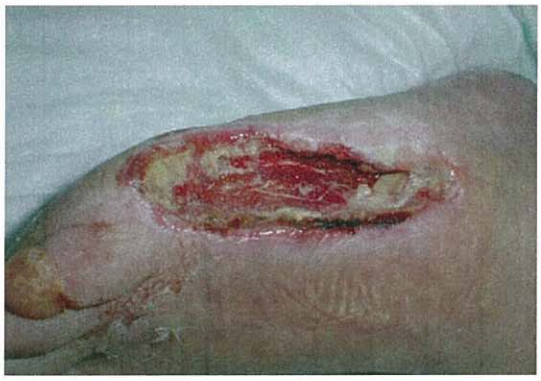
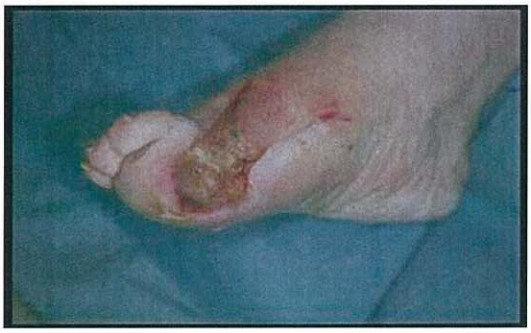
Diabetic Ulcers





THE V.A.C.®
VACUUM ASSISTED CLOSURE™

KCI
Wolfgang Imendörffer
Marketing Manager CEE
25 August, 2009

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The Clinical Advantage

Clinical Summary Sheet

Comparison of Negative Pressure Wound Therapy using V.A.C.® with advanced moist wound therapy in the treatment of diabetic foot ulcers. A Multicenter Randomised Controlled Trial.

Authors: *Blume P.A., Walters J., Payne W., Ayala J., Lantis J.*
Journal: *Diabetes Care, Vol 31; No 4; 631-636; 2008*

Background

- A disabling complication of diabetes is foot ulcer development which leads to nonhealing chronic wounds that are difficult to treat
- Diabetic foot ulcers (DFU) are a significant risk factor for nontraumatic foot amputations in individuals with diabetes.

Purpose

To evaluate the safety and efficacy of V.A.C.® Therapy compared with advanced moist wound care (AMWC) for the treatment of DFUs.

Methods

- Concealment of randomisation
- Off loading therapy
- Independent wound assessments

Main entry criteria

≥18 year old

Ulcer Wagner stage 2 or 3

Calcaneal, dorsal or plantar foot ulcer ≥2cm²

Adequate blood circulation (perfusion)

No active Charcot disease

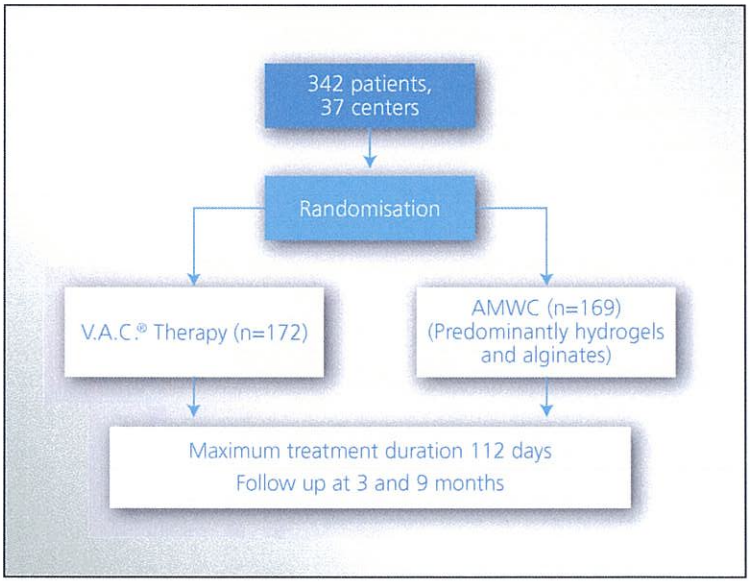
No ulcer malignancy

No untreated osteomyelitis

No uncontrolled hyperglycemia

No normothermic or hyperbaric oxygen therapy within 30 days of study start

No use of corticosteroids, immunosuppressive medication or chemotherapy within 30 days of study start



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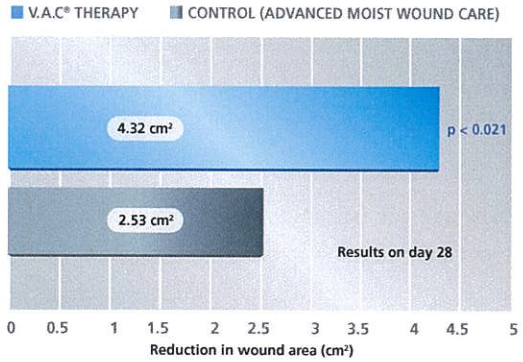
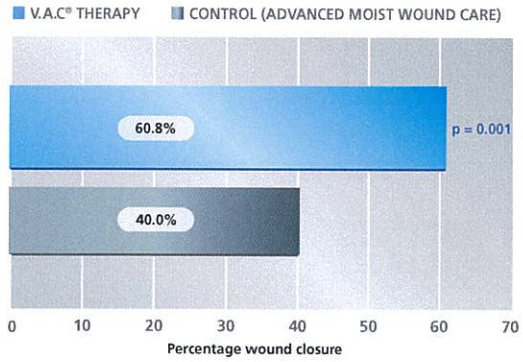
Clinical Summary Sheet

Results and Conclusions

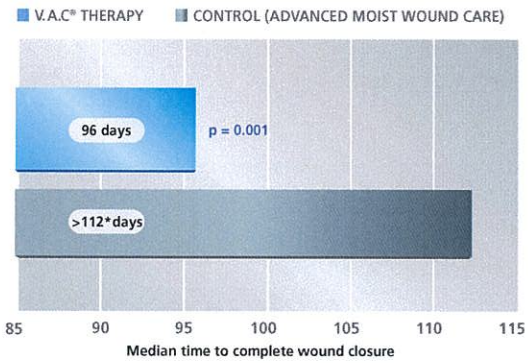
V.A.C.® Therapy leads to greater wound area reduction



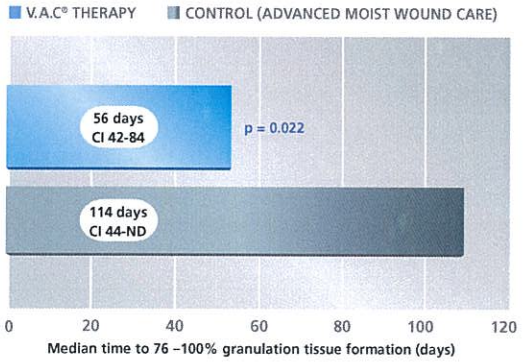
V.A.C.® Therapy leads to higher rate of wound closure



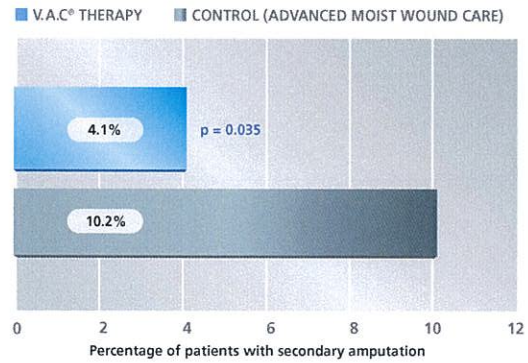
V.A.C.® Therapy reduces time to wound healing



V.A.C.® Therapy shows faster wound bed preparation



V.A.C.® Therapy reduces the rate of secondary amputations



*The duration of the control treatment could not be estimated (Kaplan-Meier).

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KCII1072

Clinical and Economical Summary Sheet

Resource utilisation and economic costs of care based on a randomised trial of vacuum-assisted closure therapy in the treatment of diabetic foot wounds.

Authors: *Apelqvist J., Armstrong D.G., Lavery L.A., Boulton A.J.M*
Journal: *The American Journal of Surgery, 2008 Jun;195(6):782-8*

Background

- Direct treatment costs for diabetic foot complications are high, exceeding $30,000. The costs for performing a single amputation are approximately $34,000.
- These costs do not account for increased utilisation of inpatient services, prosthetic/rehabilitation, or home care/social services.
- Societal costs are especially high in cases of amputations and ulcers that fail to heal as patients require prolonged hospitalisation, rehabilitation, need home nursing care, lose work production (for the disabled patient and his or her family).
- Important clinical factors related to short-term costs include healing rate and the presence and severity of foot infections and ischemia.

Purpose

To estimate and compare resource utilisation and direct economic costs of treatment with V.A.C.® Therapy in patients with severe postoperative diabetic foot wounds.

Methods

- Retrospective analysis of patients enrolled in a randomised clinical trial (Armstrong, Lancet 2005), using payer and societal perspectives.
- RCT with 162 patients with partial diabetic foot amputation of 16-week duration comparing V.A.C.® Therapy and Advanced Moist Wound Care (AMWC).
- Patients fulfilling a minimum of 8 weeks participation in the study period were included when comparing and analysing resource utilisation and economic calculations.

Resource Utilisation and Cost Calculation	
Inpatient care	• Average cost per treatment day including resource use • Costs of surgical procedures (flaps, grafts, amputations, surgical debridements)
Antimicrobial treatment	• Costs for oral and systemic antibiotics
Outpatient treatment visits	• Number of outpatient clinic visits • Number of visits to patient's home • Estimated cost for caregiver time • Estimated cost of clinic visit
Topical wound treatment	• Actual number of dressing changes • Estimated material costs (primary dressing material) • Estimated time consumption for dressing changes • Staff who performed dressing changes (cost/hour)

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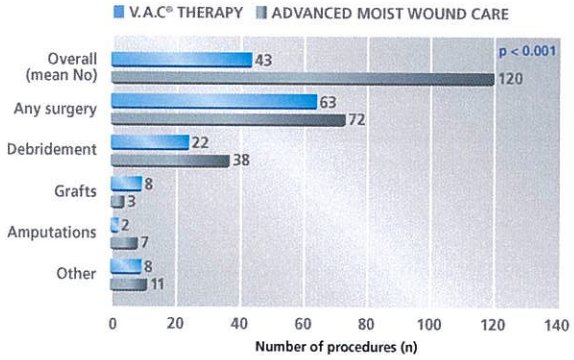
Clinical and Economical Summary Sheet

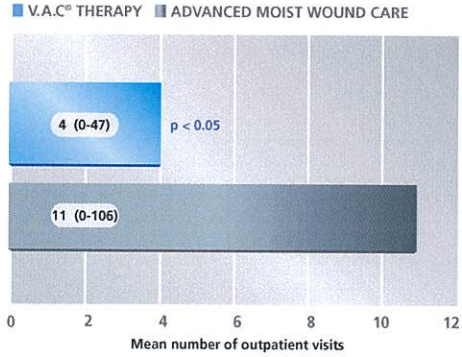
Results and Conclusions

- **A higher proportion of wounds treated with V.A.C.® Therapy healed compared to AMWC (55.8% vs 38.8%, p=0.040).**
- **89.1% of patients were treated in homecare setting after acute care intervention.**
- **V.A.C.® Therapy is a cost-effective intervention for patients with complex postoperative wounds.**
- **Treatment with V.A.C.® Therapy resulted in a greater proportion of patients obtaining wound healing at a lower overall cost of care when compared to AMWC.**

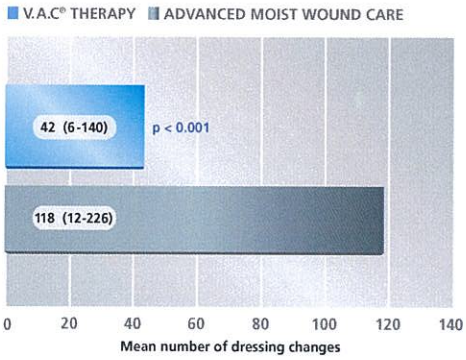
V.A.C.® Therapy reduces the number of procedures



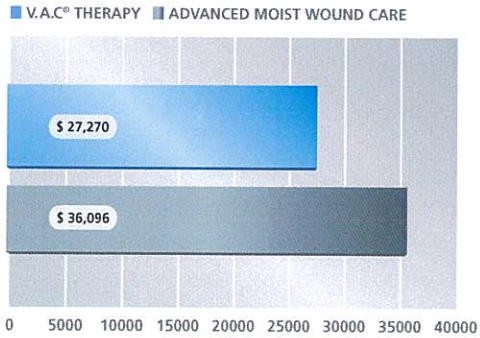
V.A.C.® Therapy reduces the number of outpatient visits



V.A.C.® Therapy reduces the number of dressing changes

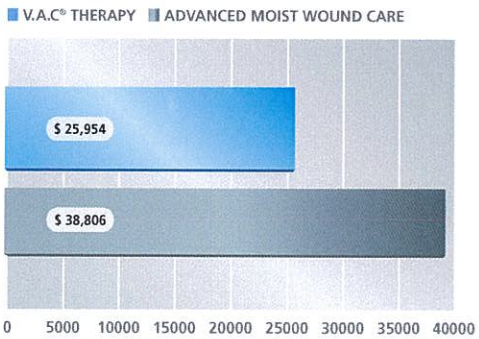


Lower average direct treatment costs for V.A.C.® Therapy



Cost difference: $8,826

Lower average total cost of treatment for V.A.C.® Therapy



Cost difference: $12,852

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KCII1073

VAC-THERAPY AND LASER-INDUCED FLUORESCENCE OF INDOCYANINE-GREEN (IC-VIEW), AN ASSESMENT OF WOUND PERFUSION IN DIABETIC FOOT SYNDROME

Zöch, Gerald MD,
Surgical Department, SMZO–Donauspital-Vienna Langobardenstrasse 122. A 1220 Vienna, Austria

Aim of the study was the use of IC-View for monitoring the effect of VAC-therapy on perfusion in diabetic wounds and the surrounding skin. We present data of ten patients with diabetic foot syndrome.

Methods:

IC-VIEW is a near-infrared video system, which visualises and quantifies tissue perfusion. The measurement is based on the fluorescence of the near-infrared absorbing and fluorescent agent indocyanine green (ICG). A measurement consists of following actions: Positioning the IC-VIEW in a distance of 50 cm from the tissue of interest, iv-injection of 0,5 mg/kg ICG, recording of ICG fluorescence for 1-8 minutes, quantification of fluorescence signal using the IC-CALC software and automated calculation of perfusion (%). Data for the improvement (%) of perfusion for the wound and the surrounding skin are shown.

Seven men and three women with age from 56 to 86 (mean 68) years were treated with VAC therapy for 7 to 24 (mean 12) days. The perfusion index was calculated for the wound itself and for the surrounding skin before and at the end of VAC- therapy.

Results:

The perfusion of the wound showed an increase under VAC-therapy of 31% (6-62,5%). The perfusion index calculated for the skin around the defect achieved an increase of 14% (1,5-38%). All defects were covered with meshed skin grafts and healed.

Conclusion:

IC-View enables to quantify the improvement of perfusion and granulation tissue in diabetic wounds due to VAC therapy.

Age/sex	VAC-therapy (days)	perfusion (%) of the skin before	after	improvement	perfusion (%) of the wound before	after	improvement
01 B.E./ 86 m	9	55	71	22	21	24	12,5
02 S.J./ 65 m	9	39	44	10	30	56	46
03 K.F./ 73 m	7	44	51	14	31	40	22,5
04 T.I./ 63 f	24	44	52	15	32	34	6
05 T.S./ 58 f	14	41	55	25	52	00	48
06 S. E./ 56 f	20	42	80	38	47	89	47
07 G.J./ 60 m	9	72	73	1,5	21	56	62,5
08 H.E./ 72 m	7	62	65	5	54	76	29
09 Z. F./ 76 m	13	40	42	6	48	51	6
10 T.J./ 71 m	7	48	51	6	35	42	31
mean 68	12	49,7	58,4	14,0	37,1	56,8	31

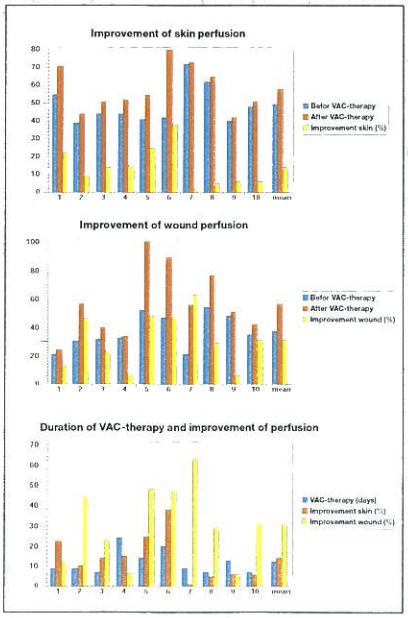


Figure 1: Before VAC-therapy

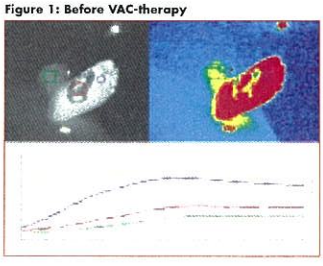


Figure 2: 21 days after VAC therapy, skin grafting

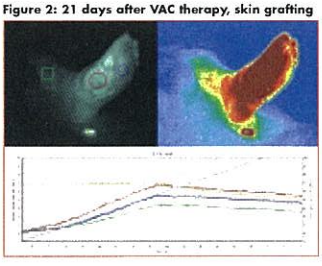


Figure 3: Before VAC-therapy

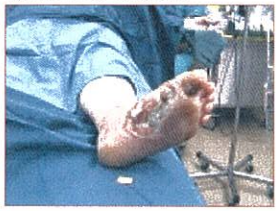


Figure 4: 21 days after VAC-therapy

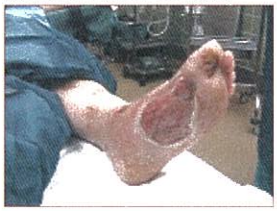
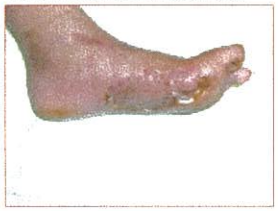


Figure 5: 10 weeks after skin grafting



Oxford Wound Healing Society

Topical Negative Pressure: Management of Complex Diabetic Foot Wounds

DG ARMSTRONG, AJM BOULTON & PE BANWELL

SERIES EDITOR: PE Banwell FRCS(Plast)

CONTENTS

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Introduction

Foot ulceration represents an all too frequent complication of diabetes, with neuropathy and peripheral vascular disease being important contributory factors in the pathogenesis of such ulceration.[1] However, it is not an inevitable consequence of having diabetes that a certain proportion of patients will develop foot lesions. Elliot Joslin, the famous Boston diabetes physician, realized this almost 70 years ago when, after observing many clinical cases of diabetic foot disease, he remarked "diabetic gangrene is not heaven sent, but earth born".[2] Foot ulceration therefore invariably occurs in certain individuals as a consequence of an interaction between specific pathologies of the lower limb and environmental hazards.

One of the most important contributory factors to the development of foot ulceration is the loss of pain, pressure, and joint position sensation that occurs as a consequence of diabetic neuropathy. The traditional medical model of disease suggests that a patient goes to the doctor because of symptoms, treatment is prescribed and then the patient recovers. Because this does not apply in the case of insensitive feet, it is often difficult for doctors to comprehend the diabetic foot syndrome: they find it difficult to take the initiative and look for early lesions or warning signs of imminent break-down. Many doctors regard such patients as being stupid – how can a sensible person walk on a swollen red foot with an active foot ulcer? What we need to realize is that an insensitive foot is not only painless, but also does not feel as if it belongs to the individual.[3] Our task is to identify patients at risk of ulceration and help them to cope with this health state by avoiding exposure to environmental hazards that may result in ulceration.

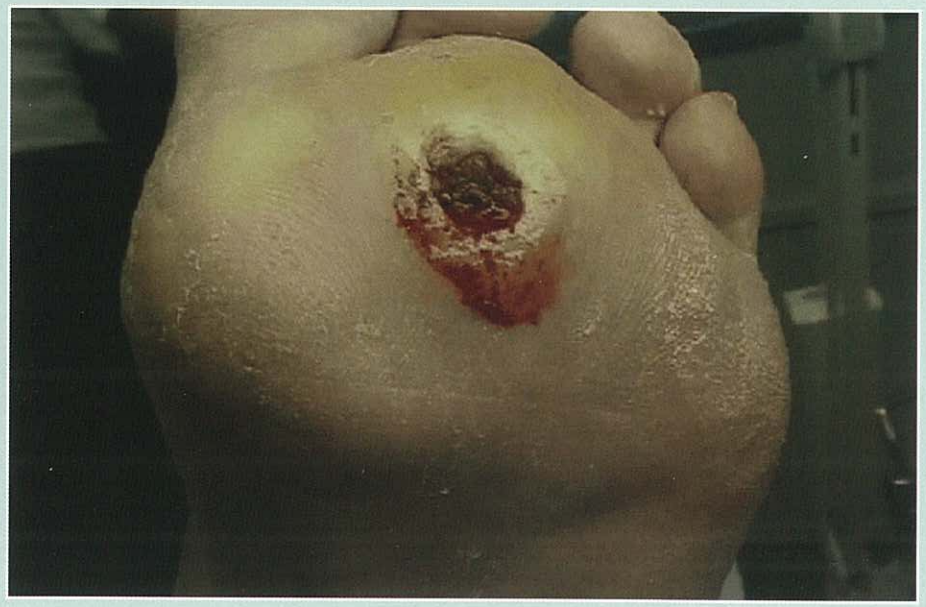


Figure 1: A diabetic foot ulcer

Epidemiology

As stated above, foot ulceration is much more common in diabetic patients with neuropathy and vascular disease: the annual incidence rises from less than 1% in those without neuropathy for example, to more than 7% in those with established neuropathy.[4,5] Globally, the diabetic foot remains a major medical, social, and economic problem that is seen in every continent.[6] In developing countries, peripheral neuropathy is the most important risk factor for foot ulceration, and ulcers are frequently associated with quite severe limb sepsis in most of these countries.[7]

Naturally there are some regional differences between countries, for example the prevalence of risk factors for neuropathy appears to be slightly lower in Australia than in the United Kingdom.[8] In the United States, it is recognized that there are differences in the epidemiology of diabetic foot problems according to ethnic background. Native Americans and Hispanics, for example, appeared to have a greater risk of lower extremity amputations amongst a population of diabetic veterans.[9]

In summary, diabetic foot ulceration and risk of lower extremity amputation remain all too common, but the study of the epidemiology of these problems has been clouded by a lack of agreement of a diagnostic criteria, and by variation in subject selection methods. In most populations, it must be assumed that at least 50% of older type 2 persons with diabetes have identifiable risk factors for foot ulceration.

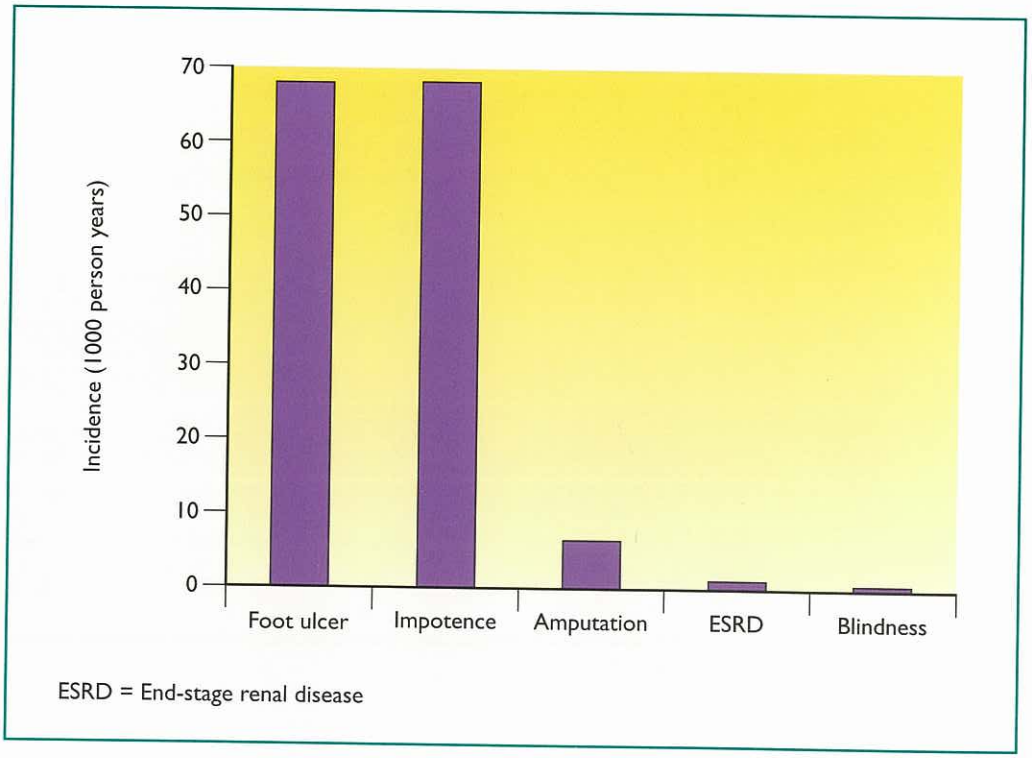


Figure 2: General incidence of diabetes complications (adapted from Armstrong DG, Lipsky BA, 'Advances in the treatment of diabetic foot infections', *Diabetes Technologies & Therapeutics*, 2004, in press)

Current Dressing Regimes for Diabetic Foot Ulcers

There are a multitude of dressings and devices designed to aid in healing of the diabetic foot. While many have proven efficacious, others have been less so. Much of the reasons associated with less than desirable results relates not to the dressing or device itself, but rather to the attention given to the wound. Diabetic foot wounds must be effectively debrided of non-viable tissue and receive effective pressure off-loading in order to heal. Any modality, including TNP, will not live up to its full therapeutic potential without appropriate attention to debridement and pressure relief.[13-15] With this caveat in place, there are a bewildering number of frequently employed dressings and techniques in diabetic foot care. They fall into numerous categories, which are outlined in Table I. The central tenet to all of the modalities listed below fall into the categories of infection control, drainage control, and control of the wound's microenvironment. Some modalities, such as topical negative pressure, are able to potentially influence all of these categories of control.

1. Antimicrobial/Silver-containing Dressings
2. Alginate Dressings
3. Biosynthetic/Hyaluronan-based Dressings
4. Cleansers
5. Collagen Dressings
6. Composite Dressings
7. Compression Bandages/Wraps
8. Conforming/Wrapping Bandages
9. Contact Layers
10. Hydrating Creams/Ointments/Hydrogels
11. Devices
12. Enzymes/ Debriding Agents
13. Foam Dressings
14. Gauze Dressings (see also Composite Dressings)
15. Growth Factors
16. Bioengineered Tissue Products
17. Hydrocolloid Dressings
18. Hydrogel Dressings (see also Impregnated Gauze Dressings)
19. Transparent Film Dressings
20. Wound Fillers: Pastes, Powders, Beads, Strands
21. Adhesive Skin Closures
22. Topical Antibiotic Preparations
23. Antimicrobials
24. Moisture Barrier Ointments/Creams/Skin Protectant Pastes
25. Moisturizers
26. Ointments
27. Biosurgical Modalities (Larvae)

Table I: Partial list of categories of dressings and advanced wound healing modalities used in the diabetic foot[16]

Topical Negative Pressure Therapy Theory

Topical negative pressure therapy (TNP)[17] has emerged as a powerful, non-pharmacological tool that can manipulate the wound healing process.[18] This technique, based upon simple principles but delivering high-tech therapy, involves the application of a vacuum force across the wound surface, using a foam dressing interface. The physical forces generated at the foam-wound interface (via mechanical transduction) lead to a variety of changes in the wound environment, positively enhancing the healing process.

Numerous studies have now reported the successful use of topical negative pressure, known commercially as Vacuum-Assisted Closure™ (KCI, San Antonio, TX), in a clinical setting.[19-26] Primary indications for use have recently been recommended[18] and include the following: upper and lower limb trauma including thermal injury, infected wounds, sternal dehiscence, abdominal dehiscence, skin graft fixation, wound bed preparation, pressure ulcers, venous leg ulcers and diabetic ulcers. Furthermore, recent experience has shown useful applications in oral and maxillofacial surgery, gynaecological problems, necrotizing fasciitis, extravasation injuries and reducing donor site morbidity.[18] However, on-going clinical trials must confirm the clinical and economic efficacy of this treatment.

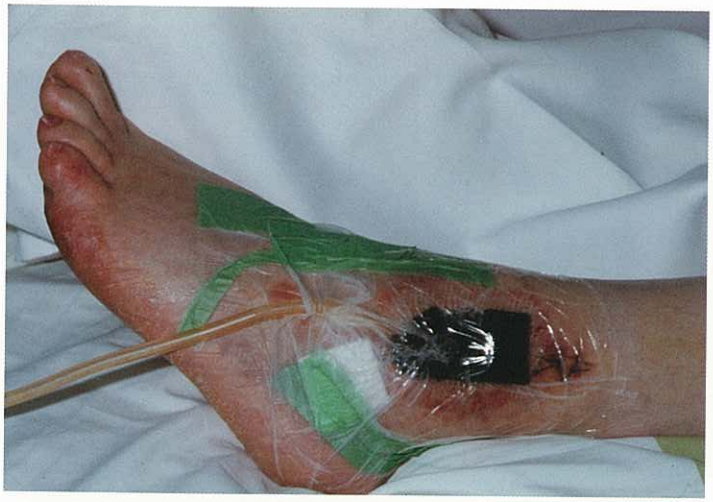


Figure 5: TNP dressing *in situ*

- Traumatic wounds – upper/lower limb, burns
- Infected wounds
- Sternal dehiscence
- Abdominal dehiscence
- Skin graft fixation
- Wound bed preparation & exudate management
- Pressure ulcers – sacral, trochanteric, ischial
- Leg ulcers – venous, diabetic

Table II: Primary indications for using topical negative pressure therapy in clinical practice

Topical Negative Pressure Components

Several components are required for optimum delivery of topical negative pressure therapy: a foam interface dressing, a hermetically sealed drape, evacuation tubing, a wound effluent collection device and a microprocessor-controlled vacuum pump.

Specially-designed open pore, reticulated foam dressing should be used to cover the wound. These may be made of either polyurethane ether (PU) – 'black' foam, or polyvinyl alcohol (PVA) – 'white' foam. Each has individual characteristics as listed in Figure 10. Either type may be used effectively although the authors predominantly use PU foam in their practice.

An adhesive drape must be used to cover the foam dressing in order to create a closed, controlled wound environment. Often it may be easier to cut this drape into strips to facilitate securing the foam in place.

The evacuation tube is attached to the closed dressing by means of a so-called TRAC™ pad (KCI, Kidlington, UK) (TRAC = Therapeutic Regulated Accurate Care). This is a highly-sophisticated technology which allows a constant feedback from the wound site to the microprocessor-controlled vacuum pump V.A.C.® ATS™ (KCI, Kidlington, UK) and ensures that a constant negative pressure is delivered to the wound. Target pressures and delivery regimes are controlled by the vacuum pump which can be set to a variety of pressures using either continuous or intermittent cycles.

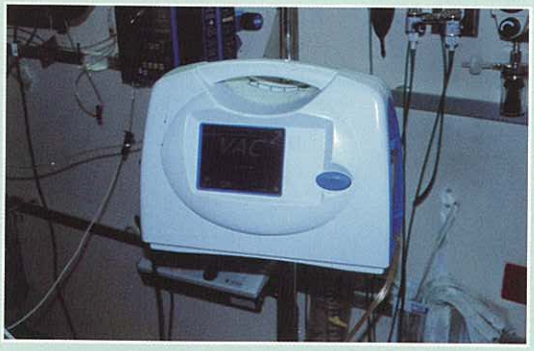


Figure 6: Microprocesor-controlled V.A.C.® ATS™ therapy unit (vacuum pump)

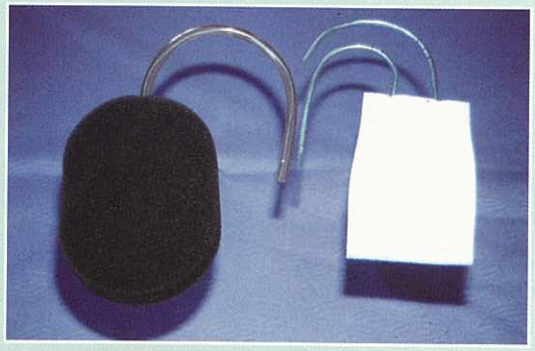


Figure 7: Foam dressings

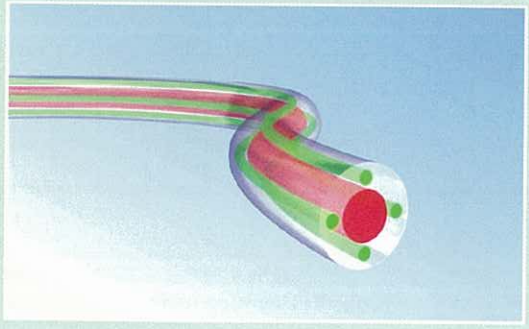


Figure 8: TRAC™ technology

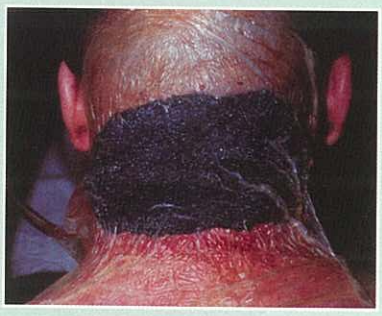
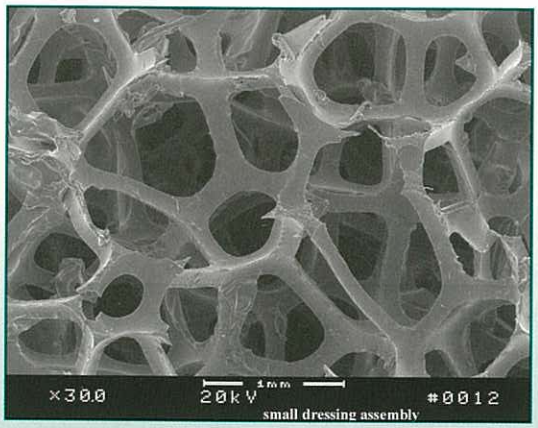
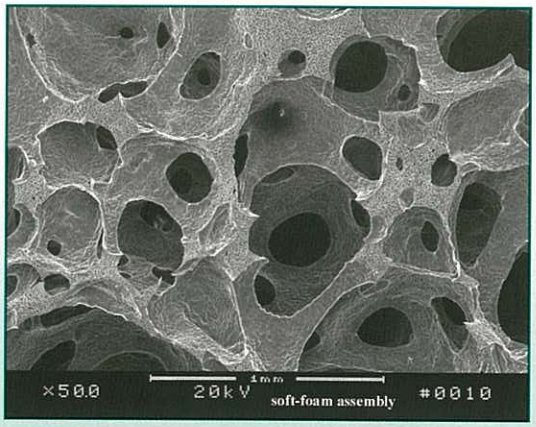


Figure 9: Dressing *in situ*



Characteristics

- Material: polyurethane foam
- Reticulated – coarse, open pore structure
- Hydrophobic foam
- Compression load deflection (firmness) 3kPa
- Tensile strength 160 kPa



Characteristics

- Material: polyvinyl alcohol foam, pre-moistened with sterile water
- Non-reticulated – denser, less open pore structure
- Hydrophilic foam
- Compression load deflection (firmness) 7 kPa
- Tensile strength 275 kPa

Figure 10: Differential characteristics of (*left*) polyurethane (PU) foam and (*right*) polyvinyl alcohol (PVA) dressing

TNP Dressing Application

Optimum results with topical negative pressure therapy can only be achieved if there is meticulous attention to detail regarding the dressing application. This is especially of paramount importance in dressing complex diabetic wounds.

The wound should first be debrided of all non-viable tissue and subsequently prepped using standard Institutional wound care regimes. This may occur in the operating room, on the ward, or in the community and should be considered one of the most important parts of the dressing regime.

Attention should also focus on peri-wound skin. It should be cleaned and dried. Barrier protectants, eg. Cavilon (3M) may be used as well as tincture of benzoin or friars balsam to ensure adhesiveness of the transparent drape. Additonally, many clinicians will also use hydrocolloid flanges to protect surround skin or augment the seal. This may also be useful to protect smaller wounds (<4 cm) from direct pressure effects of the TRAC™ pad.[27]

Foam dressings (either PU or PVA) should be then be cut to size and placed within the wound. Purpose-made, indication-specific and anatomical dressings are now also being designed although certain techniques have been employed using existing foams.[28] There has been a trend to use an interposed dressing between the foam and the wound but this may dissipate the mechanical transduction effects at a given pressure and minimize granulation tissue formation. One of the rationales for using these dressings is to reduce the discomfort of removing the foam at dressing changes. However, in neuropathic conditions it would seem sensible to defer using them.

The foam should then be sealed with the adherent drape making sure additional shear stresses are not placed on surrounding skin causing traction injuries. Once sealed, a small hole is made in the drape and the TRAC™ pad applied before connecting up to the microprocessor-controlled vacuum pump. Every effort should then be made that a good seal has been applied and that the connectors are correctly in place. Adaptations of this technique may be employed which are especially useful for plantar wounds (see pages 16 and 17).

A standard protocol is currently employed for diabetic wound regimes: continuous pressures of 125 mmHg are routinely used although this may be increased or decreased according to wound response and patient comfort. It is recommended that dressing changes are performed every 48 hours or sooner in infected wounds. However, with increasing clinical experience and in non-infected or minimal-exudative wounds, dressing changes may be increased to fit in with institutional dressing regimes.

Certain wounds may also be suitable for instillation techniques using topical antiseptics and antibiotics.[29]

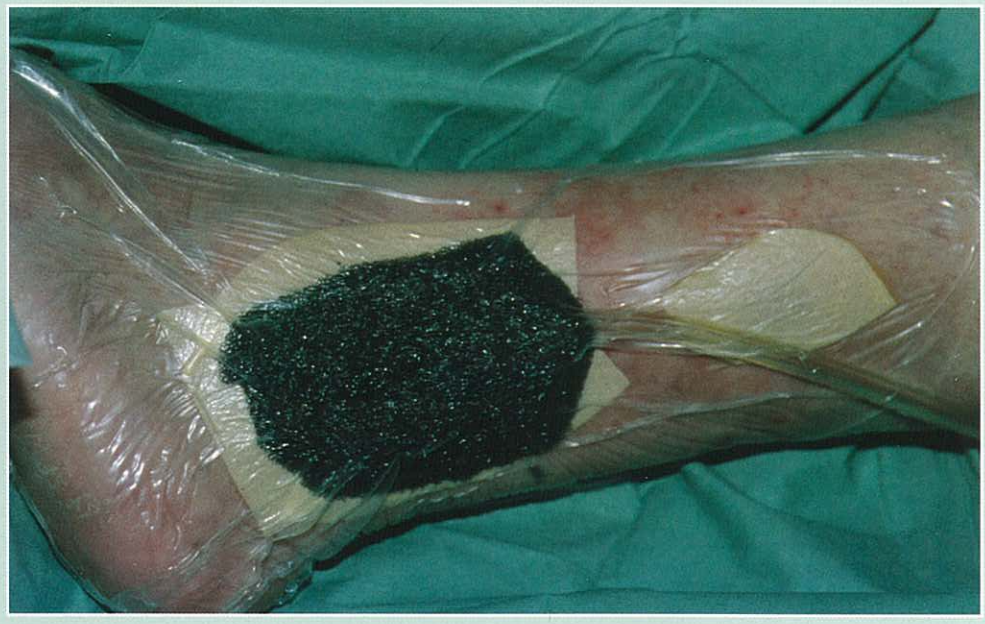


Figure 11: A leg ulcer in a diabetic patient treated with TNP. Note the protective hydrocolloid flange

Topical Negative Pressure Therapy: Mechanism of Action

At a macroscopic level TNP can be regarded as a method, which combines the benefits of both closed and open wound management. Closed treatment by approximation of skin edges protects the wound from bacterial invasion and maintains moisture, pH, gaseous concentrations and temperature at a more optimal level for healing. Open treatment, however, avoids tension, allows for the release of toxic products thereby reducing the risk of systemic sepsis in the presence of contamination and enables regular monitoring and assessment of a complex wound. The unique features of TNP therapy, which are thought to contribute to an optimised wound environment include:

1. Removal of excess interstitial fluid:

There exist two mechanisms by which removal of excess interstitial fluid is thought to accelerate healing. The first is based on the observation that fluid from chronic wounds is known to contain cytokines, collagenases and elastases whose accumulation inhibit the proliferation of fibroblasts, keratinocytes and endothelial cells.[30-33] It therefore follows that removal of such substances might serve to accelerate the wound repair process. Secondly, the localised oedema present in both acute and chronic wounds causes an increase in tissue turgor, which compresses surrounding microvascular and lymphatic channels. Diminution of interstial fluid by TNP is thought to decompress small blood vessels thereby restoring their flow.[34,35]

2. Delivery of mechanical stress to the wound:

This mechanism has been compared to those at play in the techniques of Ilizarov bone distraction[36] and tissue expansion and has led to TNP being likened to "reverse tissue expansion".[17] At a cellular level, the mechanisms believed to be involved stem from Thoma's postulation that the application of mechanical stress results in angiogenesis and tissue growth.[37] This phenomenon appears to be controlled through cytoskeletal changes, which stimulate the release of intracellular second messengers capable of stimulating cell growth.[38-40]

3. Provision of a moist wound environment:

By virtue of its sealed system, TNP therapy creates a moist wound environment, which is thought to contribute further to accelerated healing. This concept, which came to light following Winter's classic experiments in the 1960s, was based on his observations that moist wounds were seen to re-epithelialise significantly more rapidly than those left exposed to air.[41,42] His findings have been supported by numerous other investigators and have led to the current acceptance that moist wound healing is advantageous to the wound repair process.[43-45]

A full understanding of the exact microscopic mechanisms of action by which TNP exerts its beneficial effects are currently unknown but substantive evidence exists to support the following postulated mechanisms:

(a) Stimulation of angiogenesis and local blood flow:

This is realised by decompressing small blood vessels and stimulating the proliferation and differentiation of endothelial cells. Using Doppler probes in an animal model, Morykwas and Argenta demonstrated a four-fold increase in blood flow when 125 mmHg of negative pressure was applied to full-thickness porcine wounds.[20] This increase was maintained for 5–7 minutes when using continuous delivery and could be reproduced by intermittent periods of therapy. For the purposes of maximal blood flow the optimal treatment protocol was described as being intermittent delivery of 125 mmHg negative pressure for 5-minute periods with 2-minute intervals. Josephs *et al.* demonstrated enhanced angiogenesis histologically from biopsies of wounds treated with TNP[46] whilst Walgenbach and co-workers were able to demonstrate increased capillary formation using histochemical techniques to detect endothelial cell markers CD31 and CD105.[47]

(b) Reduction in bacterial count:

Increased blood flow serves to increase tissue oxygen concentrations thereby inhibiting the growth of anaerobic organisms and providing nutrition for the oxydative bursts of cells of the immune system. Gouttefangeas and colleagues have demonstrated infiltration of the foam by granulocytes and mononuclear cells.[48] Neutrophils are known to form the first line of defense against wound infections,[49] however, in contrast to macrophages and T lymphocytes they are not essential for wound healing.[50–52] Although there is no evidence to suggest that a higher concentration of such cells exists in a wound treated with TNP, the identification of their presence suggests a possible mechanism by which bacterial count is reduced as demonstrated by Morykwas and Argenta following challenge by inoculation with human isolates of *Staphylococcus aureus* or *Staphylococcus epidermidis*.[20]

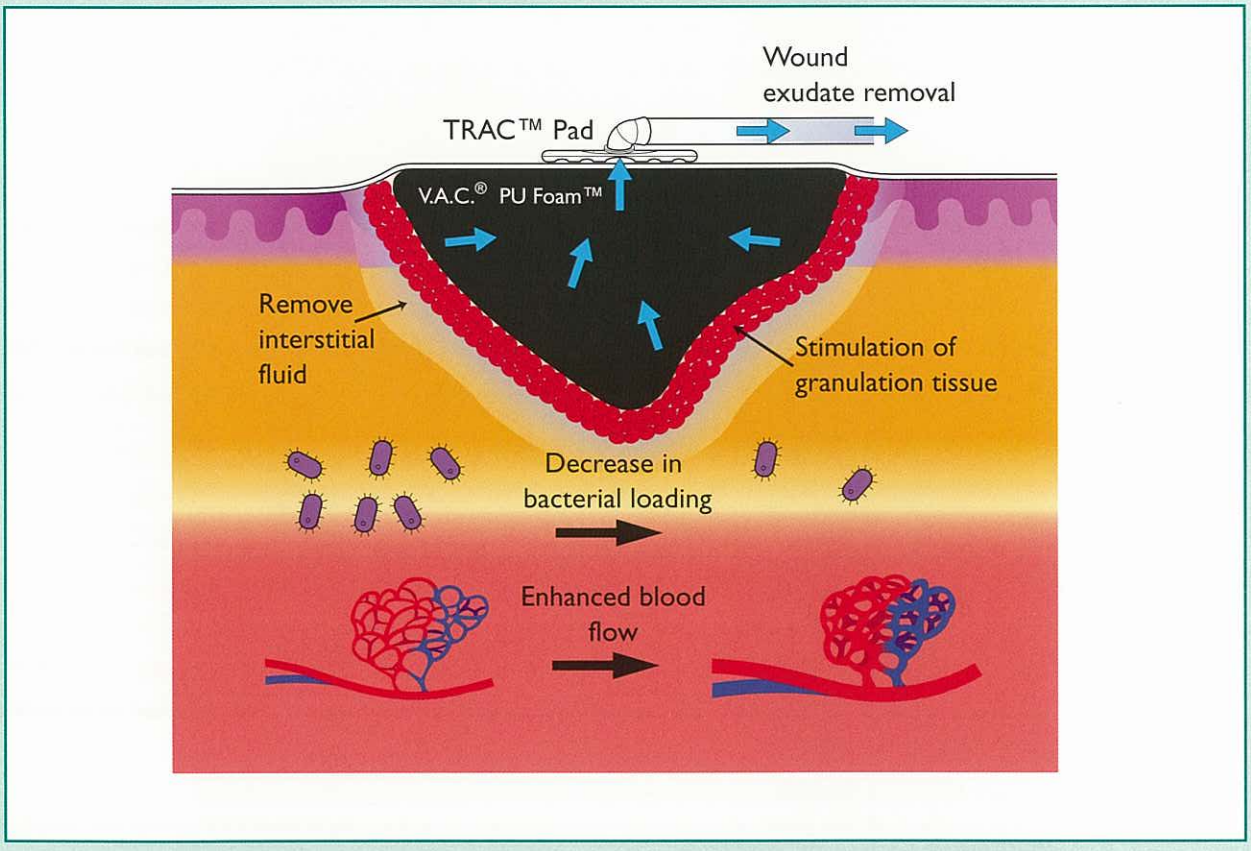


Figure 12: Mechanism of action (diagrammatic)

(c) Mitogenesis of cells involved in the wound repair process:

This proliferative response is thought to be due to a combination of mechanical force, moist environment and removal of inhibitory factors and is manifested by an increase in volume of granulation tissue which has been observed in both acute[20] and ischaemic animal models[53] of wound healing by as much as 63% with continuous TNP and over 100% with intermittent TNP. Mullner *et al.* conclude that TNP is capable of stimulating the production of granulation tissue to such an extent that musculocutaneous flap coverage was averted.[23]

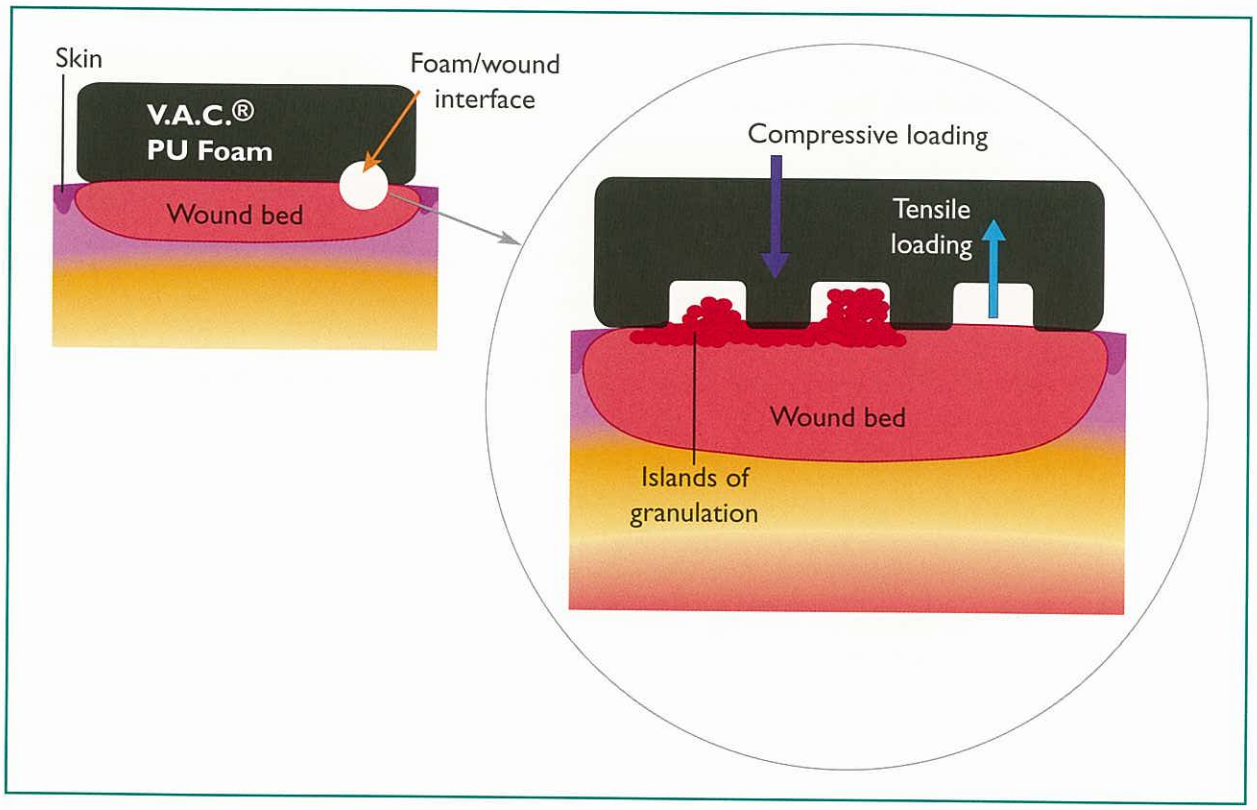


Figure 13: Foam/wound interaction illustrating granulation tissue formation

- **Removal of excess interstitial fluid**
- **Delivery of mechanical stress to the wound**
- **Provision of a moist wound environment:**
  - **Stimulation of angiogenesis and local blood flow**
  - **Reduction in bacterial count**
  - **Mitogenesis of cells involved in the wound repair process**

Table III: Mechanisms of action of TNP

(c) Mitogenesis of cells involved in the wound repair process:

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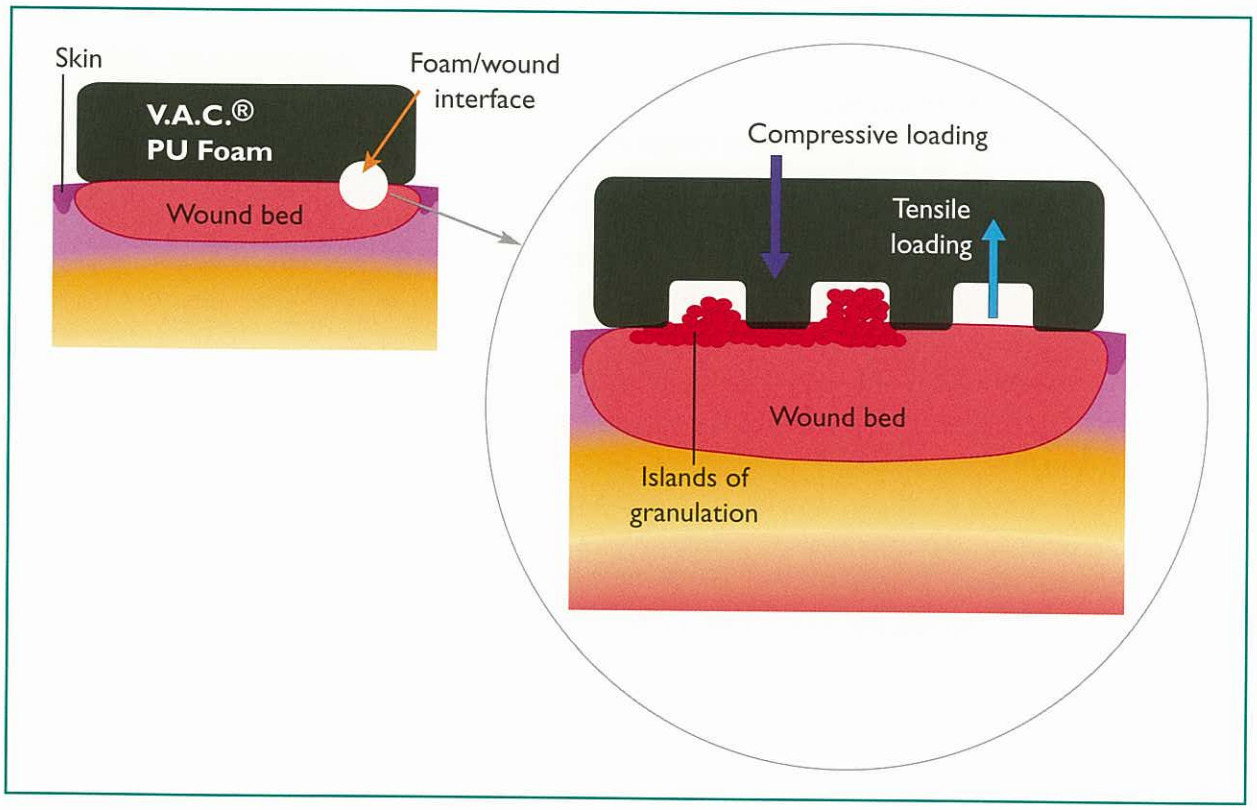

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Table III: Mechanisms of action of TNP

Use of TNP in Chronic Wounds

When using TNP in the management of chronic wounds a protocol of 125 mmHg continuous pressure has been recommended. Using this delivery strategy Joseph and colleagues[46] assessed 24 patients with 36 chronic wounds of mixed aetiology, which had been present for at least one month. Half of the wounds were treated with TNP and the other half with wet to moist saline dressings, which were changed three times a day. The change in wound volume when assessed at 6 weeks was 78% in the TNP-treated group and 30% in controls with a reduced rate of complications in the TNP-group (17% compared with 44%). Philbeck *et al.*[54] attempted to assess the cost implication of using TNP in the management of chronic wounds by comparing their cohort of individuals treated with low air loss beds and TNP with Ferrell's study[55] in which similar wounds were treated with low air loss beds ad moist dressings. Although the average cost of hiring a V.A.C.® is $100/day and the total cost of treating wounds with TNP per day was $150 compared with $95 overall costs were 38% less due to the more rapid (61% faster) rates of healing in this group.

In the literature review reported by Evans *et al.*[56] the authors describe a study in which 10 patients with diabetic foot ulceration of at least one month's duration were randomised to receive either TNP (125 mmHg continuously for 48 hours followed by intermittent therapy) or saline moistened gauze changed twice daily until definitive closure was achieved whether by secondary intention, skin grafting or flap coverage. Ulcers treated with TNP had an average period of 23 days until complete closure and a decrease in surface area of 28% compared with 43 days and 9% in the control group.[57,58] Scheufler and colleagues[59] describe a successful two-phase TNP treatment protocol used on 19 lower leg wounds each of diabetic, ischaemic and traumatic aetiology. Mean surface area prior to débridement was 24 cm^2 and all defects were full-thickness with exposed tendon or deep muscle fascia in the base of the wound, which had been unresponsive to prior conventional therapy. Their protocol consisted of surgical débridement with intravenous antibiotics as indicated and intermittent TNP at 125 mmHg (3 minutes on, 2 minutes off) for between 1 and 4 weeks until a complete layer of granulation tissue was observed. In the second phase of treatment, gentle curettage of the granulation tissue was followed by skin grafting and TNP therapy at 125 mmHg continuous pressure for a further 4–5 days. The authors achieved a 90–100% take in 17 out of 19 patients with closure achieved within 3–5 weeks. Treatment failure in the remaining 2 patients was due to infection and both responded to a repeat of the protocol.

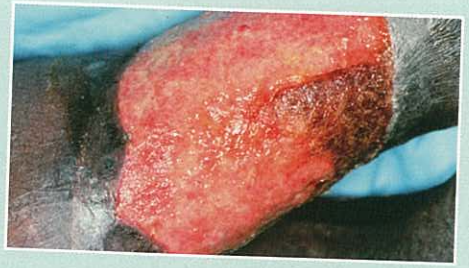

Figure 14: Non-healing leg ulcer

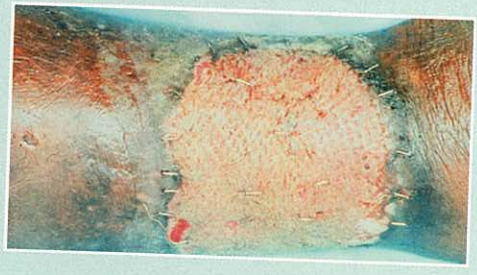

Figure 15: TNP stimulated granulation tissue prior to grafting. 100% graft take

Specific Considerations for the Use of TNP in Wounds of the Diabetic Foot

As mentioned in the preceding paragraphs, the central tenet to treatment of the non-infected, non-ischemic diabetic foot wound is appropriate debridement and offloading. Not adhering to these principles may be an explanatory variable for failure of therapy.[13,14] The patient with a diabetic foot wound is not "protected" by pain, and therefore may not perceive many warning signs of skin breakdown.[3,60] True appreciation of and accommodation for this neuropathic state is an essential component to superior wound management.

Many patients, however, have very deep, complex plantar diabetic foot wounds that are not initially amenable to simple offloading techniques. If there is not an appropriate plan for dead space management, these deep wounds are at higher risk for infection and amputation.[61] Previous treatment for these large wounds has involved extended periods of complete non-weightbearing, frequent dressing changes, and convalescence in hospital or long-term care facilities. Topical negative pressure has shown some significant utility in this patient population.[20,58,62-64] However, weight bearing on a TNP dressing has, in the past, been quite difficult because the tubing (contiguous with the polyurethane sponge) generally exits plantarly. Any weight placed on this construct could cause tissue damage.

In other parts of the body, clinicians have applied the TNP dressing using a technique known as "bridging" (Figures 16 to 19)[28,65] as a strategy to connect anatomically distant wounds to a single vacuum unit. We have modified this technique to allow for weight bearing while still using TNP. This involves applying sponges from an area of potentially high pressure and/or repetitive stress to an area that would allow for a more simple and safe connection. To be specific, the sponge is generally run from the site of the plantar diabetic foot wound to the dorsum of the foot where the TNP tubing is connected to a portable vacuum unit. The patient is then placed into an offloading device such as a removable cast walker, which can be converted into an "instant total contact cast" (Figures 16–19).[13,14,66] We have found that this allows a patient to perform many unaided ambulatory activities of daily living even while undergoing TNP therapy for a large diabetic foot wound.

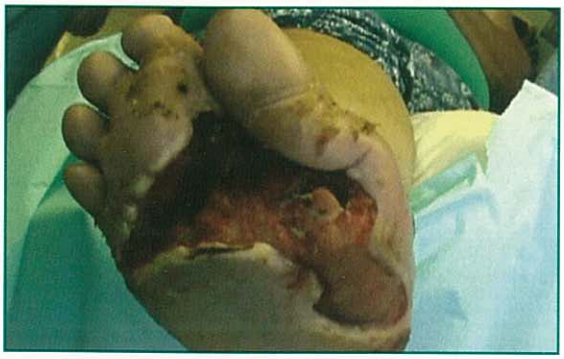

Figure 16: Large plantar diabetic foot wound prior to Topical Negative Pressure dressing application

In a recent study,[67] we evaluated the potential ability of a removable cast walker (RCW) combined with a bridged TNP dressing technique to offload the plantar aspect of the foot. The combined device offloaded the foot nearly as well as the RCW alone. The difference between the TNP-RCW and the RCW amounted to only 2% of the initial barefoot pressure imparted to the wound (Figure 20). The results of this study suggested that a modified topical negative pressure dressing coupled with a robust RCW may not impart undue additional stress to the plantar foot. This may allow patients to retain some degree of protected freedom (and a potentially reduced length of hospital stay) while still allowing for the beneficial effects of TNP therapy and sufficient offloading.

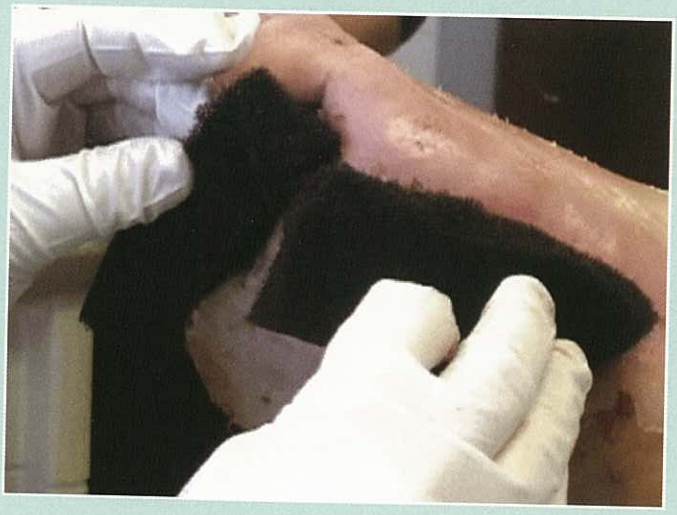

Figure 17: Open-celled foam placed into large plantar diabetic foot wound

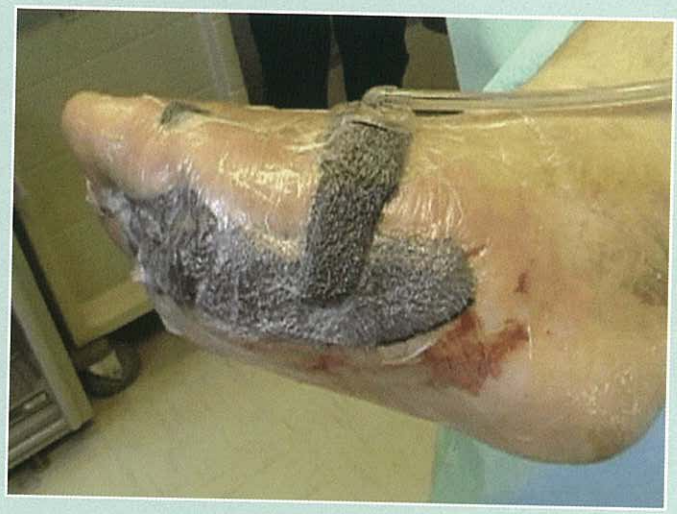

Figure 18: Clear topical negative pressure dressing applied. Note sponge bridge allowing for exit of dressing from dorsum of the foot. Tube is connected to V.A.C.® device

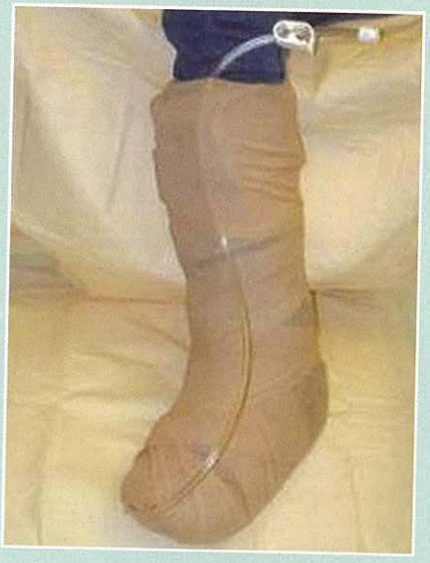

Figure 19: Topical negative pressure dressing with removable cast walker converted into "instant total contact cast", allowing for protected weight bearing. V.A.C.® device may be attached to waist-worn pack or backpack

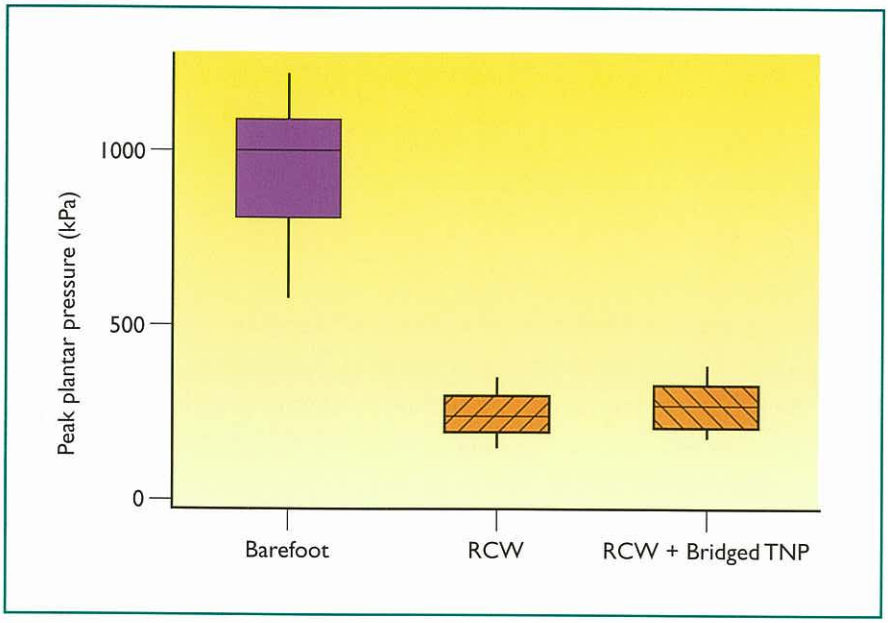

Figure 20: Plantar pressure in bridged topical negative pressure device[67]

RCW = removable cast walker

Bridged TNP = Topical Negative Pressure device applied plantarly with sponge dressing bridged to dorsum of foot

Another hybrid dressing has been developed to allow for more facility in treating heel wounds. This modality has the benefit of providing a simple, single heel cup which can completely surround the heel whilst allowing for bridging the tubing anteriorly (Figure 21). This provides the clinician the ability to offload the posterior pressure-related wound with the device of his or her choice.

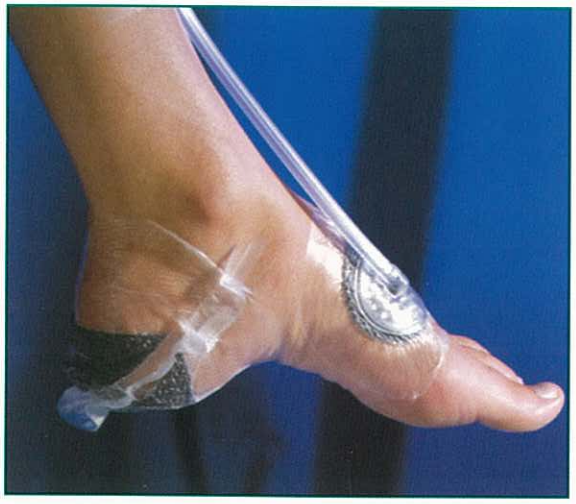

Figure 21a: V.A.C.® GranuFoam™ (black, PU foam) is conformed to fit the heel

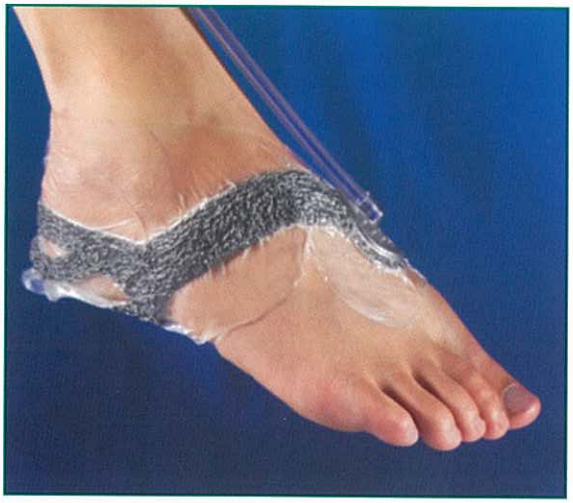

Figure 21b: TRAC™ pad bridge located on top of the foot for patient comfort

Conclusion

In conclusion, topical negative pressure therapy (TNP) appears to be a safe, efficacious, cost-effective, and practical method for promoting wound healing in persons with diabetes. Appropriate use of this modality requires careful patient selection and uncompromising attention to wound débridement, dressing application and concomitant pressure off-loading. We believe that this modality may facilitate our overall goal of improved rates of wound healing, and as a consequence, a reduction in lower extremity amputation.

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Distale Extremitätenrekonstruktion mit pedalem Bypass und Lappenplastiken beim diabetischen Fußsyndrom nach Vakuumvorbehandlung

W. Lang[1]
R. E. Horch[2]

Distal Extremity Reconstruction for Limb sSalvage in Diabetic Foot Ulcers with Pedal Bypass, Flap Plasty and Vacuum Therapy

Abstract

There are numerous factors resulting in tissue damage and foot ulcers in diabetic patients. Critical ischaemia should be routinely excluded and an examination of the limb perfusion must be done in all cases with clinical suspicion of reduced perfusion. Pedal bypass grafting procedures in combination with flap plasty techniques achieve good results in patients with non-healing diabetic ulcers. Timing of the procedure is essential to avoid progression of gangrene. Good results of pedal bypass grafts support an indication at an early stage. Vacuum assisted wound therapy and local wound surgery can be done first to prepare patients with septic foot lesions for two-staged procedures

Key words
Diabetic foot · pedal bypass · vacuum therapy · flap plasty · microvascular surgery · distal extremity reconstruction

Eine klinisch relevante periphere arterielle Verschlusskrankheit (pAVK) kompliziert bei über 50 Prozent der Diabetiker– neben statischen Veränderungen des Fußskelettes durch die diabetische Polyneuropathie – den Verlauf der Erkrankung. Bedingt durch das weit verbreitete altbekannte Vorurteil, dass beim Diabetiker eine Mikroangiopathie die alleinige Ursache der lokalen Perfusionsstörung am Fuß sei, wird diese Rate wahrscheinlich noch deutlich unterschätzt. Ein diagnostischer und therapeutischer Nihilismus ist aber aufgrund der modernen Möglichkeiten einer peripheren Revaskularisation durch krurale und pedale Bypässe bei Diabetikern mit Stenosen und Verschlüssen der Unterschenkelarterien jedoch keinesfalls gerechtfertigt. Mit gutem Recht darf man davon ausgehen, dass eine konsequente Umsetzung der Möglichkeiten einer Revaskularisation die Zahl der Majoramputationen deutlich reduzieren würde. Neben den operativen Möglichkeiten muss auch die Angioplastie (PTA) in die Therapieoptionen einbezogen werden. Dies ist Gegenstand einer gesonderten Betrachtung. Es ist aber wichtig, dass bei der Durchführung einer Angioplastie der Unterschenkelarterien (PTA) als Erstmaßnahme die distalen Anschlussgefäße am Fuß in jedem Fall geschont werden müssen, um die Anschlussmöglichkeiten für einen pedalen Bypass zu erhalten [1 – 3]. Die Konditionierung der oftmals stark verschmutzten und kontaminierten Wunden vor einer arteriellen Rekonstruktion mit Hilfe der kontinuierlichen Vakuumtherapie hat im eigenen Vorgehen eine Verbesserung der Heilungsraten und Senkung der Wundheilungsstörungen bewirkt.

Diagnostische und anatomische Voraussetzungen

Bildgebende Verfahren bei der Revaskularisation des diabetischen Fußulkus – unabhängig ob Duplexsonographie, Kernspinangiographie (MRA) oder Katheterangiographie in digitaler Subtraktionstechnik (DSA) – müssen grundsätzlich die Anschlussarterien des Fußes mit erfassen. Eine Therapieentscheidung

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Bibliografie
Zentralbl Chir 2006; 131: S146–S150 © J. A. Barth Verlag in Georg Thieme Verlag KG
DOI 10.1055/s-2006-921472
ISSN 0044-409X

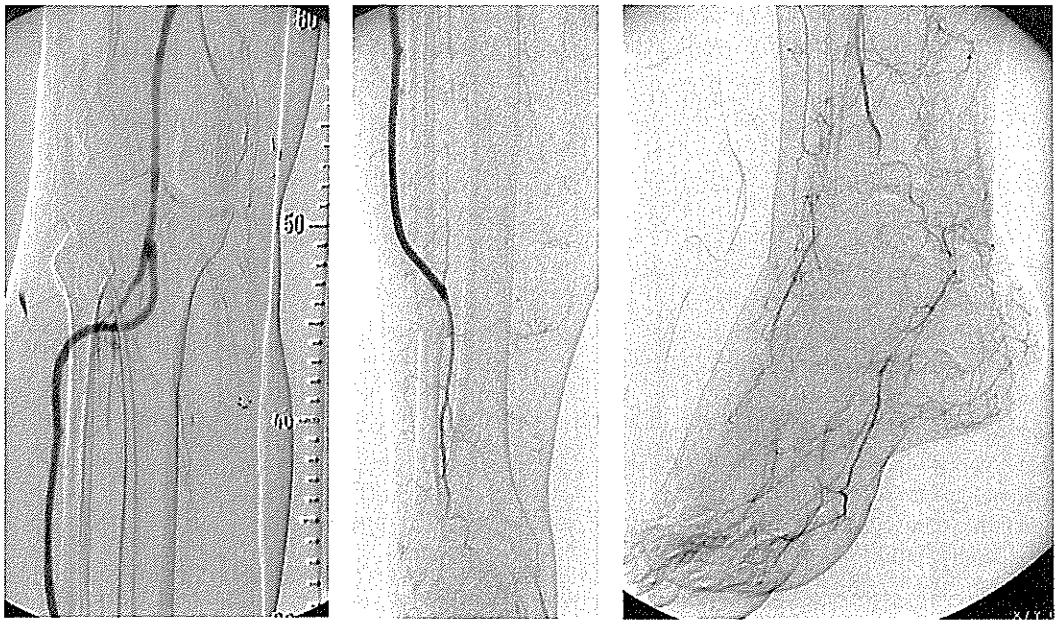

Abb. 1 Popliteo-kruraler Venen-Bypass mit lateralem Zugang an die Arteria fibularis. Indirekte Revaskularisation des Fußes über Kollateralen. **a** Proximale Anastomose und Bypassverlauf, **b** distale Anastomose, **c** Versorgung der Fußgefäße. (Bilder der Autoren, mit freundlicher Genehmigung der Dr. R. Kaden Verlag GmbH & Co. KG, Heidelberg).

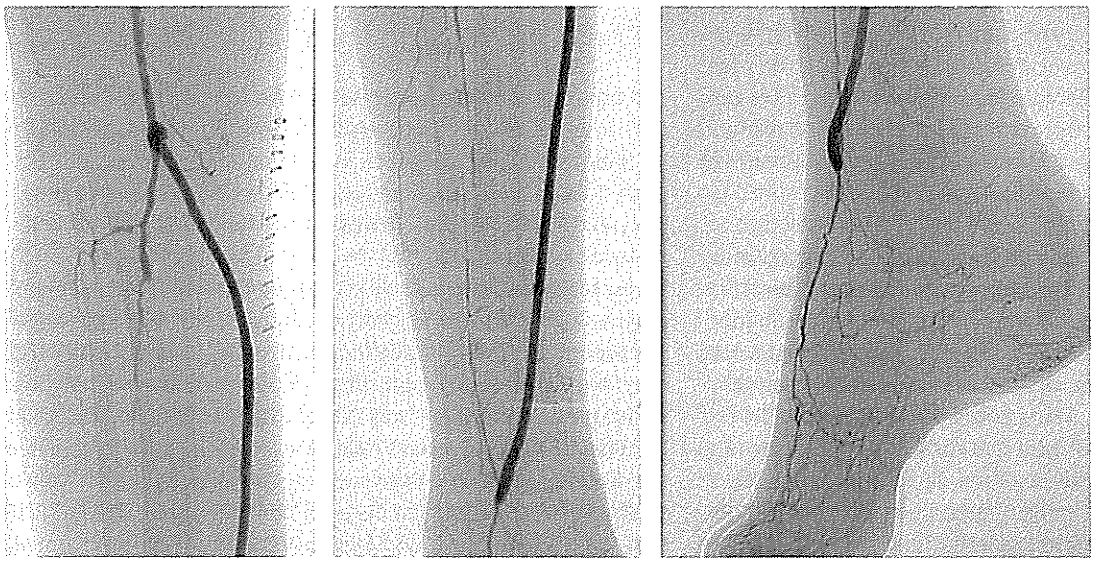

Abb. 2 Popliteo-pedaler Venen-Bypass von der infragenualen Arteria poplitea auf die Arteria dorsalis pedis. Direkte Revaskularisation der Arteria dorsalis pedis. **a**, **b** Proximale Anastomose und Bypass-Verlauf, **c** distale Anastomose auf die A. dorsalis pedis. Der Arcus plantaris ist verschlossen. (Bilder der Autoren, mit freundlicher Genehmigung der Dr. R. Kaden Verlag GmbH & Co. KG, Heidelberg).

gegen eine Revaskularisation darf nur bei korrekter und hinreichender Diagnostik erfolgen. Völlig obsolet ist hier eine Angiographie mit zentralvenöser Kontrastmittelinjektion, die so genannte venöse DSA. Unter Ausschöpfung der modernen bildgebenden Verfahren ist eine Probefreilegung einzelner Gefäße – wie sie früher häufig geübt wurde – nur noch in Ausnahmefällen erforderlich.

Die Kernspinangiographie ist bei ausgedehnterer Infektion in der Fußregion wegen der häufigen Überlagerung oftmals unbrauchbar. Sie sollte deshalb in diesen Fällen primär durch eine DSA mit selektiver Kontrastmittelinjektion ersetzt werden. Die Darstellung kruraler Arterien mit der Computertomographie wurde in den letzten Jahren immer weiter verbessert, nachteilig sind immer noch der Kontrastmittelbedarf und die schlechtere Visualisierung der pathologischen Veränderungen bei schwerer Wandkalzifikation. Hier sind viele Darstellungsoptionen anfällig für Fehler bei der Beurteilung.

Die Wiederherstellung des peripheren Pulses ist das wichtigste Therapieprinzip beim Diabetischen Fußsyndrom mit Stenosen oder Verschlüssen der Unterschenkelarterien. Obwohl scheinbar banal, ist wissenschaftlich belegt, dass das Risiko einer Majoramputation (Unterschenkel-, Oberschenkelamputation oder Kniegelenksexartikulation) bei tastbarem Fußpuls geringer ist. Häufig ist gerade beim Diabetiker trotz desolater Gefäßsituation am Unterschenkel im Bereich der Knöchel- und Fußarterien eine Anschlussmöglichkeit gegeben.

Die Arteria fibularis kann über Kollateralen Anschluss an die Gefäße des Arcus plantaris haben, so dass eine Bypass-Rekonstruktion auch auf dieses Gefäß beim Diabetiker sinnvoll ist. Der Fuß wird allerdings über die Arteria fibularis nur indirekt erreicht (Abb. **1**). Die wenn möglich bessere Lösung ist jedoch in der Erfahrung der Autoren der pedale Bypass mit direkter Revaskularisation des Fußes (Abb. **2**). Er entspricht ideal dem therapeutischen Prinzip der Wiederherstellung des Fußpulses. Bei aus-

gedehnten Weichteildefekten kann dann in gleicher Sitzung eine mikrochirurgische Gewebetransplantation mit arteriellem Anschluss der Empfängergefäße an den Bypass simultan interdisziplinär vorgenommen werden.

Indikationsstellung

Die Indikationsstellung zur Rekonstruktion mit oder ohne plastisch-chirurgische Gewebetransplantation hängt von verschiedenen Faktoren ab. Das Hauptproblem bei der Indikationsstellung zum pedalen Bypass liegt darin, den optimalen Zeitpunkt der Revaskularisation zu finden. Viele Veränderungen des diabetischen Fußes resultieren aus der Neuropathie und bedürfen meist keiner Revaskularisation. Demgegenüber ist die rein akral-ischämische Form mit Zehennekrosen etc. zwar gut zu erkennen, tritt allerdings in dieser isolierten Form sehr selten auf. Praktisch alle Patienten leiden unter einer Kombination aus peripherer Minderdurchblutung und neuropathischen Veränderungen. Die rein angiographische Darstellung des Gefäßsystems ist zur Festlegung des optimalen Operationszeitpunktes nicht geeignet.

Liegen nur isolierte Läsionen vor, kann möglicherweise mit einer Abheilung unter konservativer Behandlung gerechnet werden; versagt die konservative Therapie jedoch, dann ist es unter Umständen für einen pedalen Bypass zu spät oder der Lokalbefund ist zu weit fortgeschritten und führt zum Verlust des Beines trotz erfolgreicher Revaskularisation [2].

Da die Dopplersonographie mit Messung der Knöchel- sowie der Zehenarteriendrücke beim Diabetiker zur Klärung dieser Fragestellung nicht immer sicher beitragen kann, sollten wenn möglich in Zweifelsfällen weitere Untersuchungen der regionalen Perfusion angeschlossen werden. Hierfür eignet sich beispielsweise die Messung des transkutanen Sauerstoffdruckes ($TcPO_2$), deren Resultate wegen des Fehlerpotenzials der Untersuchung stets kritisch hinterfragt werden sollten. Um optimale Ergebnisse zu erreichen, ist es bei der Indikationsstellung zum pedalen Bypass wichtig, dass ein morphologisches und funktionelles Gesamtbild der Fußdurchblutung erstellt wird [2]. Die sehr guten Ergebnisse der pedalen Bypass-Chirurgie rechtfertigen in Zweifelsfällen eher eine großzügige Indikationsstellung [3].

Das Vorliegen eines ausgedehnten Weichteilinfektes beim zu revaskularisierenden diabetischen Fußulkus stellt an sich noch keine Kontraindikation gegen den Eingriff dar. Hier muss dann in gleicher Sitzung eine freie mikrochirurgische Rekonstruktion angeschlossen werden. Hierzu haben sich fasziokutane oder myokutane Lappen bzw. Muskellappen mit Spalthauttransplantaten bewährt.

Bypass – Technik und Materialien

Der Bypass wird fast ausschließlich von der Arteria poplitea auf eine Knöchel-/Fußarterie angelegt (popliteo-pedaler Bypass). Je nach Angiogramm und Darstellung der Fußgefäße mit Füllungsmuster des Arcus plantaris wird auf die Endstrecke der Arteria tibialis posterior oder Arteria tibialis anterior anastomosiert (A. plantaris/A. dorsalis pedis).

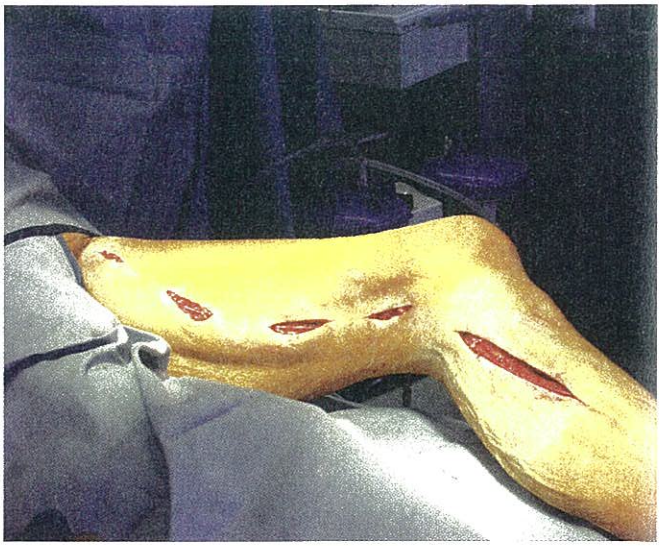

Abb. **3** Entnahme der Vena saphena magna von der Leiste bis unterhalb des Kniegelenks. Die infragenuale Inzision dient gleichzeitig als Zugangsweg zur Arteria poplitea. (Bilder der Autoren, mit freundlicher Genehmigung der Dr. R. Kaden Verlag GmbH & Co. KG, Heidelberg).

Fast immer ist der Einstrom bis in die Arteria poplitea – meist sogar bis unterhalb des Kniegelenkes – normal. Stenosen der Arteria femoralis können gegebenenfalls vor oder während des Eingriffes durch eine Ballondilatation behandelt werden. Sehr selten werden lange Bypässe von der Leiste zum Fuß erforderlich.

Verwendet wird fast ausschließlich die autologe Vena saphena magna. Ist die Vene nicht geeignet, kommen die Vene des anderen Beines, die ipsi- und/oder kontralaterale Vena saphena parva oder Armvenen in Betracht. Einzelne Arbeitsgruppen berichten auch über Erfahrungen mit Nabelschnurvene. Alloplastisches Material (PTFE, Polyester) zeigt extrem schlechte Ergebnisse und findet daher keine Verwendung – bei Anschluss von Kunststoff auf eine Fußarterie ist der Sofortverschluss der Rekonstruktion vorprogrammiert. Die Bypass-Vene wird meist in umgekehrter Flussrichtung, also „reversed" verwendet. Alternativ kann auch ein „In-situ"-Bypass angelegt werden. Wir bevorzugen die Verwendung der proximalen Vena saphena magna des Oberschenkels und proximalen Unterschenkels (Abb. **3**).

Der Vorteil einer Entnahme der Vena saphena magna von proximal liegt in der guten Venenqualität mit ausreichendem Kaliber und der Vermeidung von Hautinzisionen in den meist schlecht perfundierten distalen Abschnitten des Unterschenkels. Letzteres birgt die Gefahr postoperativer Wundheilungsstörungen an der Entnahmestelle.

Die distale Präparation der Inzision am Fuß und die Freilegung des Anschlussgefäßes muss atraumatisch erfolgen – denn an dieser Lokalisation sind Wundrandnekrosen problematisch und führen bei größerer Ausdehnung zum Verlust des Bypass trotz Durchgängigkeit. Die präoperative dopplersonographisch gesteuerte Markierung des Anschlussgefäßes, etwa der Arteria dorsalis pedis am Fußrücken, optimiert die Inzision und sollte standardmäßig eingesetzt werden. Die Sonographie gibt auch wertvolle Hinweise auf die Wandbeschaffenheit (Lage und Ausdeh

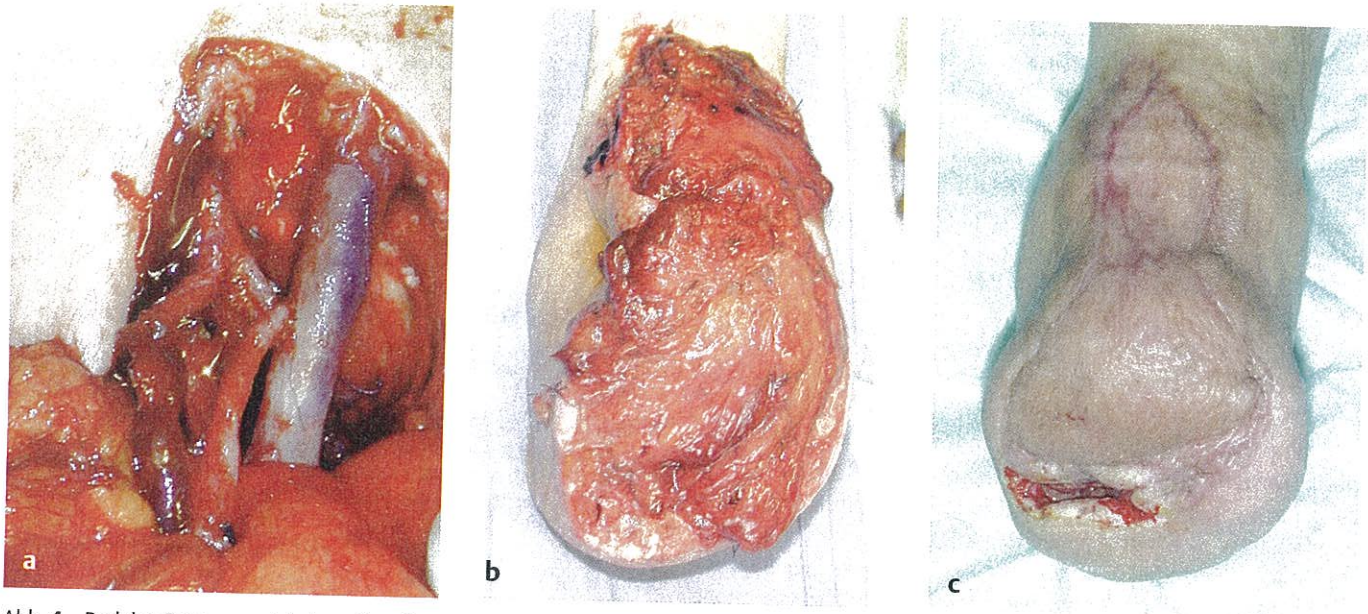

Abb. **4** Pedaler Bypass und freier mikrochirurgisch angeschlossener Omentumlappen zur Deckung eines ausgedehnten Vorfußdefekts. **a** Mikrovaskuläre Anastomose der Arteria epiploica auf den pedalen Bypass am Fußrücken, **b** Situation vor Spalthautdeckung, **c** Abheilungsergebnis. (Bilder der Autoren, mit freundlicher Genehmigung der Dr. R. Kaden Verlag GmbH & Co. KG, Heidelberg)

nung der Sklerose), schließt allerdings auch bei zirkumskripten Verkalkungen die Operabilität nicht aus.

Vorteilhaft ist die Anlage der proximalen vor der distalen Anastomose. Dies erleichtert die Längenadaptation des Bypass. Zusätzlich wird verhindert, dass bei Freigabe des Blutstroms in den Bypass abgelöste Plaquepartikel aus der arteriosklerotischen Arteria poplitea in die kleinen distalen Fußgefäße embolisieren. Bestehen größere Defekte, zum Beispiel nach ausgedehnten Grenzzonenamputationen im Vor- und Mittelfuß, kann der pedale Bypass als Spendergefäß für einen mikrovaskulären freien Lappen dienen. Hier hat sich im eigenen Vorgehen das einzeitige Verfahren mit gleichzeitiger Lappentransplantation – wenn immer möglich – als die komlikationsärmere Variante erwiesen.

Die Kombination mit dem plastisch-chirurgischen Eingriff ist zum Einen dann sinnvoll, wenn sich aus dem Situs nach der Minoramputation kein belastungsfähiger Fußstumpf ergeben würde. Zum anderen kann das Freiliegen von Knochen, Gelenken, Gefäßen, Nerven oder Sehnen – entweder bereits vor oder oft nach dem notwendigen radikalen Débridement – in der Regel nicht mit einfachen Hauttransplantaten zur Ausheilung gebracht werden [8].

Die Ausheilung von großen, insbesondere knöchernen Defekten oder beim Freiliegen von Gelenken oder Implantaten unter den klinisch schwierigen Bedingungen der schlechten Vaskularisation, erfordert die Transplantation von primär durchblutetem Gewebe zur sicheren Induktion der Knochenneubildung. Derzeit stellt der mikrochirurgische freie Gewebetransfer hier den chirurgisch-therapeutischen Standard dar. Auch ein hohes Patientenalter ist dabei heute keine Kontraindikation gegen einen solchen freien Gewebetransfer mehr, wichtiger ist die Compliance des Patienten. Bis zur definitiven Defektdeckung kann heutzutage vor der freien Transplantation etwa eine kontinuierliche lokale Unterdruckbehandlung mit einer computergestützten Therapieeinheit (V.A.C.®, KCI, Wiesbaden) zur Induktion von Granulationsgewebe und zur Verbesserung des Wundgrundes erforderlich sein [4, 5, 10]. Dadurch entfallen die häufigen Verbandswechsel und eine weitere Kontamination der Wunde wird ebenso vermindert wie die Verbreitung der oft resistenten Wundkeime im Krankenhaus, da es sich bei der Vakuumtherapie prinzipiell um ein geschlossenes System handelt.

Im Einzelfall ist auch bei der hier beschriebenen kombinierten Vorgehensweise selbstverständlich die Sanierung vorliegender Skelettdeformitäten des Fußes – wie sie gerade beim Charcot-Fuß anzutreffen sind – für den langfristigen Erfolg beim Diabetiker erforderlich. Hier ist vor allem die orthopädische Fußchirurgie gefordert, deren Hauptziel eine knöcherne Sanierung unter Berücksichtigung biomechanischer Gegebenheiten am Fußskelett sein sollte. Je nach Art und Ausmaß des Defektes kommen entweder Muskellappen mit Spalthauttransplantaten [6, 7, 9, 12–14] oder fasziokutane Lappen [11] in Kombination mit dem pedalen Bypass zur Anwendung [6]. Im eigenen Vorgehen konnte in der interdisziplinären Zusammenarbeit das neue Konzept der simultanen Extremitätenrekonstruktion durch einen pedalen Bypass und der Anschluss eines minimal-invasiv gehobenen, freien mikrochirurgischen Omentum-majus-Transplantates mit Spalthauttransplantation als ein elegantes Verfahren mit vergleichsweise geringer Hebemorbidität und hoher angiogener Potenz des Lappens etabliert werden (Abb. **4**). Diese Technik eröffnet auch Optionen, die gelegentlich hohe Spendermorbidität nach myokutaner Lappenentnahme zu minimieren und ein Gewebe mit sehr hoher Infektresistenz zu transplantieren.

Postoperative Behandlung

Da eine starke postoperative Schwellung zu einer Wundrandnekrose und Wundinfektion führen kann, ist die lokale Nachbehandlung der distalen Wunde am Fuß großer Bedeutung. Da

der Bypass an dieser Stelle praktisch keine Weichteildeckung hat, muss auch ein erhöhter Druck durch Verbände, Schuhe etc. strikt vermieden werden. Die abgestufte Mobilisation des Patienten kann erfolgen, wenn sich keine relevante Schwellung mehr zeigt. Da im Bereich der Fußwunde auch bei primärer Wundheilung mit verzögertem Verlauf zu rechnen ist, verbleiben die Hautfäden meist sechs bis zehn Tage länger als sonst üblich. Die Empfehlungen zur medikamentösen Nachbehandlung sind nicht einheitlich [3].

Bei einer postoperativen Antikoagulation mit Heparin ist die Gefahr einer Hämatombildung, im Vegleich zur alleinigen Gabe von Thrombozytenfunktionshemmern (z.B. Acetylsalicylsäure 100 mg p.o.) in Kombination mit einem niedermolekularen Heparin (Dosierung wie zur Thromboseprophylaxe), unserer Erfahrung nach erhöht. Ob eine längerfristige orale Antikoagulation empfohlen wird hängt – neben den allgemeinen Kontraindikationen – im Einzelfall auch von der Beschaffenheit der Bypass-Vene und den Zu- und Abstromverhältnissen ab. Überträgt man die Ergebnisse der BOA-Studie auf pedale Bypässe würden sich hieraus Vorteile einer oralen Antikoagulation unter Inkaufnahme einer höheren Rate an Blutungskomplikationen ergeben.

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Samstag, 28. März 2009
11.00–12.00 Diabetologie, Dermatologie

Konsolidierung schwieriger Wundflächen beim Diabetischen Fuß – Ein Fallbericht

Consolidation of difficult wound areas at diabetic foot syndrome – a case report

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Zusammenfassung
Im Folgenden berichte ich über einen Patienten, der sich aufgrund einer rechtsseitigen Vorfußphlegmone bei peripherer arterieller Verschlusskrankheit (pAVK) und bisher unzureichend behandeltem Diabetes mellitus Typ II über insgesamt 98 (85+13) Tage in unserer stationären Behandlung befand. Nach initial konservativer Therapie, Neueinstellung des Diabetes Mellitus, der Hypertonie und Behandlung der begleitenden Niereninsuffizienz wurde eine erfolgreiche perkutane transluminale Angioplastie (PTA) der A. tibialis posterior durchgeführt. Im Anschluss daran wurde in zwei Operationen der ausgedehnte Lokalbefund debridiert sowie die 3. und 4. Zehe reseziert. Durch ein phasenadaptiertes Wundmanagement sowie eine begleitende Prostavasintherapie und hyperbare Sauerstoffbehandlung konnte eine Konsolidierug der Wundverhältnisse erreicht werden. So wurde im weiteren Verlauf mit einer VA.C.®-Therapie mit dem GranuFoam® begonnen, welche eine deutliche Granulationsförderung erbrachte. Die letzten beiden Wochen der V.A.C.®-Therapie wurden ambulant in Absprache mit der Krankenkasse und der Firma KCI im Wundzentrum der Paracelsusklinik in Hannover weitergeführt. Im Anschluss daran wurde die plastische Deckung des Defektes des rechten Fußes mit autologer Spalthaut durchgeführt. Dabei wurde am distalen Wundpol die 2. Zehe nachreseziert. Postoperativ zeigte die Meshgraft unter zwei V.A.C.®-Therapie Zyklen mit dem V.A.C.®-WhiteFoam eine gute Einwachsungstendenz, welche sich nach Entlassung in nachstationären Kontrollen bestätigte.

Schlüsselwörter
Vakuumtherapie, Wundmanagement, Diabetisches Fußsyndrom

Summary
In the following I comment on a patient in advanced stage IV of paod with phlegmon of the right lower leg. Duration of hospital treatment was 98 days. After conservative therapy, new settings in the treatment of diabetes mellitus, hypertension and associated renal insufficiency a successful subintimal angioplasty (PTA) of the posterior tibial artery was carried out. Subsequent to that the vast local findings have been debrided as well as the 3rd and 4th toe have been resected. By stage adapted wound management as well as accompanying Prostavasin®-therapy and hyperbaric oxygen treatment consolidation of the extended wound could be achieved. Ongoing treatment under V.A.C.®-therapy with the GranuFoam® results in good granulation process. The last two weeks of the vacuum therapy were continued outpatiently in arrangement with the health insurance and the KCI company in the local wound-centre Hannover. For covering the remained wound defect of the right foot autologous mesh graft plastic was carried out later on. Thereby the 2nd toe has been further resected. Postoperatively the mesh graft showed good ingrowing tendencies after two cycles of V.A.C.®-therapy with the WhiteFoam®. After discharge consistently outpatient examinations confirmed these findings.

Key words
Vacuum-therapy, wound management, diabetic foot syndrome

Einleitung
Der 63-jährige Patient wurde am 30.11.2007 aufgrund einer rechtsseitigen Vorfußphlegmone bei eigenanamnestisch vorbekannter peripherer arterieller Verschlusskrankheit (pAVK), Diabetes Mellitus Typ II und arterieller Hypertonie über unsere Not- und Unfallaufnahme aufgenommen. Der rechte Fuß zeigte sich bei Aufnahme am Dig. Ped. III blau livide verfärbt, Dig. Ped. I und II waren ebenso wie der Fußrücken gerötet und überwärmt. Bei intakter Motorik war die Sensibilität eingeschränkt. Es bestand eine Lymphangiitis bis zum proximalen Unterschenkel begleitet von einer erheblichen Schwellung (Abbildung 1). Eine bei Aufnahme angefertigte Röntgenaufnahme des Vorfußes in zwei Ebenen zeigte bis auf ein kleines Enchondrom im medialen Anteil des Köpfchens des Os metatarsale I die Phalangen und Metatarsale sowie mitabgebildeten Fußwurzelknochen regelrecht bei erhaltener Grenzlamelle und glatt abgrenzbarer Kortikalis ohne Nachweis eines osteomyelitischen Geschehens. Die Dopplerverschlussdruckmessung erbrachte rechtsseitig einen Knöchel-Arm-Index von 0,66 für die A. tibialis posterior und 0,25 für die A. dorsalis pedis. Linksseitig lagen die Werte bei diabetischer Mediasklerose weit über 1,2.

Hauptteil
Aufgrund der Vorfußphlegmone sowie Zeichen einer begleitenden systemischen Entzündungsreaktion (bei Aufnahme: CRP 20,5 mg/dl, Leukozyten 23,82x10*9/l, Temperatur 36,8°) erfolgte zunächst eine konservative Behandlung mittels Entlastung, Ruhigstellung des Fußes und kalkulierter Antibiose nach Abstrichentnahme. Der Patient wurde vollheparinisiert. Es erfolgte auch eine Blutdruckneueinstellung. Neben der lokalen Symptomatik war vor allem eine schwere Niereninsuffizienz mit erhöhten Retentionswerten und einer folgenden Elektrolytentgleisung auffällig (bei Aufnahme: Kreatinin 234 µmol/l, Harnstoff 20,96 mmol/l, Kalium 4,4 mmol/l). Nach Verbesserung der Nierenfunktion wurde zunächst eine DSA der Becken-Beinstrombahn durchgeführt. Dabei zeigte sich eine pAVK vom Unterschenkeltyp rechts mit reduziertem peripheren Ausstrom über

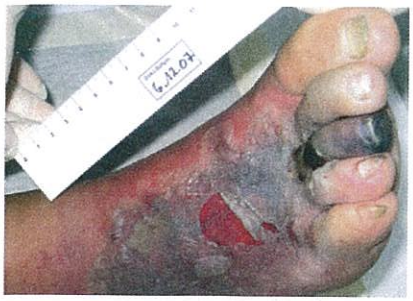

Abb. 1: 06.12.07 – Initialer Befund mit rechtsseitiger Vorfußphlegmone und Nekrose der 3. Zehe

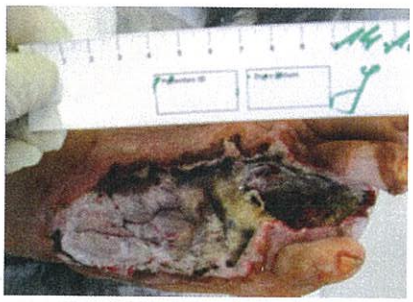

Abb.3: 14.12.2007 – Befund nach Wunddébridement und Amputation der 3. und 4. Zehe

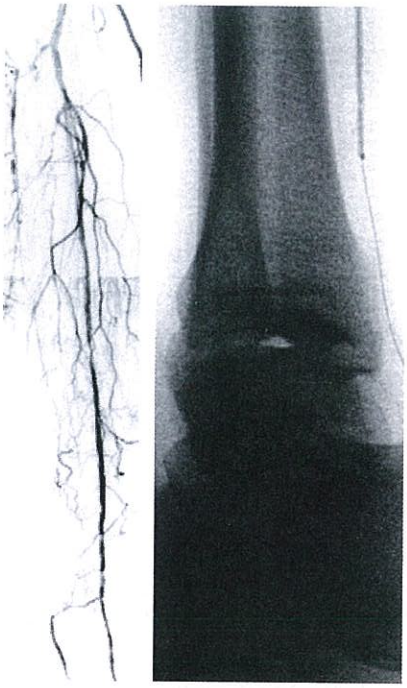

Abb. 2a: 04.12.07 – Befund vor PTA; Abgangsverschluss und langstreckige Stenosierung der A. tibialis posterior am Truncus

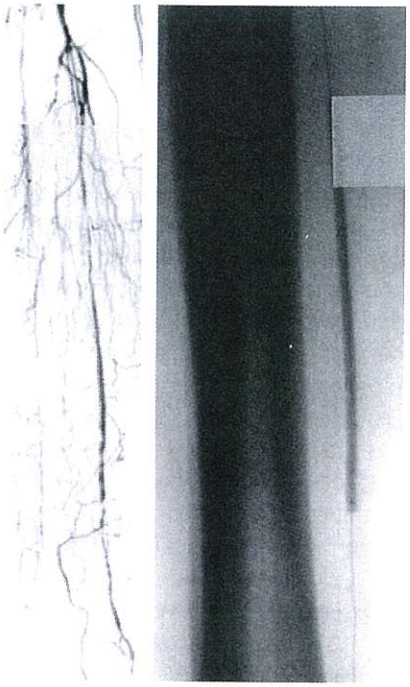

Abb. 2b: 04.12.07 – Befund nach PTA; Wiederauffüllung der A. tibialis posterior nach Dilatation der multiplen Stenosierungen

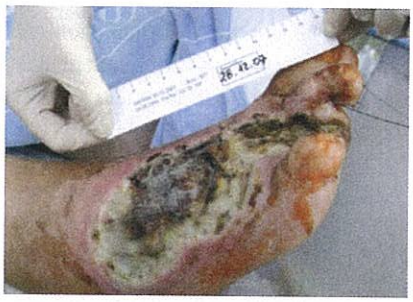

Abb. 4: 28.12.2007 – Befund 2 Wochen nach operativem Débridement; nekrotisch belegte Wundfläche

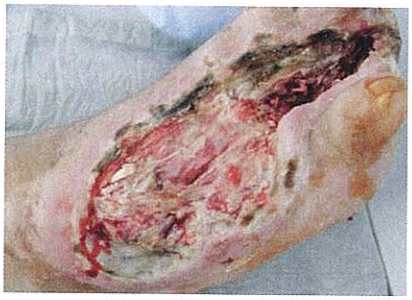

Abb. 5: 28.12.2007 – Befund 2 Wochen nach operativem Débridement; nach Abtragung der nekrotisch belegten Wundfläche

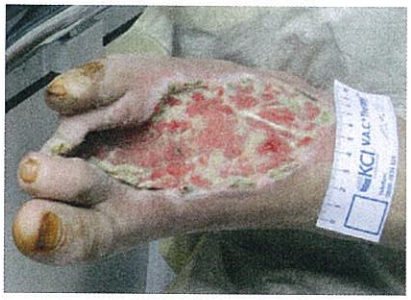

Abb. 6: 19.01.2008 – Befund nach 1. Zyklus (4 Tage) V.A.C.®-Therapie

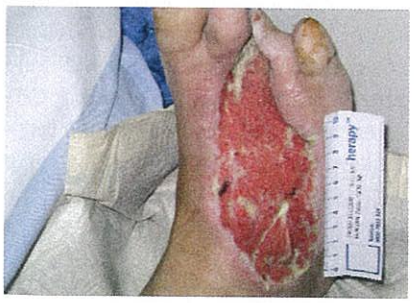

Abb. 7: 08.02.2008 – Befund nach 5. Zyklus V.A.C.®-Therapie

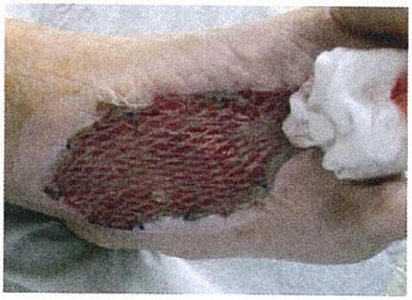

Abb. 8: 13.03.2008 – Befund nach 1 Zyklus V.A.C.®-Therapie (3. Tag) nach plastischer Deckung mittels Spalthauttransplantation

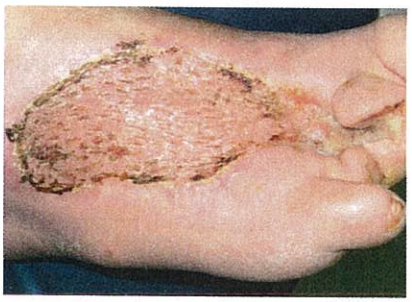

Abb. 9: 27.03.2008 – Befund 17 Tage nach plastischer Deckung; die Spalthaut ist bereits gut eingewachsen

die A. tibialis posterior, die multiple, z.T. hochgradige Stenosierungen aufwies. Im Rahmen unserer interdisziplinären Gefäßkonferenz entschlossen wir uns daher für einen PTA-Versuch (perkutane transluminale Angioplastie) der multiplen Stenosierungen der A. tibialis posterior im gesamten Verlauf als Ultima Ratio vor einer sich abzeichnenden Grenzzonenamputation. Die PTA wurde am 04.12.2007 erfolgreich durchgeführt (Abbildung 2a und 2b). Die postinterventionelle Dopplerverschlussdruckmessung ergab rechts eine Verbesserung des Knöchel-Arm-Index der A. tibialis posterior von 0,66 auf nun über 1 und der A. dorsalis pedis von 0,25 auf 0,65.

Trotz sofort begonnener systemischer Antibiose, erfolgreicher PTA und lokaler Wundbehandlung kam es zu einer raschen Ausbreitung der Fußrückennekrose und zu einer kompletten Nekrose der 3. Zehe rechts. Daher erfolgte im Rahmen eines operativen Débridements der Fußrückennekrose am 10.12.2007 auch eine transmetatarsale, offene Amputation der 3. Zehe (Abbildung 3). In der Tiefe der Wunde traten im Verlauf weitere Nekrosen auf, so dass drei Tage später, am 13.12.2007, eine Wundrevision mit Nachamputation des 3. Mittelfußknochens und Amputation der nun auch nekrotischen 4. Zehe durchgeführt wurde. Danach herrschten saubere Wundverhältnisse, wobei in der Tiefe des distalen Wundpols noch der 2. Mittelfußknochen freilag (Abbildung 4, 5).

Bevor nun weitere chirurgische Maßnahmen erfolgen sollten, wurde ein erster Versuch mittels Anlage eines V.A.C.®-Verbands unternommen. Allerdings zeigte die Wunde darunter keine wesentliche Granulationstendenz, so dass zunächst weiter Feuchtverbände mittels Lavasept® getränkter Kompressen angelegt wurden. Des Weiteren begannen wir eine hyperbare Sauerstofftherapie, welche in Zusammenarbeit mit dem Druckkammerzentrum Hannover durchgeführt wurde. Unter dieser Therapie und unter phasenadaptierter lokaler Wundbehandlung kam es erfreulicherweise zu einer deutlichen Besserung der Wundverhältnisse. Flankierend führten wir über drei Wochen eine Prostavasintherapie durch.

Nach Stabilisierung des Lokalbefunds wurde erneut eine V.A.C.®-Therapie mit dem GranuFoam® begonnen. Darunter kam es nun zu einer guten Granulation des Gewebes (Abbildungen 6, 7). Wir führten insgesamt 38 Tage (8 Zyklen) diese Therapie durch. Ein Vorfußentlastungsschuh wurde angepasst, so dass der Patient frühzeitig mobilisiert werden konnte. Bei klinisch deutlicher Besserung des Allgemeinzustandes des Patienten konnte er nach 85 Tagen Krankenhausaufenthalt am 22.02.2008 aus der stationären Behandlung entlassen werden. Die Wunden waren jedoch noch nicht ausreichend konsolidiert, um eine plastische Deckung mittels einer autologen Spalthauttransplantation durchzuführen. Außerdem war das Areal um den 2. Mittelfußknochen am distalen Wundpol noch fibrinbelegt und teilweise nekrotisch, so dass eine Nachresektion der 2. Zehe im Verlauf noch ausstand. Die Wundverhältnisse hatten sich aber so weit stabilisiert, dass unter engmaschiger Wundkontrolle und Fortführung der V.A.C.®-Therapie zur Sicherung der weiteren Wundkonditionierung eine ambulante Weiterbehandlung möglich war. Nach Rücksprache mit der zuständigen Krankenkasse und individueller Darstellung der Therapieindikation bei diesem Patienten wurden die Kosten für die ambulante V.A.C.®-Therapie letztlich übernommen. Die ambulante Betreuung erfolgte in Absprache mit der Krankenkasse und der Firma KCI in einem ambulanten Wundzentrum in Hannover.

Nach 2 Wochen (5 Zyklen) ambulanter V.A.C.®-Therapie stellte sich der Patient bei jetzt ausreichend konsolidierten Wundverhältnissen in unserer Abteilung erneut vor. Es sollte nun die plastische Deckung des ca. 12x5 cm betragenden dorsalseitigen Defektes sowie bei freiliegendem 2. Mittelfußknochen auch eine transmetatarsale Nachresektion der zweiten Zehe des rechten Fußes erfolgen. Diese wurde am 10.03.2008 durchgeführt. Noch intraoperativ wurde auf die transplantierte Meshgraft ein V.A.C.®-WhiteFoam und im Bereich der Nachresektion am distalen Wundpol ein GranuFoam® angelegt. Die Operation wie auch der postoperative Verlauf gestalteten sich komplikationslos. Beim ersten Verbandwechsel am 2. postoperativen Tag zeigte sich die Spalthaut vital mit einer guten Einheilungstendenz (Abbildung 8). Wir führten noch einen weiteren V.A.C.®-Therapy Zyklus mit dem V.A.C.®-WhiteFoam durch, wobei der distale Wundpol mit Alginaten (suprasorb®) gesondert verbunden wurde. Am 22.03.2008 konnten wir den Patienten aus unserer stationären Behandlung entlassen. In nachstationären Kontrollen zeigten sich eine gut eingewachsene Meshgraft auf dem Fußrücken und saubere Wundverhältnisse unter Alginatverbänden am distalen Wundpol (Abbildung 9).

Tab. 1: Indikationen der Vakuumversiegelungstherapie

Indikationen der Vakuumversiegelungstherapie	
Wunden, die alleine keine ausreichende Heilungstendenz zeigen	• Ulcus cruris - venosum - arteriosum - diabeticorum • Deukubitalulcus
Wunden, die besonderen Schutz benötigen	Akute/postoperative Wunde: • Hidradenitis suppurativa • Versorgung sekundär heilender Wunden, Tumorchirurgie • Sicherung von Hauttransplantaten • Exulzerierte Tumoren in der Palliativversorgung
Seltenere Wunden durch	• Vaskulitiden • Pyoderma gangraenosum • Kalziphylaxie

Fazit

Zusammenfassend kann man sagen, dass unter entsprechender Indikation sowie insbesondere in der richtigen Phase der Wundheilung, also während der Proliferationsphase, die V.A.C.®-Therapy eine erfolgversprechende Möglichkeit zur Konsolidierung schwieriger oder größerer Wundflächen ist. In diesem Fall konnte durch ein komplexes Therapiekonzept mittels Revaskularisation, Diabetesneueinstellung sowie flankierender Maßnahmen wie der Prostavasintherapie und einer hyperbaren Sauerstoffbehandlung auch durch die V.A.C.®-Therapy mit dem GranuFoam® und V.A.C.®-WhiteFoam der Verlust des rechten Fußes des Patienten verhindert werden. Durch die Möglichkeit der ambulanten V.A.C.®-Therapy und Wundkontrolle im Wundzentrum Hannover konnte auch der Krankenhausaufenthalt verkürzt werden.

european surgery
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12 Jahre Erfahrung mit der V.A.C.® bei der Therapie des diabetischen Fuss-Syndroms

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Zusammenfassung. Grundlagen: Nach Teilverlust des Fusses durch diabetische Wunden stellt die Therapie mit negativem Druck die wirksamste Therapieform zur Vermeidung von Majoramputationen dar.

Methodik: Während der letzten 12 Jahre kam die V.A.C.® Therapy im SMZ-Ost Donauspital, Wien, bei 209 Patienten mit diabetischen Fussläsionen in den Stadien II B, D bzw. III B, D nach *dem Armstrong-Score* zum Einsatz. Der Altersdurchschnitt betrug 64 (35–86) Jahre und die Therapiedauer 21 (15–34 Tage).

Ergebnisse: Bei 95 Patienten (87,9%) war die Therapie erfolgreich, und es gelang, eine Majoramputation zu vermeiden.

Schlussfolgerungen: Unsere langjährige Erfahrung zeigt, dass die V.A.C.® Therapy es ermöglicht, die Zahl der Majoramputationen bei Stadien II bzw. III B und D zu verringern.

Schlüsselwörter: Diabetisches Fuss-Syndrom, V.A.C.® Therapy

12 years experience with V.A.C.® Therapy in diabetic foot syndrome

Summary. Background: Negative pressure wound therapy (V.A.C.® Therapy) is proven as the most effective treatment after partial diabetic foot amputation.

Methods: During the last 12 years we treated 209 patients with diabetic foot lesions in stage II B, D and III B, D, respectively, according the *Armstrong-Score* in the SMZ Ost Donauspital, Vienna. Mean age was 64 (35–86) years and duration of V.A.C.® Therapy was 21 (15–34) days.

Results: In 95 patients (87.9%) major amputation was avoided using the negative pressure wound therapy.

Conclusions: In our hands V.A.C.® Therapy is proven to lower the number of major amputation in patients with diabetic foot syndrome.

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Keywords: Diabetic foot syndrome, V.A.C.® Therapy

Grundlagen: Die V.A.C.® Therapy ist nun seit mehr als einem Jahrzehnt in der Behandlung des diabetischen Fuss-Syndroms etabliert [1, 2] und ist die wirkungsvollste Möglichkeit durch Fuss-erhaltende Teilamputationen Majoramputationen zu vermeiden. Bei schlechter Durchblutung und Infektion ermöglicht die kontinuierliche Sekretableitung eine Keimreduktion und eine Verringerung des Ödems in der Wundumgebung. Eine raschere Granulationsgewebsneubildung ist die Folge. Die Anwendung des mit Silberionen versetzten Schwammes aus Polyurethanschaum ermöglicht den kombinierten Einsatz der negativen Druckbehandlung und der topischen Anwendung von Silberionen [3–5].

Methodik: Von 11.10.1995 bis 31.12.2007 wurden im SMZ-Ost Donauspital, Wien, 209 Patienten mit diabetischen Fussläsionen in den Stadien II B, D bzw. III B, D nach *dem Armstrong-Score* behandelt. Bei 108 dieser Patienten kam nach einer Fuss-erhaltenden Teilamputation (Minoramputation) die V.A.C.® Therapy zur Anwendung (Tab. 1). Bei den Patienten ohne V.A.C.® Therapy wurde entweder die Resektionen von einer oder mehrerer Zehen ohne grösserer Weichteildefekte durchgeführt, oder es bestand eine inkurable Situation mit Totalgangrän des Fusses ohne Möglichkeit einer Revaskularisation.

Die mit V.A.C.® behandelten Patienten wiesen grössere Defekte auf, die nach der Wundkonditionierung mit Spalthaut gedeckt wurden. Das Durchschnittsalter dieses Kollektivs betrug 64 (35–86) Jahre. Die Behandlung der Grundkrankheit (Blutzuckereinstellung), die Infektionsbehandlung (systemische Antibiotikagabe und lokale antiseptische Therapie) sowie die Optimierung der Durchblutung (interventionell bzw.

Tab. 1: Eingesetzte Geräte

N	Gerät
5	mini-V.A.C.®
6	V.A.C. Freedom®
25	V.A.C.® Classic
67	V.A.C. ATS®
3	InfoV.A.C.®
2	ActiV.A.C.®
108	

medikamentös) wurden gleichzeitig mit der Behandlung der diabetischen Läsion durchgeführt. Nach weitgehend kompletter Entfernung aller Nekrosen und bradytropher Strukturen kam nach Beherrschung der Infektion die V.A.C.® Therapy zum Einsatz. Ziel war ausreichend Granulationsgewebe zu bilden, um die Defekte zu decken. Bei 105 Patienten war die durch Spalthauttransplantation und bei drei Patienten mit Lappenplastiken möglich Die Therapiedauer bis zum Defektverschluss betrug 21 (15–34) Tage. Zur Fixation der Spalthauttransplantate kam die V.A.C.® Therapy für weiter 4–5 Tage zum Einsatz.

Ergebnisse: Bei 95 von 108 (87,9%) mit der V.A.C.® Therapy behandelten Patienten gelang es, den Fuss zu erhalten und eine Majoramputation zu vermeiden. Allerdings war in der ersten Periode zwischen 1995 und 2000 die Rate an Abbrüchen höher (4 von 16) als ab 2001 (9 von 92) (Tab. 2). Die grössere Erfahrung und damit eine strengere Indikationsstellung sind als Gründe dafür anzusehen.

Tab. 2: Rate an Therapieabbrüchen (Majorampuationen)

Zeitraum	Anzahl
1995–2000	4 von 16
2001–2007	9 von 92
	13

Es ist auch der Altersdurchschnitt niedriger geworden, da vermehrt jüngere Patienten mit der Fussläsion als Erstmanifestation des Diabetes mellitus in dieser Gruppe zu finden sind. Die Einführung des Granufoam-Silberschwamms scheint den Einsatz der V.A.C.® Therapy zu einem früheren Zeitpunkt zu ermöglichen. Die ersten Erfahrungen zeigen, dass der Einsatz nun auch in den Stadien C und D (nach *Armstrong*) ohne wesentliches Risiko möglich ist.

Fallbeispiel 1 (Abb. 1a–d): Bei diesem 36-jährigen Patienten trat die diabetische Fussläsion als Erstmanifestation der Erkrankung auf. Er behandelte die „Blase" an der Fusssohle, die nach einer längeren Wanderung aufgetreten war, 2 Wochen selbst. Mit einer ausgedehnten Nekrose und Phlegmone kam er mit folgenden Laborwerten zur Aufnahme: CRP: 339 mg/dl, BZ 228 mg% und Leukozyten 19.600. Nach mehrfachen Nekrosektomien und der Infektionsbehandlung mit einer Wundfolie mit nanokristalinem Silber (Acticoat®, Smith & Nephew) kam die V.A.C.® Therapy für 22 Tage zum Einsatz. Anschliessend erfolgte die Spalthautdeckung und die Läsion heilte ab.

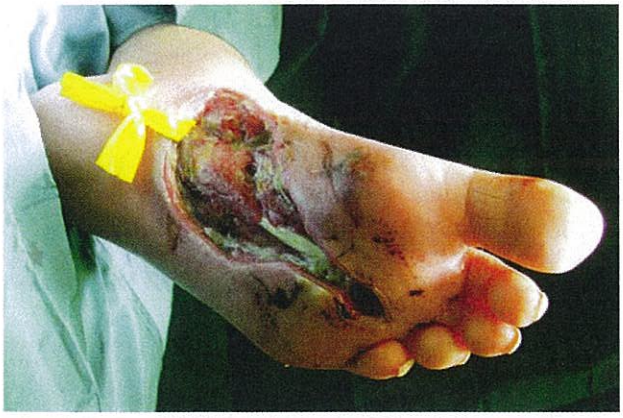

Abb. 1a: Wunde am Beginn der V.A.C.® Therapy

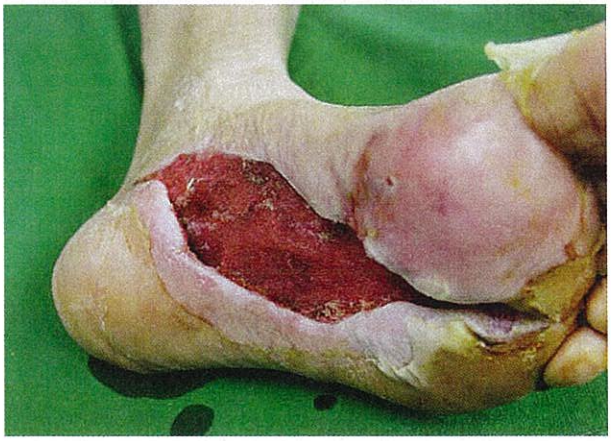

Abb. 1b: Nach 22 Tagen V.A.C.® Therapy, vor der Spalthautdeckung

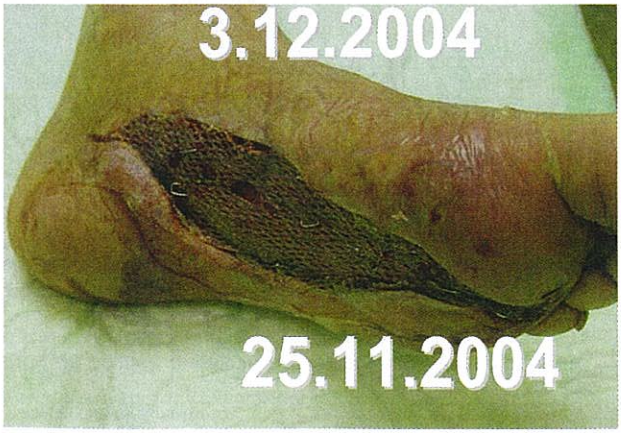

Abb. 1c: Wunde fünf Tage nach Spalthautdeckung

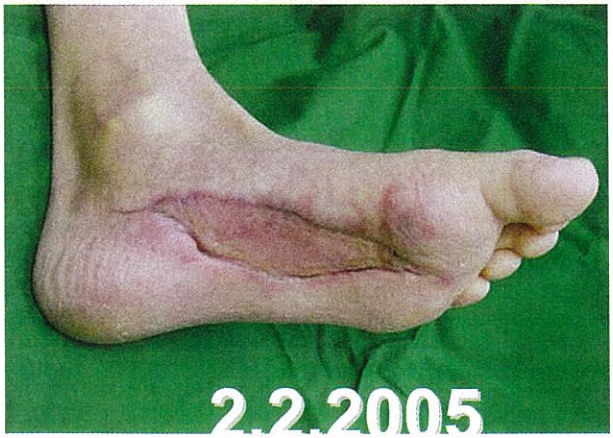

Abb. 1d: Abgeheilte Läsion nach zwei Monaten

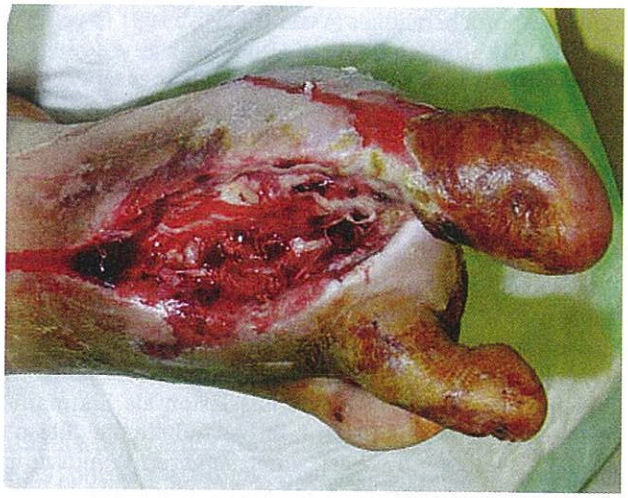

Abb. 2a: Wunde am Beginn der V.A.C.® Therapy

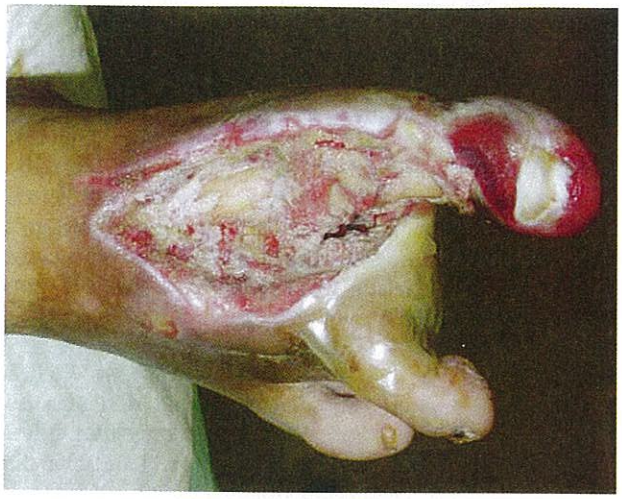

Abb. 2b: Nach 21 Tagen V.A.C.® Therapy mit dem V.A.C. GranuFoam Silver® Dressing, vor der letzten operativen Revision

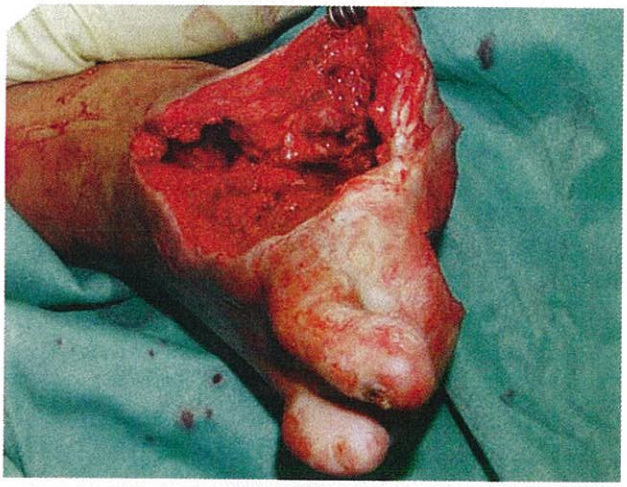

Abb. 2c: Intraoperatives Bild: Entfernung des 1. Zehenstrahls unter Bildung eines Weichteillappens

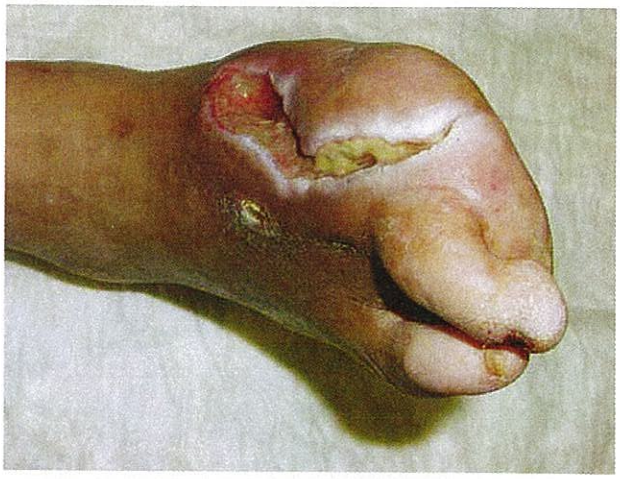

Abb. 2d: Wunde am Ende der V.A.C.® Therapy

Fallbeispiel 2 (Abb. 2a–d): Der 49-jährige Patient ist mit einer diabetischen Nephropathie dialysepflichtig. Wegen einer Vorfussphlegmone wird er mehrfach nekrosektomiert und mit dem V.A.C. GranuFoam Silver® Dressing für 21 Tage behandelt. Die Wunde reicht vom Fussrücken durch die erste Interdigitalfalte bis an die Fusssohle, wo sich ebenfalls ein ausgedehnter Hautdefekt befindet. Bei jedem Verbandwechsel werden mit der Ringcurette bzw. mit dem Skalpell Nekrosen entfernt. Die Wunde ist mit einem *Pseudomonas* kolonisiert. Es gelingt, soviel an vitalem Gewebe zu erhalten, dass nach Amputation des 1. Zehenstrahls der resultierende Defekt mit einem Weichteillappen gedeckt werden kann. Nach weitern 8 Tagen Therapie mit dem V.A.C. GranuFoam Silver® Dressing ist die Wunde soweit abgeheilt, dass mit einem Schaumstoffverband weiterbehandelt wird.

Schlussfolgerungen: Die V.A.C.® Therapy hat es ermöglicht, die Zahl der Majoramputationen bei Stadien II bzw. III B und D zu verringern. Sie stellt heute die Therapie der Wahl zur Wundkonditionierung und zur Spalthautfixierung nach Teilamputationen beim diabetischen Fusssyndrom dar. Die Kombination des V.A.C.®-Schwamms mit Silber verbindet nun auch die Vorteile der negativen Druckbehandlung und der topischen Anwendung von Silberionen.

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Diabetes Care Publish Ahead of Print, published online December 27, 2007

Comparison of Negative Pressure Wound Therapy Utilizing Vacuum-Assisted Closure to Advanced Moist Wound Therapy in the Treatment of Diabetic Foot Ulcers– A Multicenter Randomized Controlled Trial

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Running Title: VAC NPWT: Diabetic Foot Ulcer RCT

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Received for publication 19 November 2007 and accepted in revised form 18 December 2007

ABSTRACT

Objective: To evaluate safety and clinical efficacy of Negative Pressure Wound Therapy (NPWT) compared to Advanced Moist Wound Therapy (AMWT) to treat diabetic patients with foot ulcers.

Research Design And Methods: This multicenter randomized controlled trial enrolled 342 patients mean age 58 years; 79% male. Complete ulcer closure was defined as skin closure (100% re-epithelization) without drainage or dressing requirements. Patients were randomized to either NPWT (Vacuum-Assisted Closure) or AMWT (predominately hydrogels and alginates) and received standard off-loading therapy as needed. The trial evaluated treatment until Day 112 or ulcer closure by any means. Patients whose wound achieved ulcer closure were followed at 3 and 9 months. Each study visit included closure assessment by wound exam and tracings.

Results: A greater proportion of foot ulcers achieved complete ulcer closure with NPWT (73/169, 43.2%) than AMWT (48/166, 28.9%) within the 112-day Active Treatment Phase (p=0.007). Kaplan-Meier median estimate for 100% ulcer closure was 96 days (95% CI: 75.0, 114.0) for NPWT and not determinable for AMWT (p=0.001). NPWT patients experienced significantly (p=0.035) fewer secondary amputations. The proportion of home care therapy days to total therapy days for NPWT was 9471/10579 (89.5%) and 12210/12810 (95.3%) for AMWT. In assessing safety, no significant difference between the groups was observed in treatment-related complications such as infection, cellulitis, and osteomyelitis at 6 months.

Conclusions: NPWT appears to be as safe as, and more efficacious, than AMWT for the treatment of diabetic foot ulcers.
This study was registered with ClinicalTrials.gov as NCT00432965.

In 2005, the Centers for Disease Control estimated the prevalence of Diabetes in the United States to be 20.8 million people.(1) A disabling complication with this disease is foot ulcer development (2, 3), which leads to non-healing chronic wounds that are difficult to treat. Moreover, diabetic foot ulcers (DFUs) are a significant risk factor for nontraumatic foot amputations in persons with diabetes.(4)

Various DFU treatments have been reported in the literature, including advanced moist wound therapy (AMWT) (5, 6), bioengineered tissue or skin substitutes (7, 8), growth factors (9, 10), electric stimulation (11), and negative pressure wound therapy (NPWT) (12). The treatment success is dependent on ulcer chronicity, patient compliance, appropriate off-loading of the appendage, and the therapy's mechanisms of action.

NPWT is a non-invasive system that creates a localized controlled subatmospheric (negative) pressure environment. In this study NPWT was provided by the Vacuum-Assisted Closure Therapy System (KCI USA, San Antonio, Texas) which promotes wound healing by delayed primary or secondary intention through creating a moist wound environment, preparing the wound bed for closure, reducing edema, and promoting granulation tissue formation and perfusion. Vacuum-Assisted Closure Therapy is indicated for use in all care settings and in patients with a variety of wound types including diabetic foot ulcers.

This multicenter randomized controlled trial (RCT) evaluated the safety and efficacy of NPWT compared to AMWT (predominately hydrogels and alginates) for the treatment of DFUs. The cost benefit analysis will be reported in a future publication.

RESEARCH DESIGN AND METHODS

The patient population consisted of diabetic adults ≥18 years with a Stage 2 or 3 (as defined by Wagner's Scale) calcaneal, dorsal or plantar foot ulcer ≥ 2 cm^2 in area after debridement.(13) Adequate blood circulation (perfusion) was assessed by Dorsum Transcutaneous Oxygen Test ($TcPO_2$) ≥ 30 mmHg, Ankle Brachial Index (ABI) ≥ 0.7 and ≤ 1.2 with toe pressure ≥ 30 mmHg, or Doppler arterial waveforms that were triphasic or biphasic at the ankle of the affected leg. Patients with recognized active Charcot disease; ulcers resulting from electrical, chemical or radiation burns; presence of untreated osteomyelitis, cellulitis, collagen vascular disease, or ulcer malignancy were excluded from the study. Patients with uncontrolled hyperglycemia (HbA_{1c} >12%) or inadequate lower extremity perfusion were not enrolled. Exclusion criteria also included ulcer treatment with normothermic or hyperbaric oxygen therapy; concomitant medications such as corticosteroids, immunosuppressive medications, or chemotherapy; recombinant or autologous growth factor products; skin and dermal substitutes within 30 days of study start; or use of any enzymatic debridement treatments. Pregnant or nursing mothers were excluded from study participation.

The NPWT system utilized in this study was Vacuum Assisted Closure Therapy. The system consists of 3 components: a negative pressure generating unit with a disposable canister, a pad with evacuation tube, and a reticulated, open cell sterile polyurethane or a dense open-pore polyvinyl alcohol foam dressing cut to fit the wound. The system unit is programmed to deliver controlled negative pressure ranging from 50 to 200 mmHg. NPWT was applied to the ulcer as specified by manufacturer's guidelines(14) and treated until ulcer closure, sufficient granulation tissue formation for healing by primary, secondary or surgical intention, or Day 112.

AMWT dressings were used according to Wound, Ostomy and Continence Nurses (WOCN) Society guidelines (6), and institutional treatment protocols, consistent with standards of care for treating DFUs. Skin substitutes, cytokines, recombinant human platelet-derived growth factors, or similar therapies as outlined in the exclusion criteria were not used in either group during the Active Treatment Phase (ATP).

The primary efficacy endpoint was incidence of complete ulcer closure. Secondary endpoints included reduction of ulcer surface area over time, time to achieve ulcer closure by either surgery or secondary intention, and reduction in complications, including secondary amputations. Complete ulcer closure was defined as skin closure (100% re-epithelization) without drainage or dressing requirements.

The sample size was based on a type I error probability set at 0.05, with 80% power. Detection of a 20% difference between treatment groups required 206 evaluable patients with a treatment-to-study ratio of 1:1. Sample size was set at 338 to account for subject withdrawal or loss to follow-up.

Randomization was accomplished by generating blocks of numbers through www.randomizer.org. Numbers were assigned to a treatment group and sealed in opaque envelopes containing black paper labeled with treatment and patient ID. Envelopes were sequentially numbered prior to clinical trial site distribution. At patient randomization, treatment was assigned based on the next sequentially labeled envelope.

FDA guidelines (15) state that in some devices, it is impractical or unethical to implement a control treatment that mimics the test product and allows masking. In this study, the physical differences between treatment regimens (eg, hydrogels and NPWT) can be so distinctive that it is not possible to blind either the patient or physician to the treatment post randomization.

Study design. This study was a prospective RCT initiated at 37 diabetic foot and wound clinics, and hospitals. A total of 342 patients were enrolled at 1 Canadian and 28 USA sites. Prior to randomization, patients were screened for neuropathy, adequate perfusion, and glycemic control. All foot ulcers were assessed and debrided as needed within two days of randomization.

Patients were examined weekly for the first 4 weeks (Day 28) then every other week until Day 112, or ulcer closure by any means. At each study visit, ulcers were assessed for area via wound tracing, ulcer closure, and/or adequate granulation tissue formation. NPWT dressing changes were performed every 48 to 72 hours, no less than 3 times per week. AMWT randomized patients were treated based on manufacturer's guidelines. All patients received off-loading therapy as deemed necessary. Patients achieving ulcer closure were followed at 3 and 9 months.

Statistical analysis. The KCI Global Biometrics Group conducted the safety and effectiveness data analyses for this trial. Primary analysis was based on an intention-to-treat (ITT) dataset composed of all randomized patients who signed an informed consent and received at least one post-baseline treatment.

Continuous demographic variables (age, gender, etc.) were summarized for the study population as descriptive statistics (number, mean, Standard Deviation [SD]), median, minimum, and maximum values, and 95% two-sided confidence limits and compared between groups with a two-sample *t-test* or Wilcoxon Rank-Sum test.

An interim ITT analysis of the primary endpoint was conducted at the enrollment of 275 patients to confirm the consistency of trial design assumptions with observed data. The Lan-Demets group sequential boundaries (two-sided symmetric boundaries) were calculated

using the alpha-spending function of O'Brien-Fleming.

Data were analyzed based on differences in incidence of closure between treatment groups and assessed with a test of proportions, using chi-square or Fisher's Exact test, as appropriate. Treatment differences in ulcer area (cm^2) were calculated (ulcer area [cm^2] = ulcer length [cm] x ulcer width [cm] x $\pi/4$) and analyzed using Analysis of Covariance (ANCOVA) with baseline area used as a covariate. Median time to closure was based on number of days from baseline until closure via Kaplan-Meier (KM) survival analysis. Patients not achieving closure were censored using last date of observation.

RESULTS

Figure 1 describes the patient flow through each stage of this RCT including discontinued patients. During the course of the study, 384 patients were consented and screened for inclusion. Of these, 42 patients were excluded due to inclusion/exclusion criteria, patient refusal to participate, or withdrawal of consent, and 342 were enrolled. Seven patients did not receive treatment and 335 patients were analyzed. All patient data collected during ATP were included in the ITT analyses.

The data suggest that no statistically significant demographic differences existed between treatment arms (Table 1). The mean patient population age was 58 years and predominantly male (78.5%). Percentages of patients treated for study ulcer infections at baseline were 29.6% (50/169) for NPWT and 27.1% (45/166) for AMWT. The randomization method resulted in an even distribution of characteristics between treatment groups.

Patients receiving off-loading were 164/169 (97.0%) for NPWT and 162/166 (97.6%) for AMWT. Patients were treated in both acute and home care settings. The proportion of home care therapy days to total therapy days was 9471/10579 (89.5%) for NPWT and 12210/12810 (95.3%) for AMWT.

Efficacy. Complete ulcer closure was defined as skin closure (100% re-epithelization) without drainage or dressing requirements. Within ATP, the NPWT group proportion was significantly (p=0.007) greater for complete ulcer closure than the AMWT group (73/169, 43.2% vs. 48/166, 28.9%). For patients completing ATP, completers analysis significantly (p=0.001) confirmed that a greater percentage of NPWT treated ulcers (60.8%, 73/120) achieved ulcer closure compared to AMWT (40.0%, 48/120). After sufficient wound bed preparation, 9.5% (16/169) NPWT-treated ulcers and 8.4% (14/166) AMWT-treated ulcers were surgically closed by split thickness skin grafts, flaps, sutures, or amputations. KM median time to complete ulcer closure was 96 days (95% CI: 75.0, 114.0) for NPWT (p=0.001). AMWT median time to complete ulcer closure could not be estimated.(Figure 2). The NPWT mean duration of therapy was 63.6 days (SD 36.57) versus 78.1 days (SD 39.29) for AMWT.

To further evaluate NPWT effects, 75% ulcer closure, degree of granulation tissue formation, and ulcer area reduction were assessed. Significantly more NPWT patients (105/169, 62.1%) achieved 75% ulcer closure than AMWT patients (85/166, 51.2%; p=0.044). NPWT KM median estimate for 75% ulcer closure was 58 days (95% CI: 53.0, 78.0) and 84 days (95% CI: 58.0, 89.0) for AMWT (p=0.014). In assessing ulcer area, a significant difference between NPWT (-4.32 cm^2) and AMWT (-2.53 cm^2) from baseline was achieved on Day 28 (p=0.021).

The clinical treatment effect on wound bed preparation was assessed in 46 patients (24 NPWT, 22 AMWT), who presented with 0-10% granulation at baseline and achieved 76-100% granulation. Of these, 17/24 (70.8%) NPWT and 8/22 (36.4%) AMWT patients achieved 76-100% granulation tissue formation

(p=0.019). NPWT KM median estimates for 76-100% granulation tissue formation were 56 days (95% CI: 42.0, 84.0) and 114 (95% CI: 44.0, -) for AMWT (p=0.022).

Safety. Table 2 reports treatment-related rates for secondary amputations, edema, wound infection, cellulitis, osteomyelitis, staphylococcal infection, and infected skin ulcers at 6 months. Significantly (p=0.035) fewer amputations were observed in NPWT patients (7/169, 4.1%) compared to AMWT patients (17/166, 10.2%). The majority of these amputations (2 and 13, respectively) were minor amputations. In all other categories, no significant differences were observed.

CONCLUSIONS

Results of the largest NPWT RCT to date demonstrate that NPWT is as safe as, and more efficacious, than,AMWT in the treatment of DFUs. A significantly greater number of NPWT patients achieved complete ulcer closure and granulation tissue formation compared to AMWT patients. This was supported by a significant reduction in median time needed to heal DFUs. Approximately 90% of therapy days occurred in the home care setting for both treatments.

No significant difference was observed in ulcer related complications such as infection, cellulitis, and osteomyelitis. However, the study showed that AMWT patients had more than twice as many secondary amputations than those receiving NPWT.

Chronic DFUs present a significant challenge to treating physicians.(16) Treatment involves multiple modalities including debridement, assessment and treatment of infection, revascularization if indicated, and sufficient off-loading of the foot.(17) A key component of the healing process is debridement because it enables removal of devitalized and necrotic tissue. Debridement is critically important to the initiation of healing. NPWT and other wound healing technologies work in conjunction with debridement as the foundation upon which the wound healing process can begin.(18) As observed in this clinical trial, the use of NPWT in concurrence with debridement of the affected foot increases the number of DFUs healed and decreases the length of time required for ulcer healing as compared to AMWT. In addition, the prescription of off-loading may have also contributed to positive results in both groups. Therefore, it appears that NPWT in addition to established standards of care enhances successful healing and closure of DFUs.

In this study, 14.3% more NPWT patients achieved complete ulcer closure in less median time to closure than those treated with AMWT. This parallels the findings by Argenta and Morykwas in 1997, in which they reported that the success of NPWT in chronic wounds is associated with removal of excess interstitial fluid, an increase in vascularity and associated decrease of bacterial colonization, and stimulation of granulation tissue formation through the response of wound tissue to the mechanical forces exerted by the application of negative pressure through the foam dressing.(10) In separate studies, Saxena (18) and Greene (19) have further elucidated the role of open pore foam dressing in the creation of micromechanical deformations of the wound surface. These micromechanical deformations are caused when negative pressure draws tissue into the foam pores. This stretches cells and promotes cell division that stimulates granulation tissue formation.(18)

As NPWT use has grown, the use of NPWT for wound bed preparation in conjunction with either delayed primary or secondary wound closure has also increased. In 2005, Armstrong and Lavery reported that the use of NPWT may be an alternative therapy to achieve an improved granulating wound bed in diabetic foot wounds in order to prepare the wound bed

for other closure techniques.(20) As shown in these data and previous studies, NPWT promotes granulation tissue formation, thereby allowing the clinician to determine course of closure.

DFUs are a significant risk for amputation.(4) In this study, the incidence of secondary amputations was significantly less (p=0.035) for NPWT (4.1%) compared to AMWT (10.2%). This finding substantiates other reports, in which diabetic foot wounds treated with NPWT trended towards fewer secondary amputations (p=0.060) than those treated with AMWT.(20) While the exact mechanism of the decrease in secondary amputations remains unclear, treatment of DFUs with NPWT appears to promote significant healing.

This study of 342 patients with DFUs showed that NPWT is as safe as and more efficacious than AMWT for the treatment of diabetic foot ulcers.

ACKNOWLEDGMENTS

KCI USA Incorporated (San Antonio, TX) supported this study. Conference abstracts reporting preliminary and interim study data were presented at the 2003 Symposium on Advanced Wound Care, 2004 World Union of Wound Healing Societies meeting, 2007 Symposium on Advanced Wound Care, and 2007 American Podiatric Medicine Association meeting. Investigators who enrolled patients for the V.A.C.® Therapy Diabetic Foot Ulcer Study were: Charles Anderson, MD, Madigan Army Hospital, Tacoma, WA; David Armstrong, DPM, North Chicago VA Medical Center and Rosalind Franklin University, North Chicago, IL; Jose Ayala, DPM, Valley Baptist Hospital, Brownsville, TX; John Bennett, DPM, Des Moines University, Des Moines, IA; Scott Berman, MD, Tucson Vascular Surgery, Tucson, AZ; Peter Blume, DPM, North American Center for Limb Preservation, New Haven, CT; Milton Boden, MD, Aim Research, Atlanta, GA; William Bogey, MD, East Carolina University, Greenville, NC; Marc Dolce, DPM, Cleveland Foot and Ankle Clinic, Cleveland, OH; Kenneth Dolynchuk, MD, Saint Boniface General Hospital, Manitoba, Winnipeg, Canada; Tamara Fishman, DPM, Primary Foot Care Center, Incorporated, North Miami Beach, FL; Gabriel J. Halperin, DPM, Innovative Medical Technologies, Los Angeles, CA; Allen Holloway, MD, Maricopa Medical Center, Phoenix, AZ; John Lantis, MD, Saint Luke's Roosevelt, New York, NY; Brock Liden, DPM, Circleville Foot and Ankle, LLC, Circleville, OH; Jeffrey Page, DPM, Carl T. Hayden VA Medical Center, Podiatry Section, Phoenix, AZ; Marc Passman, MD, Vanderbilt University Clinical Trials Center, Nashville, TN; Wyatt Payne, MD, Bay Pines Veterans Affairs Medical Center, Bay Pines, FL; Alexander Reyzelman, DPM, Bay Area Foot Care, Castro Valley, CA; Bret Ribotsky, DPM, Podiatric Success, Inc., Boca Raton, FL; Kathleen Satterfield, DPM, Texas Diabetes Institute - University of Texas Health Science Center San Antonio, San Antonio, TX; Bhavesh Shah, DPM, South Texas Foot Institute, Poth, TX; David Skrobot, DPM Genesis Health Care System, Zanesville, OH; Rodney Stuck, DPM, Hines Veterans Affairs Hospital, Hines, IL; Arthur Tallis, DPM, Hope Research Institute, Phoenix, AZ; Mike Vaardahl, DPM, Banner Health at North Colorado Medical Center, Greely, CO; Jodi Walters, DPM, Southern Arizona Veterans Affairs Medical Center, Department of Surgery, Tucson, AZ; Robert Wunderlich, DPM, San Antonio, TX

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TABLE 1. Patient demographics

Characteristics	NPWT* n=169	AMWT n=166
Age (years)	58 ± 12	59 ± 12
Sex (M/F)	141/28 (83/17)	122/44 (73/27)
Race		
African American	28 (16.6)	22 (13.3)
Caucasian	95 (56.2)	100 (60.2)
Hispanic	41 (24.3)	40 (24.1)
Native American	3 (1.8)	3 (1.8)
Other	2 (1.2)	1 (0.6)
Weight (kg)	99.2 ± 25.1	93.8 ± 25.6
Height (cm)	175.0 ± 9.6	175.0 ± 12.4
Current Smoker	34 (20.1)	32 (19.4)
Currently Use Alcohol	37 (21.9)	45 (27.1)
Type of Diabetes		
Type 1	15 (8.9)	14 (8.4)
Type 2	154 (91.1)	152 (91.6)
Pre-albumin (g/L)	21.1 ± 7.6	19.9 ± 7.9
Albumin (g/L)	3.4 ± 0.6	3.4 ± 0.8

Characteristics	NPWT* n=169	AMWT n=166
HbA_{1c}	8.3 ± 2.0	8.1 ± 1.9
ABI (mmHg)	1.0 ± 0.2	1.0 ± 0.2
Transcutaneous oxygen tension ($TcPO_2$; mmHg)	43.2 ± 10.4	43.3 ± 12.5
Loss of Protective Sensation†	150 (90.4)	143 (88.8)
Ulcer Duration Prior to Treatment (days)	198.3 ± 323.5	206.0 ± 365.9
Baseline Wound Area (cm^2)	13.5 ± 18.2	11.0 ± 12.7
Received Off-Loading Therapy	164 (97.0)	162 (97.6)
Treated for Ulcer Infection Prior to Randomization	50 (29.6)	45 (27.1)
Therapy Received at Treatment Initiation		
NPWT	169 (100)	
Hydrogel		78 (47.0)
Alginate		31 (18.7)
Other		28 (16.9)
Saline		17 (10.2)
Collagen		11 (6.6)
Hydrocolloid		1 (0.6)

*Data are means ± SD or *n* (%) †Percentage based on available data

TABLE 2. Results of safety analysis

MeDRA System Organ Class	NPWT n=169 (%)	AMWT n=166 (%)	P-Value*
Secondary Amputations	7 (4.1)	17 (10.2)	0.035
Edema	5 (3.0)	7 (4.2)	0.571
Wound Infection	4[†] (2.4)	1[‡] (0.6)	0.371
Cellulitis	4 (2.4)	1 (0.6)	0.371
Osteomyelitis	1 (0.6)	0 (0.0)	--
Staphylococcus Infection	1 (0.6)	0 (0.0)	--
Infected Skin Ulcer	1 (0.6)	2 (1.2)	0.620

*Fisher's Exact Test
[†]1 moderate, 3 mild
[‡]1 moderate

FIGURE 1

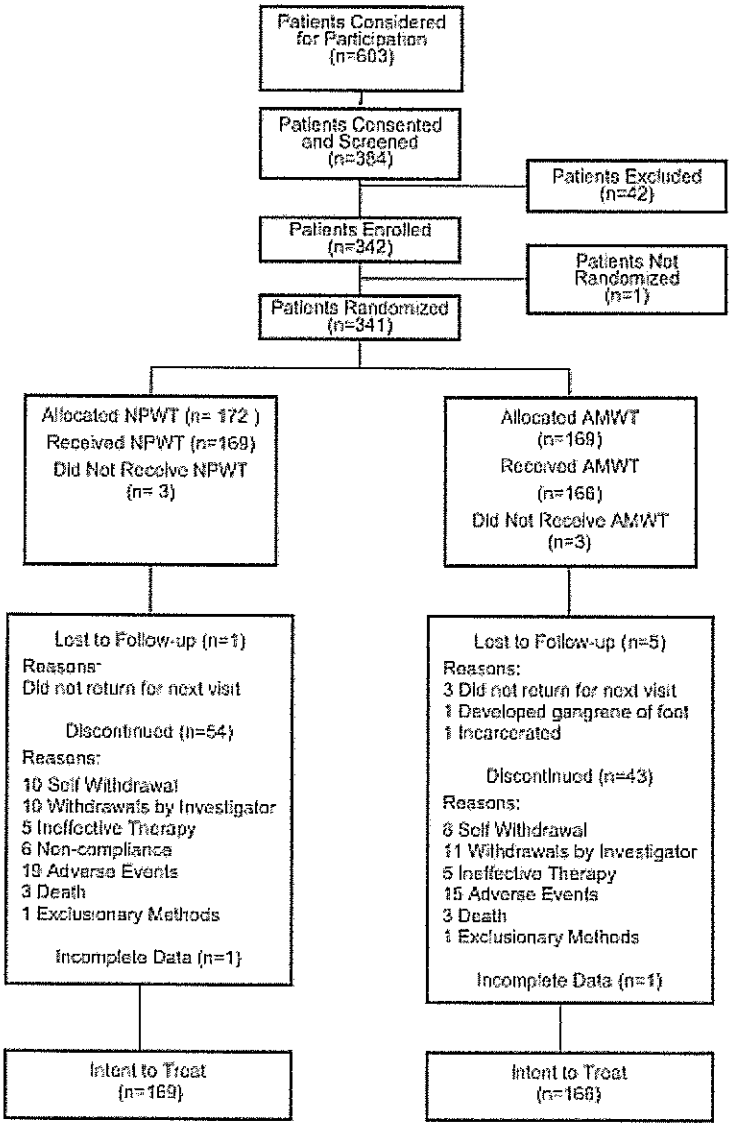
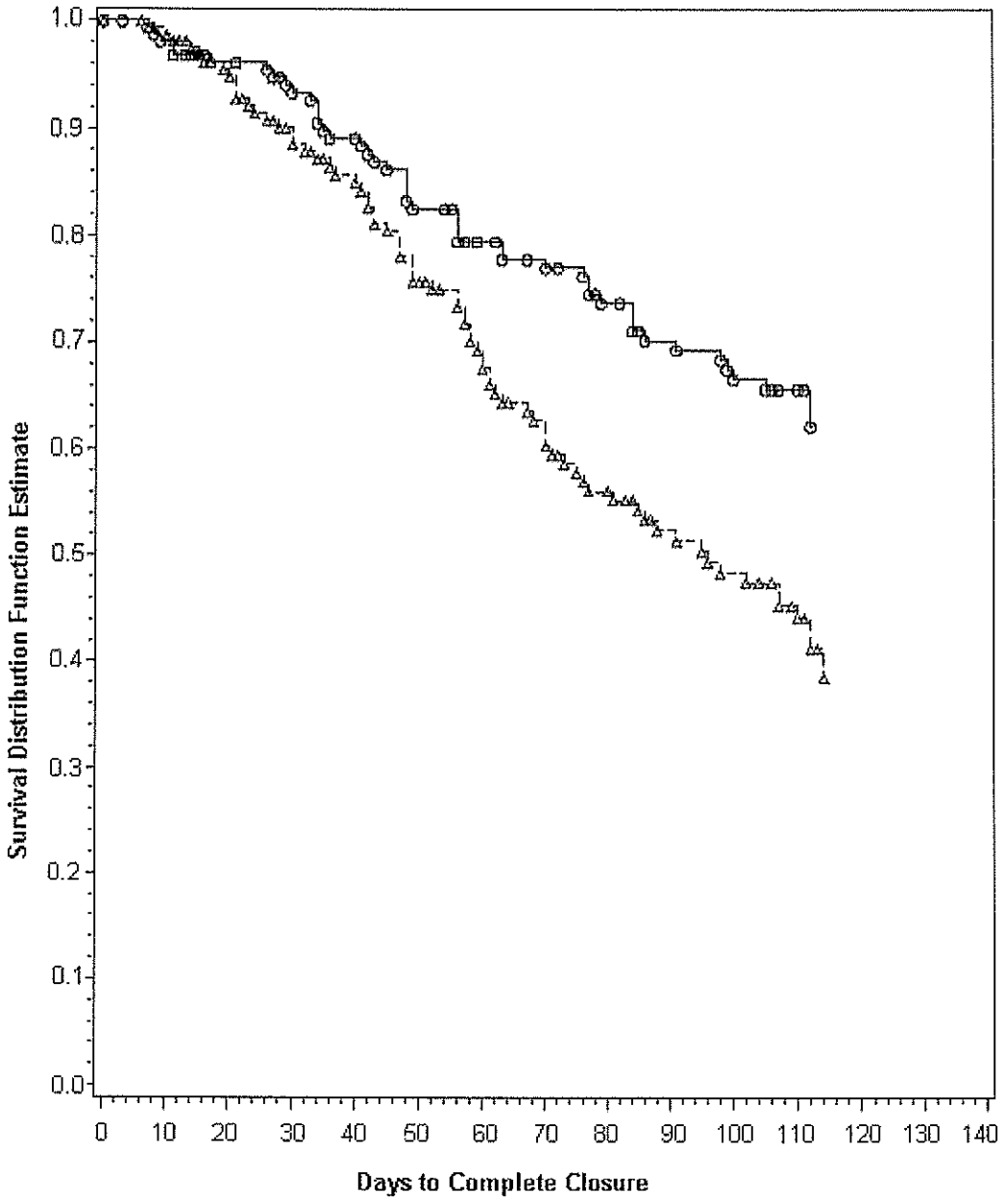

Patients Considered for Participation (n=603)
Patients Consented and Screened (n=384)
Patients Excluded (n=42)
Patients Enrolled (n=342)
Patients Not Randomized (n=1)
Patients Randomized (n=341)
Allocated NPWT (n= 172)
Received NPWT (n=169)
Did Not Receive NPWT (n= 3)
Allocated AMWT (n=169)
Received AMWT (n=166)
Did Not Receive AMWT (n=3)
Lost to Follow-up (n=1)
Reasons:
Did not return for next visit
Discontinued (n=54)
Reasons:
10 Self Withdrawal
10 Withdrawals by Investigator
5 Ineffective Therapy
6 Non-compliance
19 Adverse Events
3 Death
1 Exclusionary Methods
Incomplete Data (n=1)
Lost to Follow-up (n=5)
Reasons:
3 Did not return for next visit
1 Developed gangrene of foot
1 Incarcerated
Discontinued (n=43)
Reasons:
6 Self Withdrawal
11 Withdrawals by Investigator
5 Ineffective Therapy
15 Adverse Events
3 Death
1 Exclusionary Methods
Incomplete Data (n=1)
Intent to Treat (n=169)
Intent to Treat (n=166)

FIGURE 2


Survival Distribution Function Estimate
1.0
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0.0
0
10
20
30
40
50
60
70
80
90
100
110
120
130
140
Days to Complete Closure

Outcomes of Subatmospheric Pressure Dressing Therapy on Wounds of the Diabetic Foot

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Lawrence A. Lavery, DPM, MPH
Patricia Abu-Rumman, DPM
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Ostomy/Wound Management
April 2002;48(4):64–68

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Outcomes of Subatmospheric Pressure Dressing Therapy on Wounds of the Diabetic Foot

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The purpose of this retrospective study was to evaluate outcomes of people with large diabetic foot wounds treated with subatmospheric pressure dressing therapy immediately following surgical wound debridement. Data were abstracted from the medical records of 31 consecutive patients with diabetes, 77.4% male (n = 24), aged 56.1 ± 11.7 years, presenting for care at two large multidisciplinary wound care centers. All patients received surgical debridement for indolent diabetic foot wounds and were subsequently started on a regimen of subatmospheric pressure dressing therapy delivered using a vacuum-assisted closure device for a mean of 4.7 ± 4.2 weeks (mode = 2 weeks) using a protocol that called for cessation of therapy when the wound bed approached 100% coverage with granulation tissue with no exposed tendon, joint capsule, or bone. Outcomes evaluated included time to complete wound closure, proportion of patients achieving wound healing at the level of initial debridement, and complications associated with use of the device. The mean duration of wounds before therapy was 25.4 ± 23.8 weeks. In patients treated with subatmospheric pressure dressing therapy, 90.3% (n = 28) of wounds healed at the level of debridement without the need for further bony resection in a mean 8.1 ± 5.5 weeks. The remaining 9.7% (n = 3) went on to higher level amputation (below knee amputation = 3.2%, [n = 1] and transmetatarsal amputation = 6.5% [n =2]). Complications included periwound maceration (19.4% [n = 6]), periwound cellulitis (3.2% [n = 1]), and deep space infection (3.2% [n = 1]). The authors concluded that appropriate use of subatmospheric pressure dressing therapy to achieve a rapid granular bed in diabetic foot wounds may have promise in treatment of this population at high risk for amputation and that a large, randomized trial is now indicated.

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Diabetic foot wounds commonly proceed to lower extremity amputation. They have been identified as the key component in nearly nine in 10 of these ablative procedures.[1] Clearly, healing these wounds in as rapidly a manner as possible may result in a substantial reduction in morbidity.

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One recently introduced method used to heal defects of the skin involves topical subatmospheric pressure dressing (SPD) therapy. This modality is most commonly delivered to the wound by way of an open-cell foam dressing covered with a clear membrane over the wound. The dressing is attached to a pump that provides either intermittent or continuous suction with a standard setting of 125 mm Hg.[2-8] Several studies have reported varying levels of success in different categories of wounds in both human and animal models.[9-22] Although one randomized trial of 10 patients with diabetic foot wound exists,[5] the authors are unaware of any other studies in the peer-reviewed medical literature that have specifically assessed outcomes (by way of primary data) associated with this type of therapy in this very high risk population. Therefore, this preliminary study was conducted to evaluate outcomes associated with application of SPD therapy on diabetic foot wounds.

TABLE 1
DESCRIPTIVE CHARACTERISTICS OF PATIENTS

Number of patients	31
Age (years)	56.1 ± 11.7
% Male	77.4 (n = 24)
Wound duration before therapy (weeks)	25.4 ± 23.8
Surface area (cm^2)	27.9 ± 19.5
Depth (% University of Texas grade 1, 2, 3 respectively)	3.2 (n = 1), 45.2 (n = 14), 51.6 (n = 16)

University of Texas Grades
0. Pre or post-ulcerative wound, completely epithelialized
1. Superficial, not including tendon, capsule or bone
2. Exposed tendon, and/or closed joint capsule
3. Bone, or open joint exposed

Materials and Methods

Data were collected from 31 consecutive patients with diabetes (see Table 1), 77.4% male, aged 56.1 ± 11.7 years presenting for care at two large, multidisciplinary, referral-based wound care centers. All patients had a previous diagnosis of diabetes mellitus as assessed by their attending physician. All patients received surgical debridement for indolent diabetic foot wounds and were subsequently placed on SPD therapy delivered using VAC devices (Vacuum Assisted Closure, KCI, Inc., San Antonio, Texas, USA). Wounds tended to be large (27.9 ± 19.5 cm^2), as they were evaluated after the aforementioned surgical debridement. Data were collected from patients over a 1-year period. Retrospective collection of these data was determined to be exempt from consent policy according to the governing institutional review board.

All wounds were described and classified using the University of Texas diabetic foot wound classification system.[23] The prevalence of University of Texas grade 1, 2, and 3 lesions in this population was 3.2%, 45.2%, and 51.6%, respectively. The foot wounds were located in the digit/ray, transmetatarsal, midfoot, and heel (see Table 2). Although all wounds were initially infected, all were converted to stage "A" (noninfected, nonischemic) before device application, using a combination of surgical debridement and culture-directed systemic antibiotic therapy. Outcomes evaluated included time to complete wound closure, proportion of patients achieving wound healing at the level of initial debridement, and complications associated with use of the device. The mean duration of wounds before therapy was 25.4 ± 23.8 weeks. Following sharp debridement, patients were treated with SPD therapy at 125 mm Hg using a

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KEY POINTS

- To evaluate outcomes of subatmospheric pressure therapy in the clinical management of foot ulcers in people with diabetes, a chart review of 31 patients from two diabetic foot clinics was conducted.
- After an average of 4.7 weeks, most wounds were found to contain enough healthy granulation tissue to discontinue treatment. Periwound maceration was the most commonly observed side effect.
- Prospective, controlled clinical studies are needed to ascertain optimal treatment times and to obtain effectiveness and cost-effectiveness data.

TABLE 2
LOCATION OF WOUNDS

Location	%	N
Digit/Ray	51.6	16
Transmetatarsal	12.9	4
Midfoot	12.9	4
Heel	22.6	7
Total	100.0	31

protocol that called for consideration for cessation of therapy when the consistency of the wound bed approached 100% granulation tissue with no overtly exposed tendon, joint capsule, or bone. Subatmospheric pressure dressing therapy dressings were changed every 48 hours.

All descriptive data are described as mean ± standard deviation. The authors used Pearson's test to evaluate correlation between continuous variables such as time to healing based on wound duration. To compare differences in time to healing by gender, a Student's *t*-test for independent samples was used. For all analyses, a significance (alpha) level of 0.05 was used.[24]

Results

Subatmospheric pressure dressing therapy was used for a mean 4.7 ± 4.2 weeks (mode = 2 weeks) until the wound bed approached 100% granular tissue (see Figure 1). No significant difference in age, gender, duration of wounds, or time to healing between centers was noted. In total, 90.3% (n = 28) of wounds healed at the level of debridement without the need for further bony resection in a mean 8.1 ± 5.5 weeks. The remaining 9.7% (n = 3) went on to higher level amputation (below knee amputation = 3.2% [n = 1] and transmetatarsal amputation = 6.5% [n =2]). Complications included periwound maceration (19.4% [n = 6]), periwound cellulitis (3.2% [n = 1]), and deep space infection (3.2% [n = 1]). In this small sample, no significant difference in healing time ($P = 0.2$) or proportion of patients healing ($P = 0.6$) based on gender was noted. Likewise, no significant association was reported between age ($P = 0.4$) or duration of the wound ($P = 0.9$) and time to wound healing ($P=0.4$). Similarly, the authors could detect no association between wound size and time to healing ($P = 0.5$).

Discussion

The use of SPD therapy has been proposed as a novel method of manipulating the chronic wound environment in a way that potentially reduces bacterial burden and chronic interstitial wound fluid, increases vascularity and cytokine expression, and, to an extent, mechanically exploits the viscoelasticity of periwound tissues.[2,4,25-28] Although SPD therapy has appeared anecdotally promising, only one small randomized trial evaluating it in treatment of diabetic foot wounds can be found in the literature. McCallon et al[5] enrolled 10 patients with diabetes and concomitant foot ulceration. Patients in this study were evenly randomized (by way of an alternating randomization technique) to either SPD therapy or to a control group (twice daily dressing changes with saline-moistened gauze). At the conclusion of the trial, the authors reported a difference in time to healing in patients receiving SPD therapy compared with standard therapy (23 ± 17 vs. 43 ± 32 days). No statistical analysis was performed on this admittedly underpowered sample. Most of the patients in the SPD group received definitive closure by way of delayed primary closure (4 out of 5 SPD versus 2 out of 5 control). Although this study may have had identifiable issues related to selection and performance bias between groups (as no readily identifiable method of randomization occurred), it did suggest a guardedly optimistic assessment of this treatment regime. Further works in this area may help to substantiate the potential of SPD as noted in the McCallon study.

In the authors' study, which intended to provide pilot data for future randomized controlled trials, valuable experience was gained in determining how

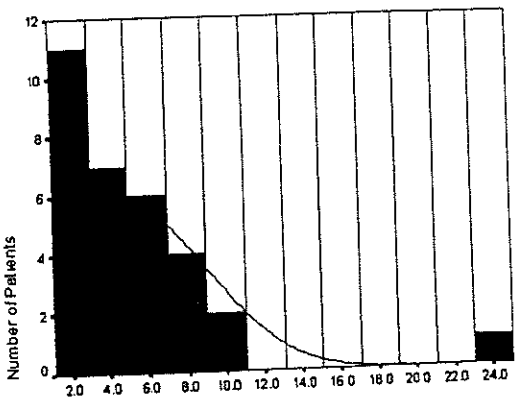

Figure 1
Duration of subatmospheric pressure therapy (weeks). The mean time of therapy was 4.7 ± 4.2 weeks (mode = 2 weeks).

this technology might be best used in the diabetic foot. It has become the authors' general protocol to treat patients with SPD therapy until they reach coverage of vital periarticular, tendinous, or osseous structures and/or a 100% granular base. The clinician may then choose to employ other wound healing modalities to move the wound toward complete epithelialization. This is reflected in the relatively short amount of time the device was used in this study. The protocol used most frequently called for SPD therapy for 1 to 3 weeks (see Figure 1) to achieve the aforementioned goals. It also should be noted that the patients in this study had proportionately much larger wounds than those in the McCallon trial, largely because the centers participating in the study utilized SPD therapy following a protocol of aggressive surgical debridement of chronic or infected diabetic foot wounds.

Limitations

This was a retrospective study and, as such, could not control for the myriad variables that could confound many conclusions. For example, the authors were unable to control for vascular status, degree of glucose control, nutritional status, activity level, or numerous other potential variables that could be important in assessing overall results. However, the objective of this study was to report outcomes and experiences using this treatment at busy diabetic foot clinics, not to provide evidence to show SPD is more (or less) effective than other modalities.

Conclusion

This study provides additional pilot data to support, in a guarded sense, the judicious use of subatmospheric pressure dressing therapy in the diabetic foot. The results of this study suggest that appropriate use of subatmospheric pressure dressing therapy to achieve a rapid granular base in diabetic foot wounds may show promise in treating this population of patients who are at high risk for lower extremity amputation. To the authors' knowledge, this is the largest study to date to evaluate vacuum therapy in this specific wound category. The study will provide pilot data for future large, multicenter, randomized controlled trials of this wound healing modality to further clarify its utility in treating indolent diabetic foot wounds. Ultimately, this may yield improved results in therapy and a reduction in the unnecessarily high prevalence of lower extremity amputations in the developed and developing world. - OWM

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