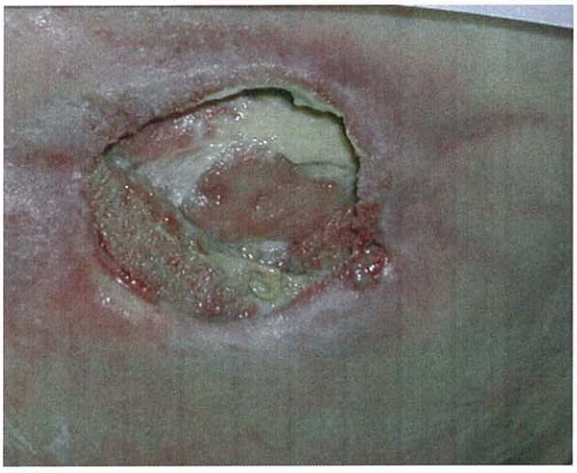
Pressure Ulcers
Decubitus



THE V.A.C.®
VACUUM ASSISTED CLOSURE™

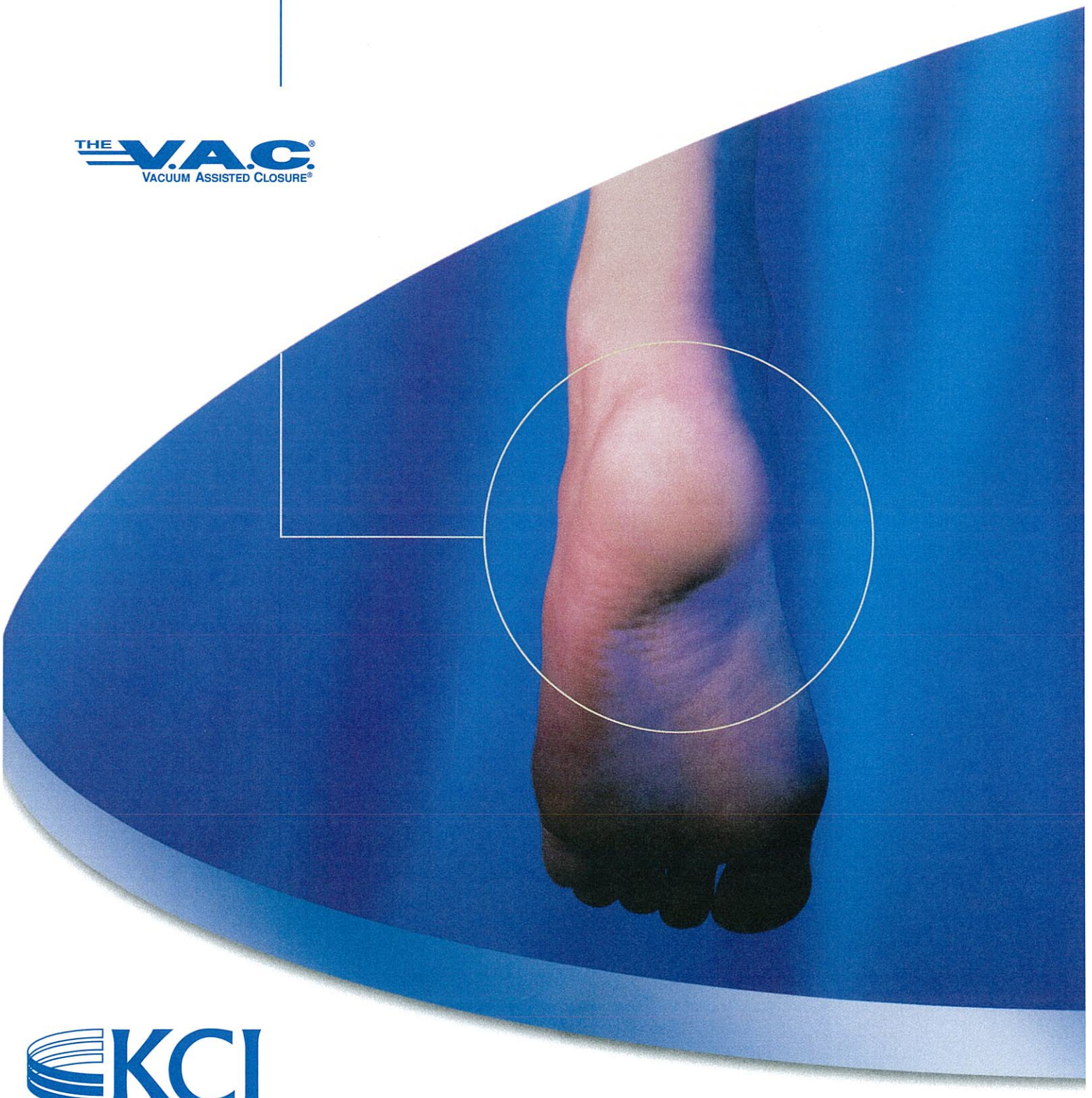
KCI
Wolfgang Imendörffer
Marketing Manager CEE
25 August, 2009

KCI
The Clinical Advantage

An Easy-to-use Dressing Specifically for Heel Wounds

V.A.C.® GranuFoam™ Heel Dressing

THE V.A.C.® VACUUM ASSISTED CLOSURE®



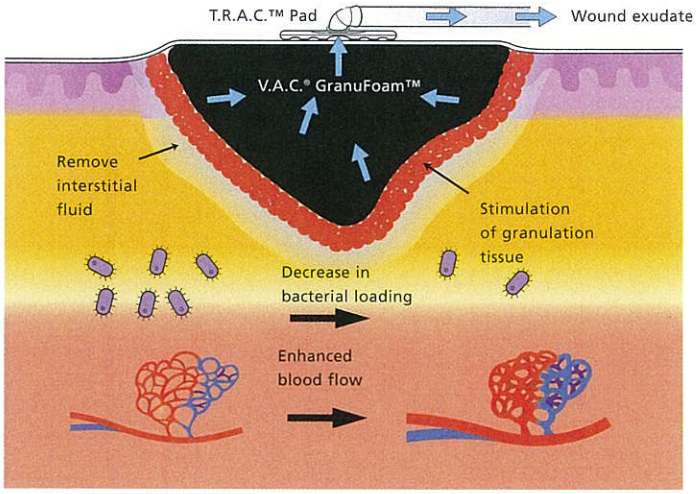
KCI® The Clinical Advantage

Optimal wound healing with V.A.C.® Therapy™

V.A.C.® (Vacuum Assisted Closure®) Therapy is a non-invasive, dynamic and unique system that helps promote wound healing through the application of controlled negative pressure to the wound site. Clinicians prescribe V.A.C.® Therapy for many chronic, acute, sub-acute and traumatic wounds – in the hospital, extended care facility and home care.

V.A.C.® Therapy clinical benefits:

- Provides a closed moist wound healing environment[1]
- Applies controlled localised negative pressure to uniformly draw wounds closed[2]
- Removes excess fluids that can inhibit wound healing[3]
- Helps remove interstitial fluid which can positively influence reduction in oedema[4]
- Promotes granulation (recent studies suggest mechanical stretching may result in increased mitosis (cell replication)[4, 5]



Deep Wound treated with V.A.C.® GranuFoam™

1 Charles K. Field et al. Overview of Wound Healing in a Moist Environment. *American Journal of Surgery*, 1994.
2 Joseph E., Hamori CA., Bergman S., Roaf E., Swann N., Anastasi G. Prospective Randomized Trial of Vacuum-Assisted Closure versus Standard Therapy of Chronic Non-healing Wounds. *Wounds*, 2000; 12(3): 60–67.
3 Brian Bucalo MD, William H. Eaglestein, MD, Vincent Falanga, MD. Inhibition of Cell Proliferation by Chronic Wound Fluid. *Wound Repair and Regeneration*, 1993.
4 Argenta, L. C., Morykwas, M. J. Vacuum-Assisted Closure: A New Method for Wound Control and Treatment: Animal Studies and Basic Foundation. *Annals of Plastic Surgery*, 1997; 38(6).
5 Argenta, A., Webb K., Simpson J., Gordon S., Kortesis B., Wanner M., Kremers L., Morykwas M. Deformation of Superficial and Deep Abdominal Tissues with Application of a Controlled Vacuum. European Tissue Repair Society, Focus group meeting Topical Negative Pressure (TNP) Therapy, 4–6 December 2003, London.

V.A.C.® GranuFoam™ Heel Dressing

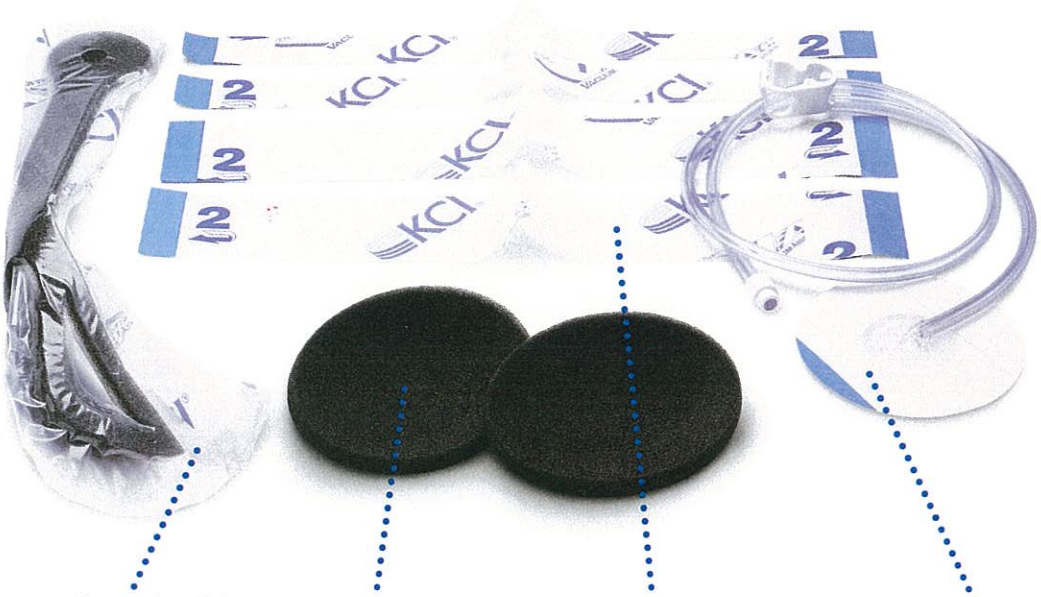
new

An easy-to-use dressing specifically for heel wounds. The V.A.C.® GranuFoam Heel Dressing is one of a wide range of KCI products that deliver advanced wound therapy. Dressing applications are now easier, faster and more comfortable for both the patient and caregiver.

Benefits of the V.A.C.® GranuFoam Heel Dressing:

- Contoured shape to fit to the heel
- Integrated drape design for easier application
- T.R.A.C. Pad bridge located on top of the foot for patient comfort and faster dressing changes
- Hydrophobic (non-absorbent) to enhance exudate removal
- Reticulated cells (open pores) to evenly distribute negative pressure therapy across the wound bed
- For use with V.A.C.® ATS and V.A.C.® Freedom Therapy Systems

Simple and efficient application

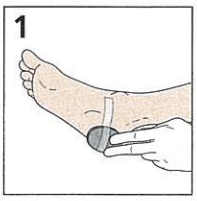


Heel Dressing (C)

Contour Dressing (2 pieces) (A)

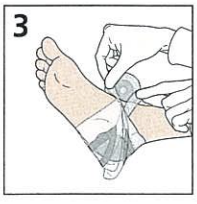
Drape Strips (B)

T.R.A.C.™ Pad (D)

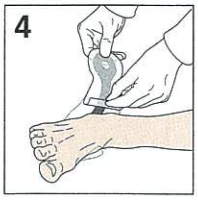


1. Trim Contour Dressing (A) to fit into the wound bed prior to placing on the heel. Secure with the drape strip (B). Note: Contour dressing can be stacked if wound is deep.

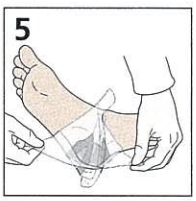
2. Place the Heel Dressing (C) on the heel. Orient as shown so that the T.R.A.C. Pad bridge wraps around to the top of the foot.



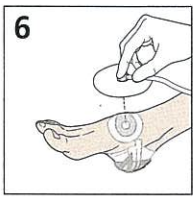
3. Remove the top liner strip and smooth it down, then remove the bottom liner strip, smoothing down the dressing edge.



4. Remove the liner strip from the T.R.A.C. Pad bridge and smooth down.

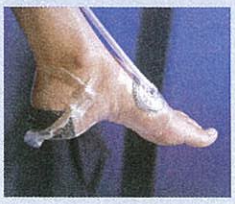


5. Remove protective film from outside of dressing.

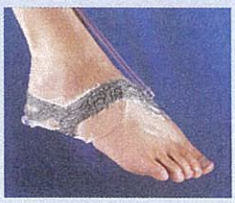


6. Align and apply the T.R.A.C. Pad (D) on the T.R.A.C. Pad bridge and smooth down the edges. Remove the protective film covering from the T.R.A.C. Pad.

Important: *Always refer to contraindications, precautions and safety tips prior to applying and using the V.A.C.® System.*

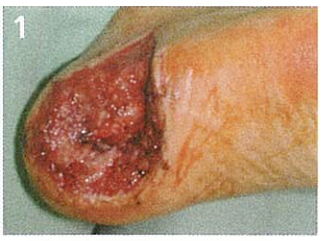


V.A.C.® GranuFoam™ is conformed to fit the heel

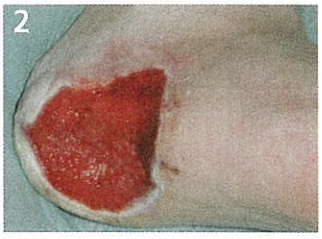


T.R.A.C. Pad bridge located on top of the foot for patient comfort

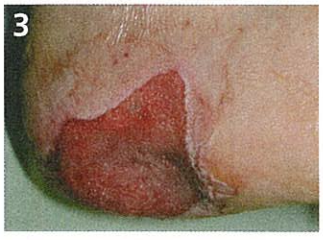
Case of primary surgical care of high risk melanoma:



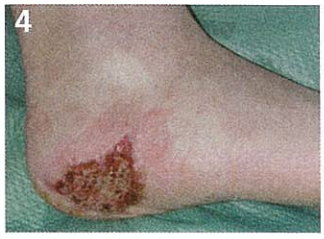
1 Excision wound with open Plantaraponeurosis after 5 days of V.A.C.® Therapy



2 Wound with good granulation tissue after 2 Weeks of V.A.C.® Therapy



3 After 4 Weeks of V.A.C.® Therapy, complete conditioned wound



4 5 days after full thickness graft and V.A.C.® Therapy with V.A.C.® VersaFoam™

V.A.C.® Therapy

Indications:
Chronic wounds (pressure ulcers and diabetic wounds), sub-acute wounds (surgical dehiscence, abdominal) and acute wounds (traumatic wounds, partial-thickness burns, flaps and grafts).

Contraindications:
Contraindicated for patients with malignancy in the wound, untreated osteomyelitis, non-enteric and unexplored fistulae, or necrotic tissue with eschar present. Do not place V.A.C.® dressing over exposed blood vessels or organs.

Precautions:
Precautions should be taken with patients with active bleeding, difficult wound haemostasis, or who are on anticoagulants. Follow Universal Precautions. When placing the V.A.C.® dressing in proximity to blood vessels or organs, take care to ensure that they are adequately protected with overlying fascia, tissue or other protective barriers. Greater care should be taken with respect to weakened, irradiated or sutured blood vessels or organs. Bone fragments or sharp edges could puncture a barrier, vessel or organ. Wounds with enteric fistula require special precautions in order to optimise V.A.C.® Therapy. Refer to the KCI V.A.C.® Therapy Clinical Guidelines for sample guidelines.

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Clinical Summary Sheet

Pressure ulcer prevalence and the role of negative pressure wound therapy in home health quality outcomes

AUTHOR: Schwien T, Gilbert J, Lang C JOURNAL: Ostomy/Wound Management 2005: Vol 51, Issue 9: 47-60

BACKGROUND

- United States governmental agency named Centers for Medicare and Medicaid Services (CMS) collects patient data from Home Health Agencies
- Standardized assessments called OASIS (Outcome and Assessment Information System) completed for every patient treated by Home Health Agencies and collected into a database
- More than 14 million OASIS records available
- Data analyzed by an independent company called OCS (Outcome Concept Systems)
- AHRQ (Agency for Healthcare Research and Quality) suggests that a 5% reduction in preventable hospitalizations could result in cost saving of more than $1.3 billion
- Patients with (chronic) wounds present a challenge to the costs of health care

PURPOSE

To quantify the impact of V.A.C.® Therapy™ in reducing acute care hospitalizations and emergency care

METHODS

- Home care patients
- Retrospective study (January 2003 - December 2004)
- Patients with pressure ulcers Stage III and IV
- Matched cases (specific inclusion and exclusion criteria)
- V.A.C.® Therapy™ treated patients compared with control group
- Control group consists of any other wound care therapy for pressure ulcers

RESULTS

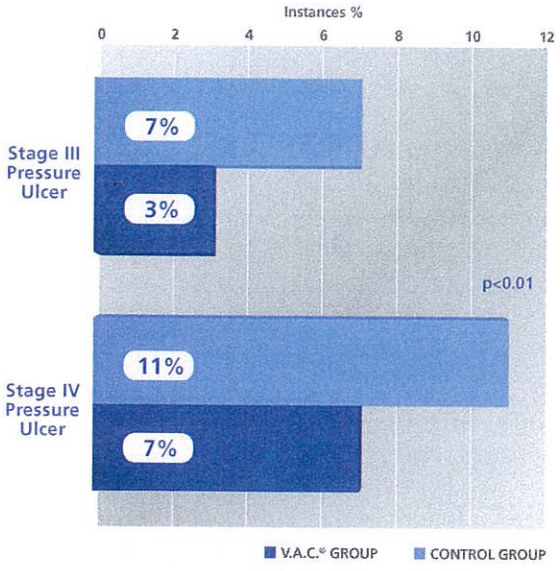
	V.A.C.® group	Control group
Stage III	29	1713
Stage IV	31	575
Total	60	2288

THE V.A.C. VACUUM ASSISTED CLOSURE®

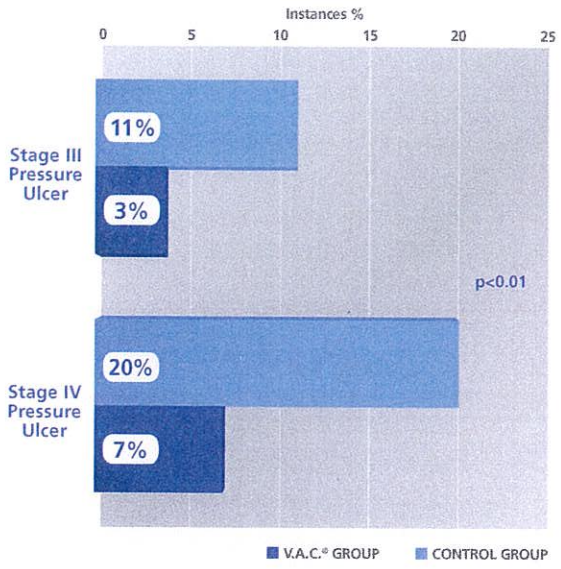
KCI The Clinical Advantage

Results and Conclusions

Instances of Emergent Care



Instances of Acute Care Hospitalization



Patients receiving NPWT were tracked during the time NPWT was applied plus 7 days following removal to take into account any wound infection or deterioration that may have related to NPWT. The comparison group was tracked from start of care through end of care

CONCLUSIONS

- Significantly lower hospitalization rates with V.A.C.® Therapy™
- Significantly lower rates for emergency care for wound problem with V.A.C.® Therapy™
- V.A.C.® Therapy™ may decrease unexpected health care cost
- V.A.C.® Therapy™ can potentially help Home Health Agencies to improve patient care

Ref: CSS2006-3

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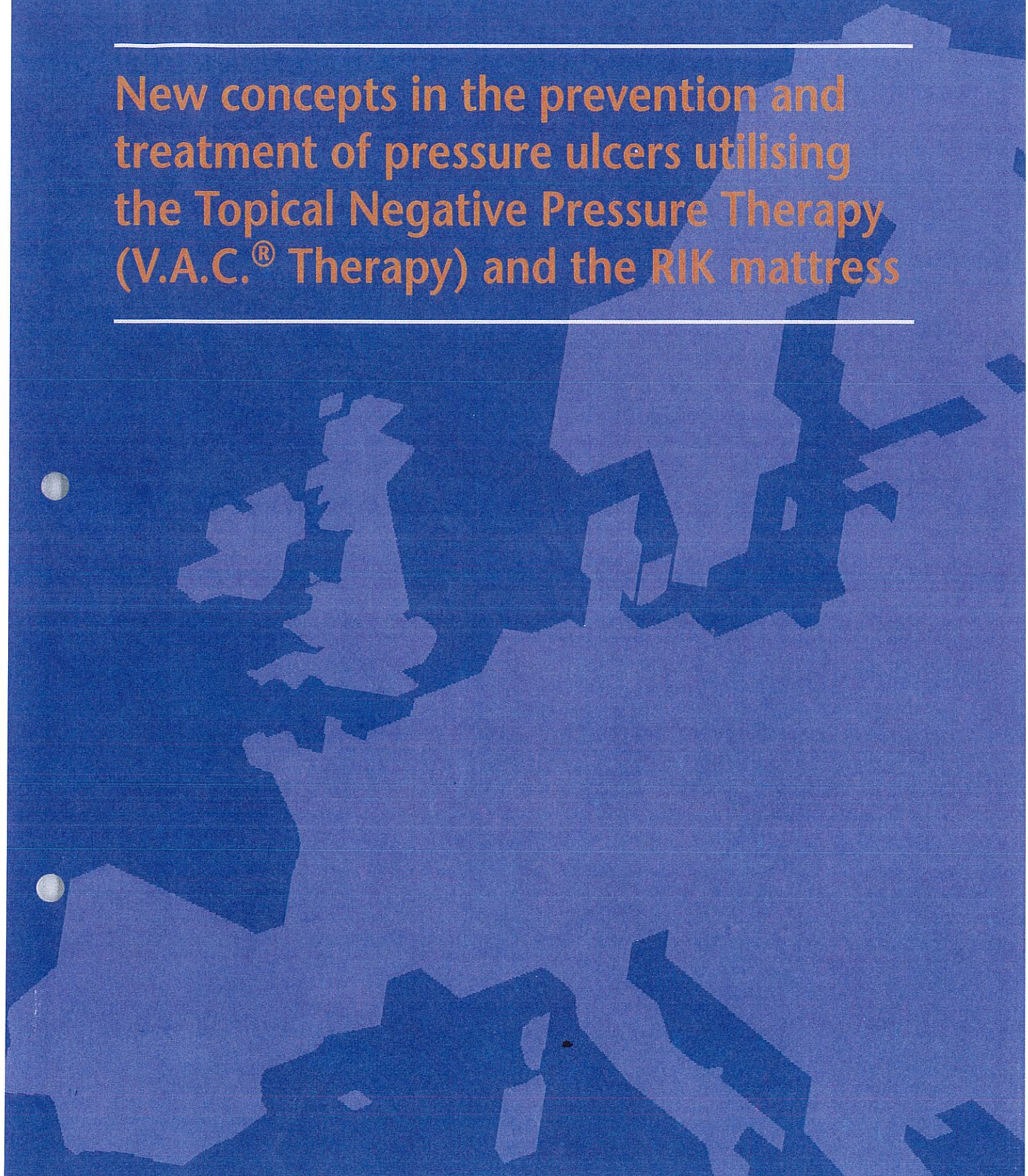
New concepts in the prevention and treatment of pressure ulcers utilising the Topical Negative Pressure Therapy (V.A.C.® Therapy) and the RIK mattress



Proceedings of the European Pressure Ulcer Advisory Panel Satellite Symposium, Tampere, Finland, September 2003

This publication is sponsored by an unrestricted educational grant from KCI The Clinical Advantage

Contents

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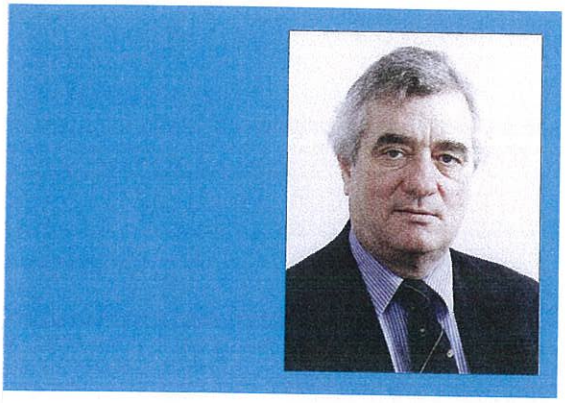
The Clinical Advantage™

Introduction



Dr George W Cherry
Chairman of the Oxford International Wound Healing Foundation, and Secretary/Treasurer of the European Pressure Ulcer Advisory Panel

THIS symposium on 'New concepts in the prevention and treatment of pressure ulcers utilising topical negative pressure therapy (VAC) and the RIK mattress' was unique in that it concentrated on the two most important aspects of pressure ulcers – prevention and treatment.

At the Sixth European Conference on Wound Management (held in Amsterdam in 1996) I personally invited Dr Lou Argenta, the inventor and clinical pioneer of the VAC, to present his work on this unique method of treating wounds. At that time he had been working on the technique for seven years and had treated 400 patients in his hospital in USA. Today the number of patients throughout the world that have been treated with the VAC is many thousands and it is used on a variety of wounds of which pressure ulcers are a major type. Probably the most important part of his presentation at that time, other than the impressive clinical results which he presented, was the following statement: 'Not only does the use of vacuum-assisted closure facilitate mechanical closure of the wound, but there is increasing evidence that, for the first time, the interstitium of the wound itself can be treated.' This latter comment has led to much research on the mechanism of VAC therapy for wounds, which at the same time has been complemented by numerous clinical studies.

In this EPUAP satellite symposium two clinical practitioners, a plastic surgeon and a tissue viability nurse, shared their experiences of using the VAC in treating pressure ulcers. The prevention of pressure ulcers by pressure-relieving mattresses is just as important as the treatment of the wound and is also a standard part of pressure ulcer therapy.

Two additional speakers discussed the importance of pressure relief; one spoke on a randomised control trial of the RIK mattress and the other on the healing of pressure ulcers with this system.

In summary, this symposium gave an opportunity for the participants to learn from clinical users of both VAC therapy and a pressure-relieving mattress for the management of pressure ulcers.

The Rationale of VAC (Vacuum Assisted Closure) Therapy in the Treatment of Pressure Ulcers

E. Tiernan,
Consultant Plastic Surgeon,
Odstock Dept. of Burns, Plastic
and Maxillofacial Surgery,
Salisbury, England.

THE controlled application of negative pressure across a wound is a non-pharmacological method of wound manipulation. Popularised by Morykwas and Argenta and Fleischman, it has been shown to decrease oedema, increase blood flow, increase granulation tissue, decrease bacterial colonisation and promote reverse tissue expansion.

THE use of the VAC machine has been described in the most complex of cases, as a stand alone treatment, for wound bed preparation, for salvage or as a adjunct to surgery (Figures 1–2).

In pressure ulcers VAC use has decreased the need for surgery and reduced the frequency of dressing changes, freeing up nursing time and allowing for earlier patient discharge. Thorough wound debridement, with the removal of necrotic tissue, and protection of adjacent delicate skin, prior to the application of VAC therapy, prevents further damage to the already comprised patient. Negative pressures from 50 mmHg to 175 mmHg are then applied to the sealed wound for between two and five days. More frequent changes are required in infected wounds. Appearance of healthy granulation is usually noted after two or three dressing changes, although VAC therapy may

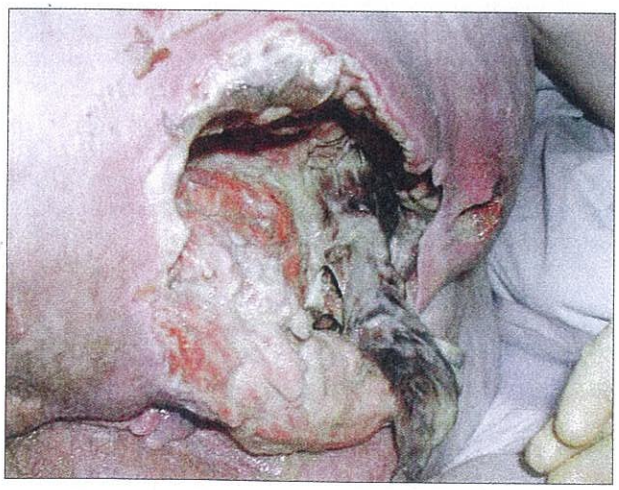


Figure 1. Necrotic ulcer

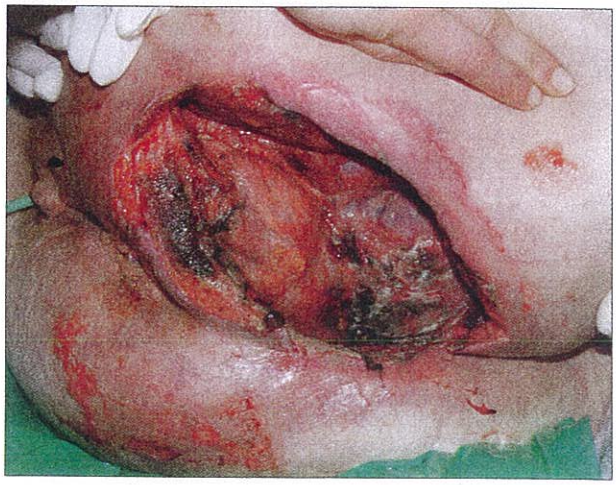


Figure 2. 2/52 post debride + VAC

also be a convenient way of managing malodorous wound discharge, minimising dressing changes and avoiding psychological distress for the patient.

In a series of 94 EPUAP Grade 3/4 pressure ulcers over a two-year period, aggressive conservative management, coupled with the use of VAC in over 30 patients, allowed 39 to heal, while 12 required surgical closure leaving the remainder currently in a healing phase (11 died). Negative pressure was also used to salvage a surgical closure of an ischial sore which dehisced (figures 3–5).

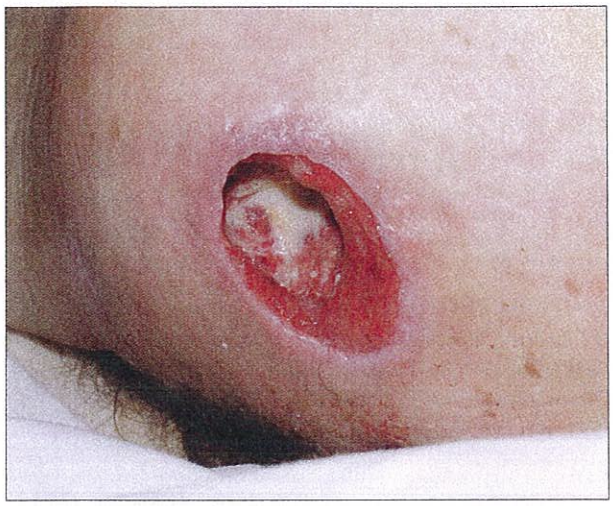


Figure 3. Ischial ulcer

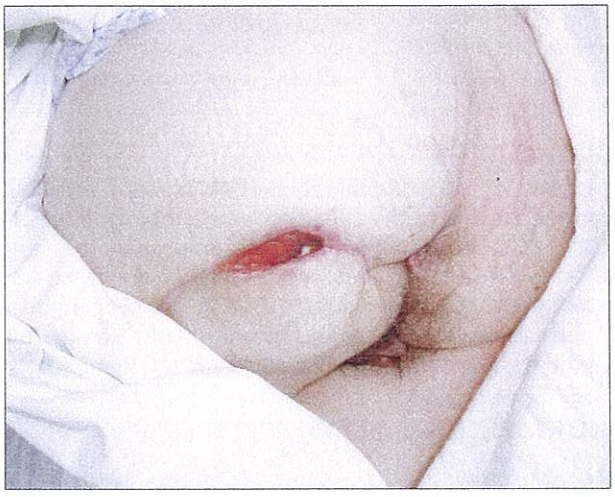


Figure 4. Post Surgery

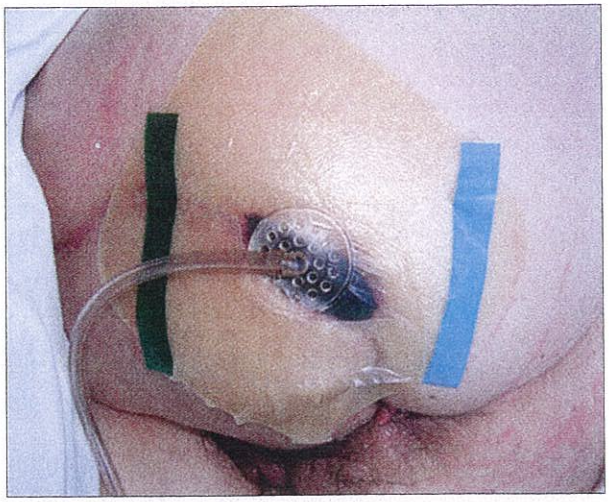


Figure 5. VAC application

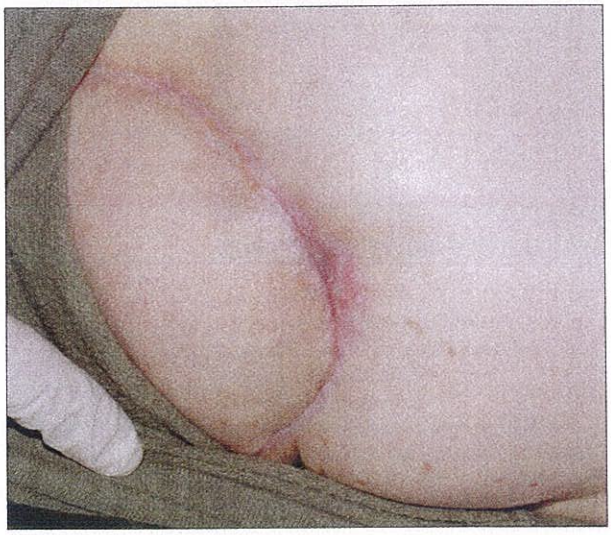


Figure 6. 6/52 post VAC

Wound care management costs in excess of £1 billion per year in the UK. VAC use allows earlier patient discharge, frees up nursing staff and may well be a cost-efficient method of managing pressure ulcers.

A Tissue Viability Nurse's Perspective of VAC Therapy in Pressure Ulcer Treatment

Maureen Benbow MSc BA RGN HERC
Tissue Viability Nurse,
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THIS paper discusses the experience of using VAC Therapy in the treatment of a series of patients who presented to hospital with sacral and ischial tuberosity pressure ulcers. The paper will begin with a brief overview of VAC therapy, it's indications and contraindications, and principles of action; it will conclude with a discussion of four case studies in which VAC therapy was used to treat pressure ulcers.

The background to VAC Therapy

Vacuum Assisted Closure (VAC) was invented by Professor Louis Argenta, an American Plastic Surgeon as a non-invasive active therapy which promotes healing. VAC therapy was introduced into the US and approved by the US Food and Drug Administration in 1995. VAC therapy is widely used throughout the UK to manage and assist healing in numerous types of wounds both in hospital and community settings.

Wound drainage is not a new idea. For many years, surgeons have used various systems to drain away excess fluid from the deep tissues of surgical wounds. In the pre-antibiotic era, drainage tubes were used to drain pus away from surgical cavities, a practice that reduced sepsis and was often lifesaving. There are wide variations in the types of drainage systems used, with each surgeon having his or her preferred methods and indications for using drainage systems (Westaby 1985). Historically, drains have ranged from corrugated rubber, tubes, gauze wicks, and catheters with or without attachment to a drainage bag. Some relied on gravity, others a material conduit to remove fluid from the wound. Newer, closed drainage systems that efficiently employ negative pressure have largely replaced older forms of drainage. Low pressure vacuum drainage is invaluable in cases where haemostasis has been difficult to achieve, haematoma formation and post-surgery sepsis. The excess fluid drains into a closed system with one-way valves to prevent back flow of drained fluid. The tubing in contact with the wound is perforated but the main problem is that the tube must be in contact with a reservoir of fluid or the draining tissue to be effective.

Other disadvantages associated with conventional drainage systems include:

- Foreign body reaction prolonging inflammation
- Strike-through of wound fluid into absorbent dressings
- Internal pressure necrosis from the tubing sometimes leading to fistula formation
- Poor positioning of the tube may lead to the build-up of fluid in the tissues increasing the risk of infection and causing inconvenience to the patient.

VAC Therapy

VAC therapy, otherwise known as vacuum-sealing technique, foam suction dressings, sub atmospheric pressure therapy among others, performs very differently from its predecessors. The main differences relate to:

- The application of topical negative sub-atmospheric pressure across the whole of the wound surface via a relatively simple foam dressing cut to fit the wound dimensions (Figure 1. Principles of Action of VAC Therapy)

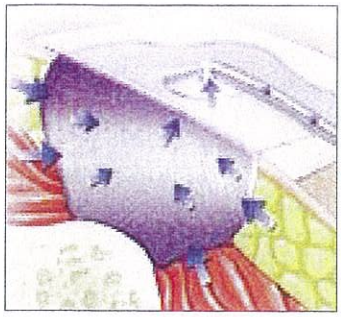

Figure 1. Principles of Action of VAC Therapy

- The application of constant controlled levels of continuous or intermittent sub-atmospheric pressure
- The reduced risk of contamination caused by contamination via the drainage tube
- The mode of application and technology used to deliver the therapy.

The positive effects of topical negative pressure VAC Therapy have been well documented in the literature, mainly presented in the form of series and case studies (Banwell 1999, Argenta and Morykwas 1997, Fleishman *et al* 1995, Mulner *et al* 1997).

VAC therapy has been shown to accelerate debridement and promote healing by the application of controlled levels of negative pressure in many different types of wounds. The technique is relatively easy to apply and manage. The application of topical negative pressure therapy removes extracellular fluid and exudate, reduces oedema and improves blood flow. The theory is, that by providing improved oxygenation and nutrition to the wound site, healing will be accelerated (Kalailieff 1998). The negative pressure is achieved by fashioning a piece of open-pore black foam to the size of the wound, placing it into the wound, covering with adhesive drape and embedding a fenestrated tube into the foam through the drape. The drape, which is vapour-permeable to facilitate gaseous exchange (Mendes-Eastman 2001), must provide a continuous airtight seal around the dressing during therapy. The negative pressure effect is achieved by the foam dressing being in contact with all surfaces of the wound and avoids the possibility of localised areas of high pressure and tissue necrosis. The evacuation of air from the foam causes the foam to collapse and provide mechanical distraction of the surrounding tissues. The suction tubing is attached to a microprocessor-controlled vacuum unit which provides either continuous or intermittent sub atmospheric negative pressure at different levels according to the needs of the wound. The VAC ATS system at 5.6kg, 37cm (W) by 28cm (H) by 18cm (D) and a canister capacity of 500ml is suitable for less mobile patients with highly exuding wounds, while the portable VAC Freedom system is more suited to mobile patients with lower exudate levels. In-built alarms alert the nurse and patient to any problems with the system such as the dressing seal being lost or the tubing being disconnected.

Exudate, containing excess metalloproteinases and bacteria, is sucked through the tubing into a sealed canister situated in the VAC machine. The dressings, tubing and canister are disposed of as clinical waste after single use.

In adults with a non-infected wound, the dressing should be changed every 48 hours, while in an infected wound the frequency should be increased to every 12 hours; VAC dressings used in children and adolescents should be changed every 24 hours (KCI recommendations). The recommended frequency of dressing change is based upon the observation after 48 hours that a biofilm develops within the wound which can block the pores of the foam dressing. The formation of a biofilm will reduce the effectiveness of the therapy as exudate will only be removed from areas around the dressing. There is some controversy relating to whether the wound surface should be lined with a non-adherent dressing to prevent the in-growth of granulation tissue into the black foam dressing. There is some evidence that lining the wound reduces the negative pressure effect and so the efficiency of the therapy and healing. However, in view of the observed problems associated with the in-growth of granulation and the trauma caused when the dressing is removed, the local policy is always to line the wound with either Urgotul or Mepitel.

Proposed mechanisms of action

The actual mechanism of action is still unclear but Azad and Nishikawa (2002) propose the following:

- Change in microvascular blood flow dynamics, with an improved local blood supply
- Removal of fluid exudate
- Stimulation of the formation of granulation tissue
- Reduction in bacterial colonisation
- Mechanical closure of wounds by reverse tissue expansion
- Maintenance of a moist wound environment with better wound healing.

Indications for VAC Therapy

VAC therapy may be used to treat a wide range of wounds successfully:

- Chronic open wounds e.g. diabetic foot ulcers, grade 3 and 4 pressure ulcers, leg ulceration.
- Acute and traumatic wounds
- Flaps and grafts
- Sub-acute wounds: dehisced surgical wounds, partial thickness burns, snake and spider bites

Contraindications to VAC Therapy

Wound and patient assessment will guide the clinician towards the suitability of VAC in individual circumstances, but there are certain situations in which VAC therapy would be contraindicated:

- Where there is a fistula of unknown source
- Necrotic tissue with eschar present
- Opening into a body cavity or where there are vulnerable body organs
- Untreated osteomyelitis
- The presence of local malignancy
- Exposed blood vessels or organs

Precautions should be exercised when there is active bleeding in the wound, difficult haemostasis or when the patient is taking anticoagulants (4–6mim clotting time). In the case of infected wounds the dressing/canister will need changing more frequently.

Possible complications

Rarely, complications attributable to VAC therapy may arise and include the following:

- Pressure necrosis from the tubing
- Skin trauma
- High pressures may cause pain
- In-growth of granulation tissue (may be alleviated by lining the wound with a non-adherent dressing or smearing a small amount of hydrogel dressing over the surface of the wound prior to placing the foam)
- Allergic reaction to the drape
- Fistula formation
- Neoplasms due to an increase in blood flow.

Desired effects of VAC Therapy

Moist wound healing is known to be the standard of care for the development of granulation tissue through the proliferation of macrophages, fibroblasts and epithelial cells. Other beneficial effects include:

- The removal of exudate
- Reduction in oedema
- Increase in blood flow
- Stimulation of granulation tissue formation
- Reduction in bacterial colonisation
- Promotion of wound contraction
- Promotion of epithelialisation
- Reverse tissue expansion leading to wound closure.

Case studies

The following section presents and briefly describes the special problems experienced when managing the complex wounds of five patients.

Case study 1

John

John was a 48 year old, previously fit and well man who contracted viral encephalitis. He was treated in the Intensive Care Unit for four weeks before being transferred to a rehabilitation ward. On transfer, John was semi-comatose, confused, immobile, incontinent, poorly nourished and in an unstable medical condition. He also suffered from post-encephalitic epilepsy. The skin over his sacrum was firstly discoloured which, after a couple of days, had developed into a grade 3–4 pressure ulcer. The ulcer was debrided to reveal a clean, full thickness wound.

John required maximum nursing and medical support to manage both his medical and confusional state, in which he was constantly removing the dressing from his sacral ulcer. VAC therapy was applied for two main reasons:

- To manage the wound and promote healing
- To discourage John from removing the dressing

Good progress was made with wound healing in spite of John's fluctuating medical condition. VAC therapy continued for a total of nine months until the wound was down to approximately 2cm round, at which time he was transferred to a long stay rehabilitation ward in another hospital. VAC therapy was continued for so long because it was the only way that a dressing could be retained and the wound protected from faecal contamination.

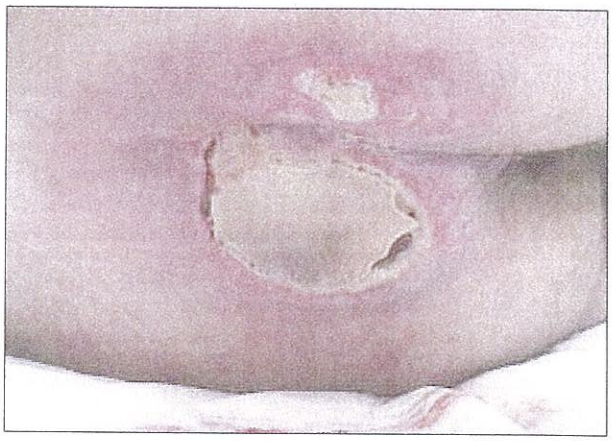

Figure 1. John – pre-debridement.

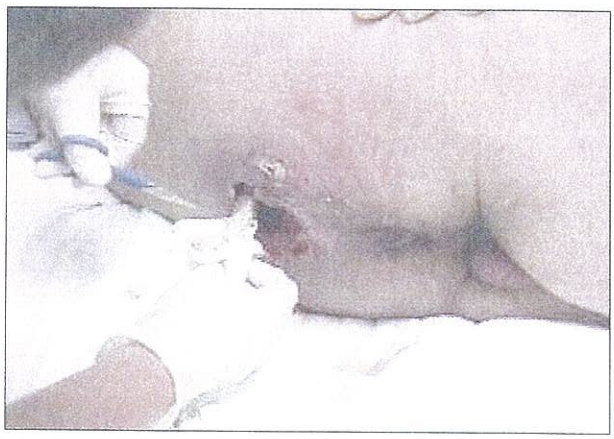

Figure 2. John – wound debridement.

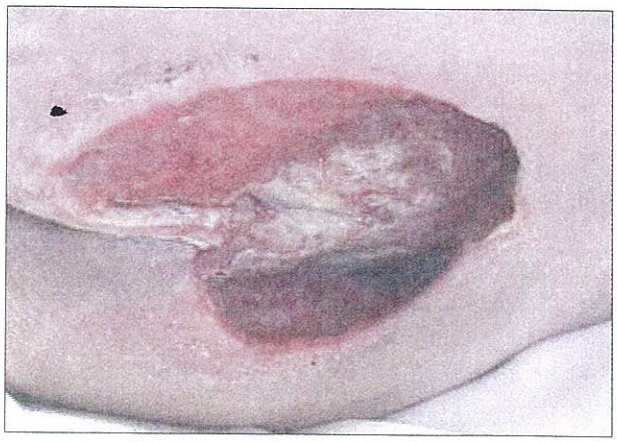

Figure 3. John – post-debridement

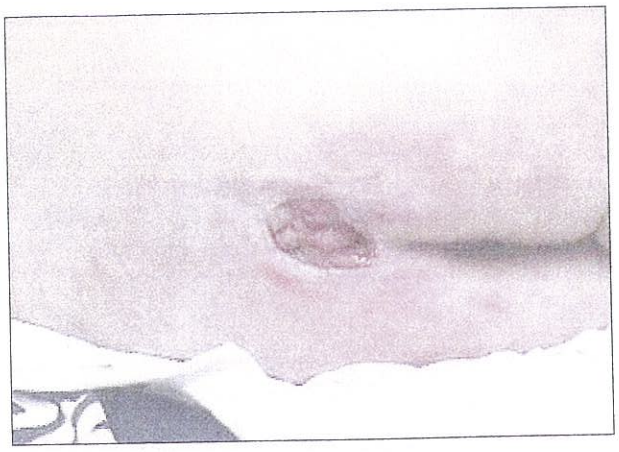

Figure 4. John – 9 months of VAC therapy

Case study 2.

Sophie

Sophie was a 72 year old Polish lady who spoke little English. She was found three days after collapsing whilst taking a bath. The cause of the collapse was unknown but an epileptic fit was suspected and she had no recollection of what had led to her admission to hospital. There was no history of previous ill health but now she was dehydrated, nutritionally compromised, and doubly incontinent. Pressure damage was evident to her heels (grade 1) and buttocks grade 3, approximately 10cm x 8cm and 8cm x 6cm and necrotic.

The buttock wounds were debrided, VAC therapy applied with an excellent result after only six weeks of treatment.

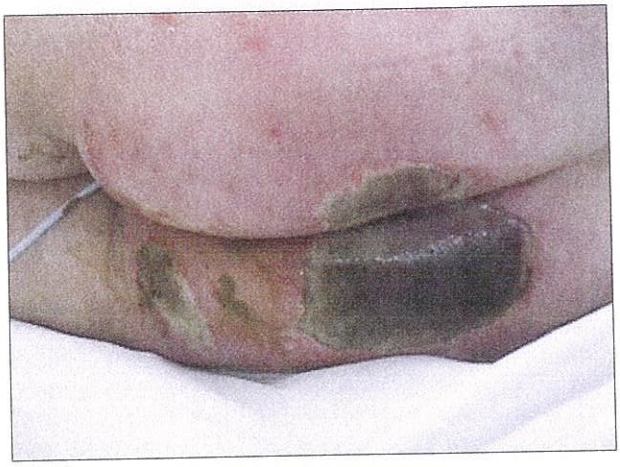

Figure 5. Sophie – pre-debridement

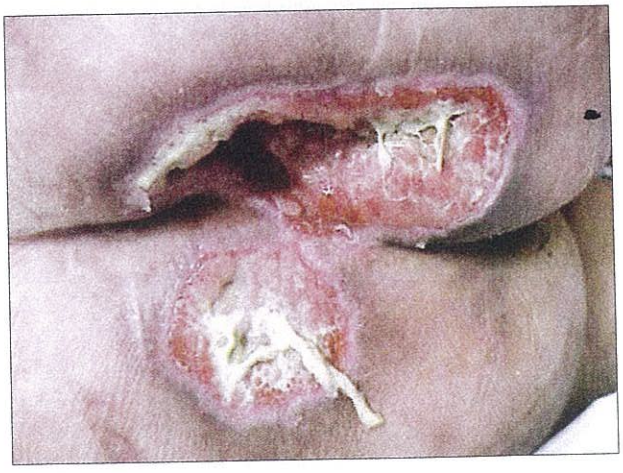

Figure 6. Sophie – post-debridement

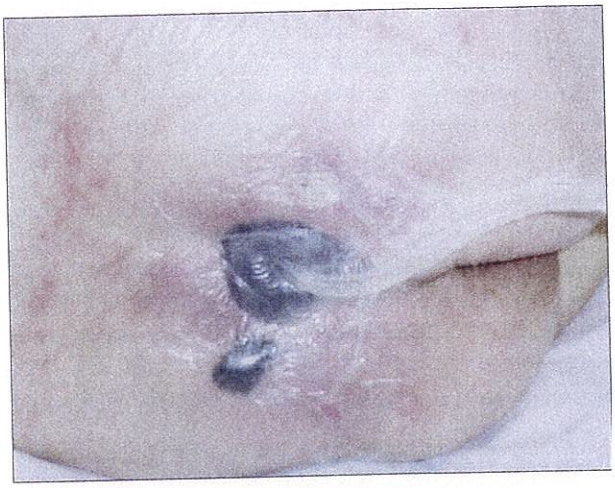

Figure 7. Sophie – VAC dressing in place

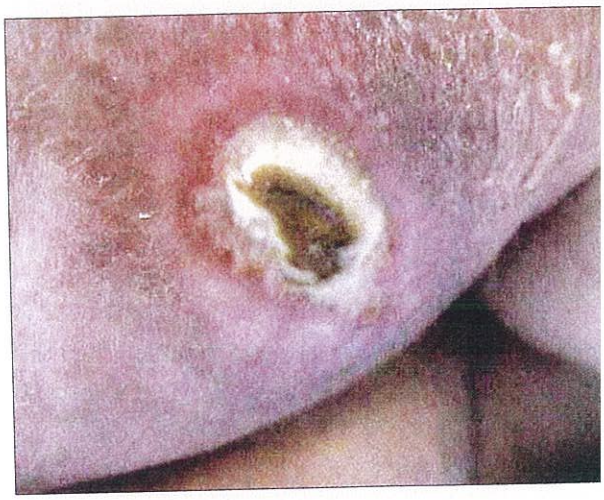

Figure 8. Sophie – healing

Case study 3.

Mary

Mary was an 86 year old lady, admitted from a nursir
home with reported 'bruising' of her sacrum; the har
warm, discoloured, indurated area was approximate
15cm x 12cm. Mary's general condition was very po
having gradually become more immobile over the pre
ous week and now she was dehydrated and not eatir
doubly incontinent, immobile and confused. Surgical c
bridement of the area revealed extensive tissue necro
that would require further debridement after a few da
The extent of the debridement encircled the anus that
quired further surgery for the formation of a colostor
VAC therapy was chosen to manage the very large wou
that resulted from debridement of the wound. In spite
excellent nursing and medical care Mary died after f

weeks. The VAC therapy was continued regardless of the poor prognosis to enable good wound management to the end.

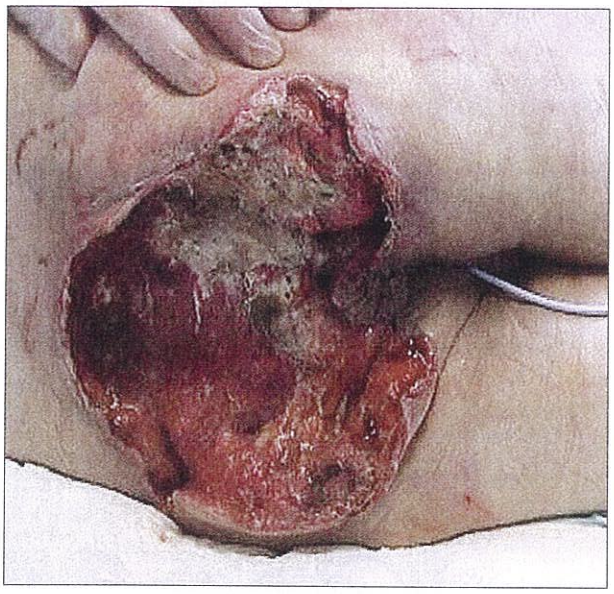

Figure 9. Mary – post surgical debridement

Case study 4.

Giles

Giles was a 38 year old man who had suffered from paraplegia since an accident at 4 years of age. He had a long-term psychotic personality problem and was totally non-compliant with any form of treatment. Giles would sit in his wheelchair without a pressure-reducing cushion for 18 hours a day; he was a heavy smoker and his dietary intake was poor. Severe ischial tuberosity pressure damage followed a gastrointestinal infection in which diarrhoea was a major problem, combined with the fact that he would not use a penile sheath to contain urinary incontinence. Giles was constantly sitting on a soiled, wet surface but unaware of the fact. He refused to lie in bed, off the damaged area, and persistently removed his dressings.

Was VAC therapy the answer? No, not in Giles' case.

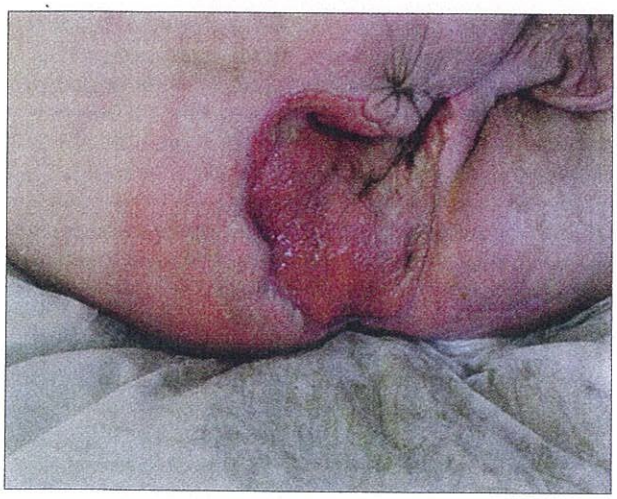

Figure 10. Giles – ischial tuberosity ulcer

Case Study 5.

James

James was a 59 year old man suffering from advanced multiple sclerosis. Dissatisfied with his social circumstances, his relationship with his wife and life in general, he deliberately sat for 48 hours non-stop without a pressure-reducing cushion, fully aware of the dangers. On admission, he was dehydrated, malnourished and low in mood. By involving James in decisions concerning his management, it was possible to talk through some of the problems that had led to his actions and gain his cooperation for the application of VAC therapy. It was important that James recovered as quickly as possible so that attempts to resolve his social and relationship problems ran in parallel to trying to resolve his physical problems. A major part of James' recovery centred on educating him of the dangers associated with the development of pressure damage in someone in his advanced disease state and persuading him not to attempt to self-harm again.

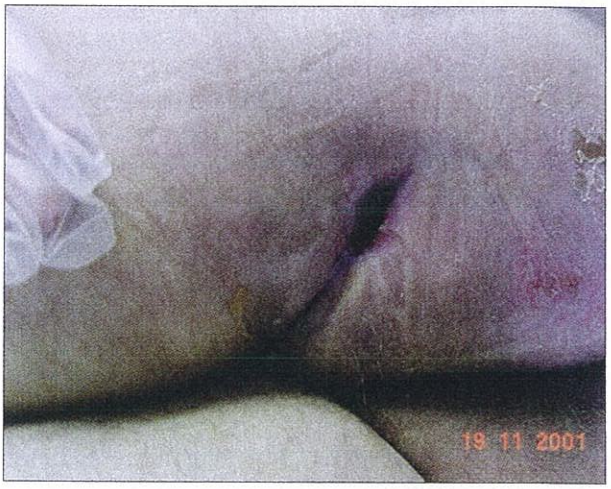

Figure 11. James – ischial tuberosity pressure ulcer

Discussion

This paper has discussed the use of VAC Therapy in the management of patients with severe sacral and ischial tuberosity pressure damage and their complex management. Patients do not just present with a wound, the wound is always a sign of other physical, psychological or, indeed, social imbalance. It is not fair to say that VAC therapy was used in all cases just to promote healing, often it was to help nurses manage wounds more effectively and improve the quality of life for the patient. Some of the patient issues touched upon include compliance to treatment or lack of it, motivation to recover, patient and staff expectations of what VAC therapy can deliver and its limitations. Organisational issues cannot be ignored in the discussion. The cost of VAC therapy is not insignificant, so sound rationale and a commitment to use for as long as it is clinically indicated is essential – healing will not happen overnight. As for any new technology, device or technique, training and education of staff, patients and carers combined with company support is vital for cost-effective and clinically effective use.

Conclusion

VAC therapy is a very effective way to manage wounds allowing earlier discharge, faster wound healing, less frequent dressing changes needing reduced nursing time. The advantages must be weighed against the cost and will usually outweigh the initial and ongoing cost of therapy. A major advantage, though sometimes overlooked, is the positive impact on the quality of life of the patient.

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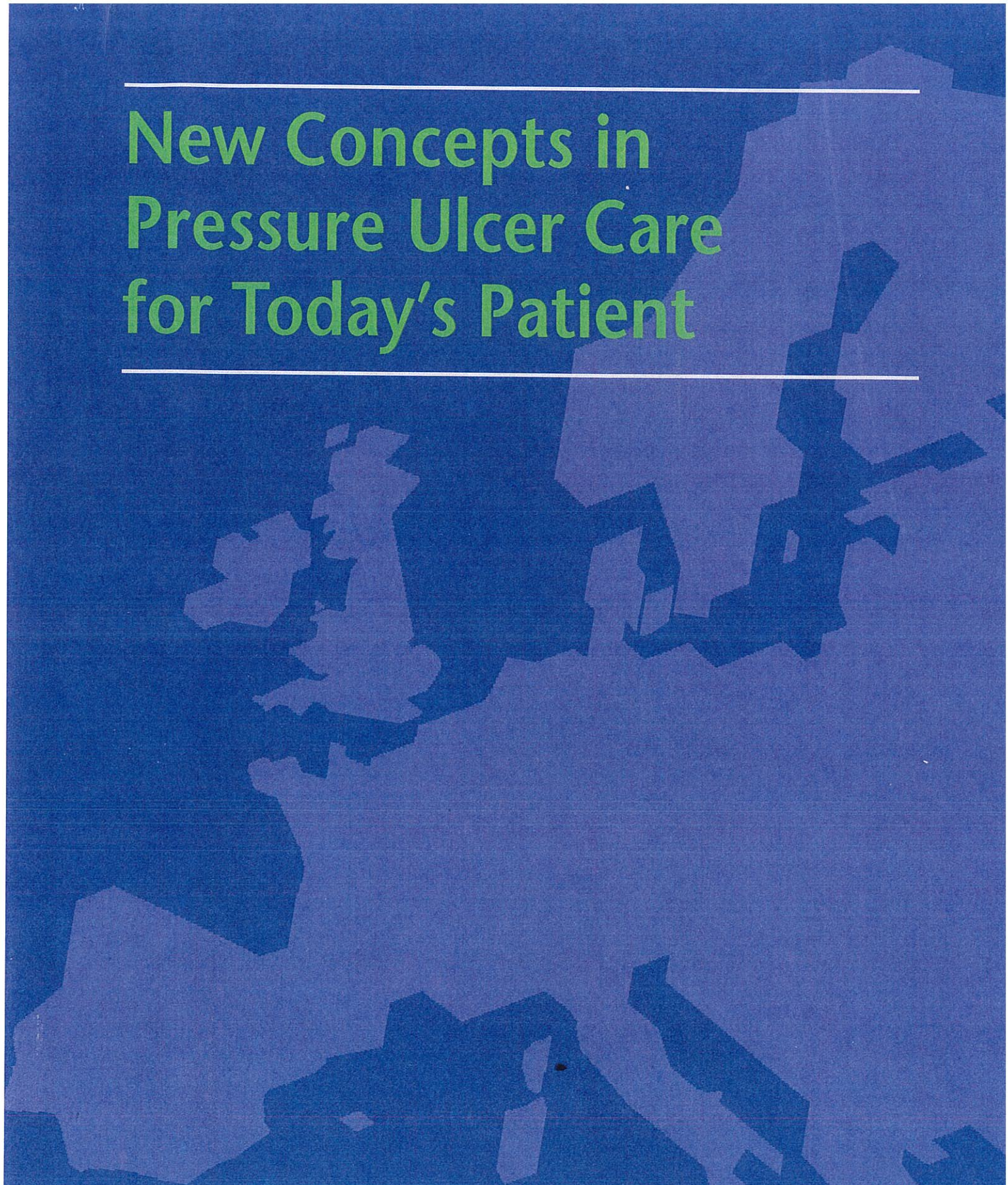
New Concepts in Pressure Ulcer Care for Today's Patient



Proceedings of the European Pressure Ulcer Advisory Panel Satellite Symposium, Aberdeen, Scotland, May 2005

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Introduction

NEW CONCEPTS IN PRESSURE ULCER CARE FOR TODAY'S PATIENTS

Dr George W. Cherry

Proceedings of the Satellite KCI Symposium
5–7 May 2005, EPUAP Panel Meeting, Aberdeen, Scotland

THIS special symposium addressed the two fundamentally important aspects of pressure ulcer management – prevention and treatment.

The objective of the symposium was to share new clinical results from the use of the V.A.C.® (Vacuum-Assisted Closure) in treating pressure ulcers from a number of different perspectives. These included a plastic surgeon's experience, and a nurse's experience in the development of an algorithm for the treatment of pressure ulcers with V.A.C.®

The symposium also stressed the importance of prevention and treatment with the advanced pressure-redistributing surface system TheraKair VISIO. The important features of TheraKair VISIO include improvement of the microcirculation and lymphatic flow with pulsation, combined with pressure relief. These aspects were highlighted, along with the maintenance of the micro-environment of the skin by the unique surface characteristics of the mattress which is conducive to prevention as well as to enhancing healing. The concept of Low Air Loss Therapy which is fundamental to the TheraKair VISIO system was described, followed by presentation of clinical cases.

The participants of this symposium increased their knowledge of these two important treatment regimens for managing pressure ulcers: V.A.C.® and TheraKair VISIO Therapy.

PRE-TREATMENT OF PRESSURE ULCERS USING SUBATMOSPHERIC PRESSURE DRESSINGS ENHANCES PLASTIC SURGICAL COVERAGE

Professor Raymund E Horch MD
with Jürgen Kopp MD, Alexander D Bach MD and Ulrich Kneser MD

Introduction

Pressure ulcers represent a major medical and socio-economic problem. They significantly impair a patient's quality of life and may even become life-threatening if left untreated or treated inadequately.[1] Although a number of innovative conservative and operative treatment options have been developed, definitive coverage of pressure ulcers remains a challenge.[2] The most common sites of predilection are the ischium, sacrum, trochanter and heel. Many factors such as medical conditions, psychological situation and social circumstances have to be considered for an adequate treatment of pressure ulcers. The prognosis of the patient with regard to his mobility and recovery is important for decision making.

Treatment of pressure ulcers includes several conservative and surgical approaches. In many instances, medical care and maintaining patient comfort should be the goals rather than the institution of major invasive procedures. Generally speaking conservative therapy is appropriate for superficial ulcers in transiently immobilized patients, whereas deep ulcers above bony prominences in long-term immobilized patients such as paraplegic patients require surgery with a flap reconstruction to achieve sufficient and durable coverage. Wound healing and prevention of recurrence become the goals following successful closure of a pressure sore. In addition, reconstruction of any pressure ulcer is aimed at improvement of patient hygiene and appearance, prevention or resolution of osteomyelitis and sepsis, reduction of fluid and protein loss through the wound, and prevention of future malignancy (Marjolin ulcer). Surgical debridement is almost always indicated in advanced ulcers with involvement of the deep tissue, and when conservative wound dressings fail to clean the wound, or when deep ulcers contain significant amounts of necrotic tissue. Surgical debridement may also be carried out to accelerate conservative treatment of more superficial ulcers. Longstanding ulcers are bacterially contaminated. In order to prepare the recipient site for successful plastic surgical flap coverage, the wound bed has to be optimized. The vacuum-assisted closure (V.A.C.®, KCI, Europe) technique is widely used to induce and promote wound healing.[3] Surgical debridement combined with topical negative pressure therapy using the VAC device represents a promising tool to facilitate definitive surgical closure with grafts and flaps.[4,7,8,9]

Methods and Techniques

Since pressure ulcers are analogous to an iceberg (small visible surface with a more extensive unknown base), those more advanced ulcers presenting with muscle involvement and exposed bone (stage III and IV) were selected to receive surgical debridement and plastic surgical closure (Figures 1 and 2). The ulcer's extent was marked with methylene blue prior to excision. The ulcer was then excised en bloc with the surrounding skin, underlying bursa and soft tissue calcifications as well as the underlying infected bone. Affected bony tissue was radically removed. Accurate haemostasis was always ensured since blood loss may be significant during and after debridement. After excision the bone was carefully recontured in order to prevent recurrence of the ulcer. In our trial surgical reconstruction was attempted after radical surgical debridement followed by continuous Vacuum therapy (V.A.C.®, KCI Int., Amsterdam) until the wound bed was ready for flap surgery (Figures 3 and 4). Continuous negative pressure was applied with –125mm Hg and the wound effluent was collected in a canister. Dressing changes were performed every 48 hours during the wound treatment period. Sequential debridement of necrotic tissue took place when considered clinically needed.

Reconstruction was only carried out after complete and radical ulcer excision and adequate preparation of the wound. Tension-free closure of the defect and donor site was always achieved. Preferably, scars were avoided in the region of the former ulcer and above bony prominences. Local fasciocutaneous or myocutaneous flaps were raised

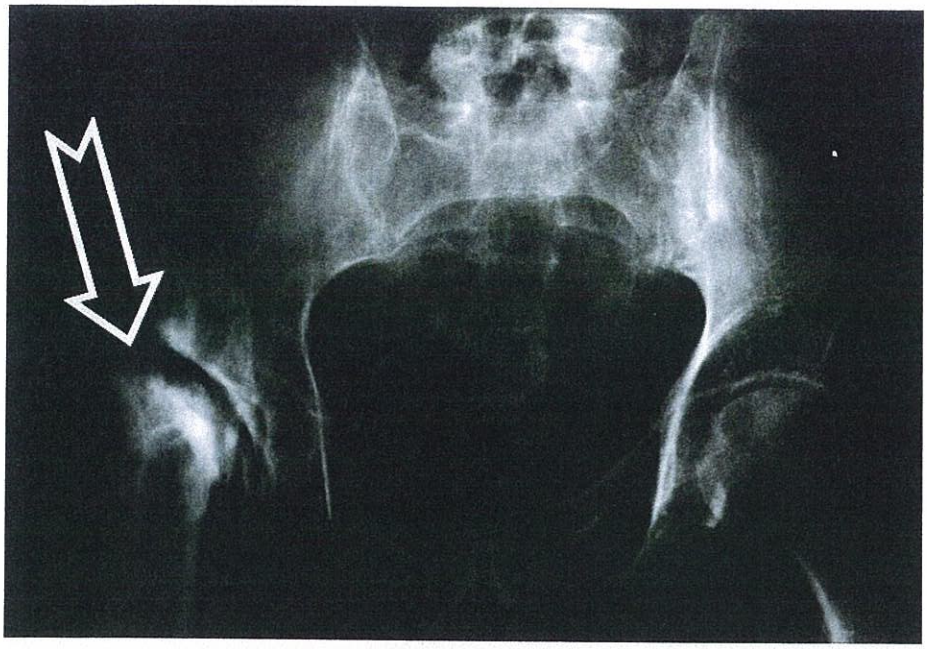

Figure 1.
Infected right hip joint with loss of both parts of the joint and chronic osteomyelitis beneath a 4th ° ischial pressure ulcer.

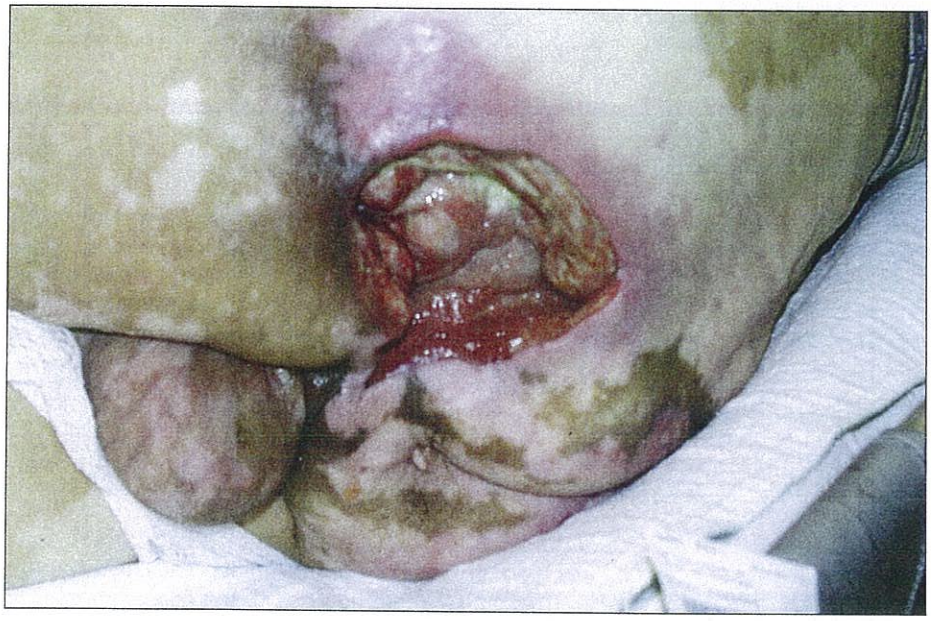

Figure 2.
Typical pressure ulcers with the hip joint still affected after three months of conservative treatment and first aggressive surgical debridement.

and placed in the defect. The choice of flaps followed an 'escalation scheme' from simple procedures to more complex coverage techniques (so called 'reconstructive ladder') to allow for secondary surgery of relapses in the future. Therefore, for many posterior pressure ulcers of the ischial and trochanteric regions an axially vascularized posterior thigh flap was the flap of first choice for many of our patients (Figures 5 and 6). However, a stepwise approach for any specific defect site was chosen according to individual needs. Free flaps remained as an ultimate solution. Closed suction drainage and perioperative antibiotics administration as well as pressure-relieving positioning in air fluidized beds for three weeks followed by three more weeks on an alternating pressure mattress were generally performed.[5] Sutures were left in place for 21 days following flap coverage.

Results

Between 1983 and 2004 a total of 89 patients with single or multiple pressure ulcers were treated with flaps. From 2001 we used the vacuum device in 14 pressure ulcer patients to prepare the wound bed after surgical debridement and prior to transposition of fasciocutaneous or myocutaneous pedicled flaps. In these patients the use of the vacuum sealing technique following irrigation and debridement decreased the dimensions of the initial wound, thus facilitating healing and the eradication of any pre-existing infection. We found that the period of wound bed preparation was significantly shortened after the introduction of VAC pre-treatment. The majority of patients (93%) with stage III and IV ulcers achieved sufficient wound closure within six weeks of debridement and continuous vacuum pretreatment. Secondary healing occurred in 3.5%

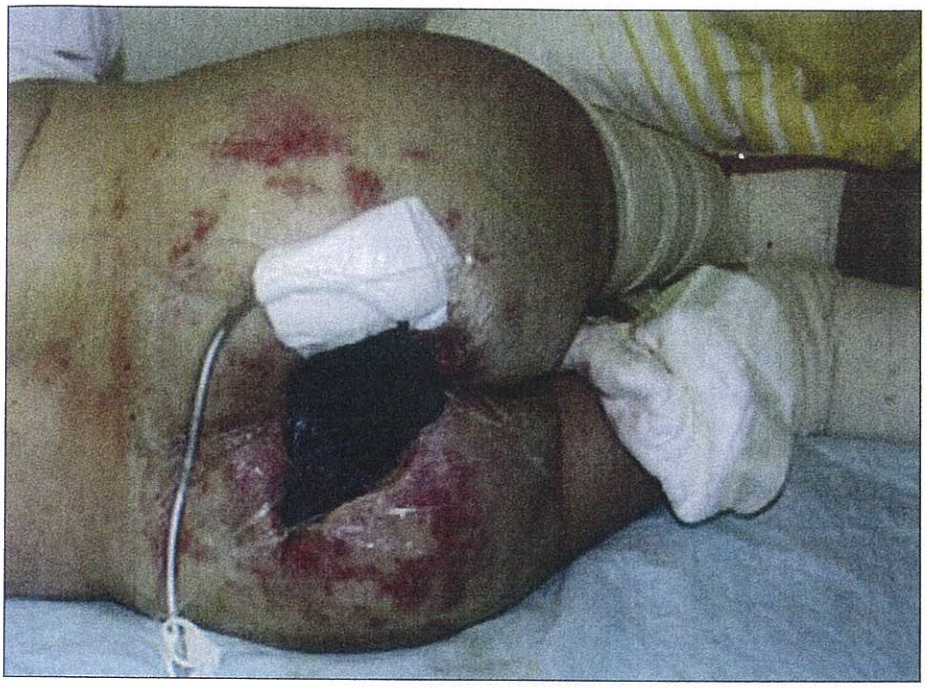

Figure 3.
Following surgical debridement a V.A.C. device is applied to a pressure ulcer with continuous negative pressure until proper wound bed preparation has been achieved.

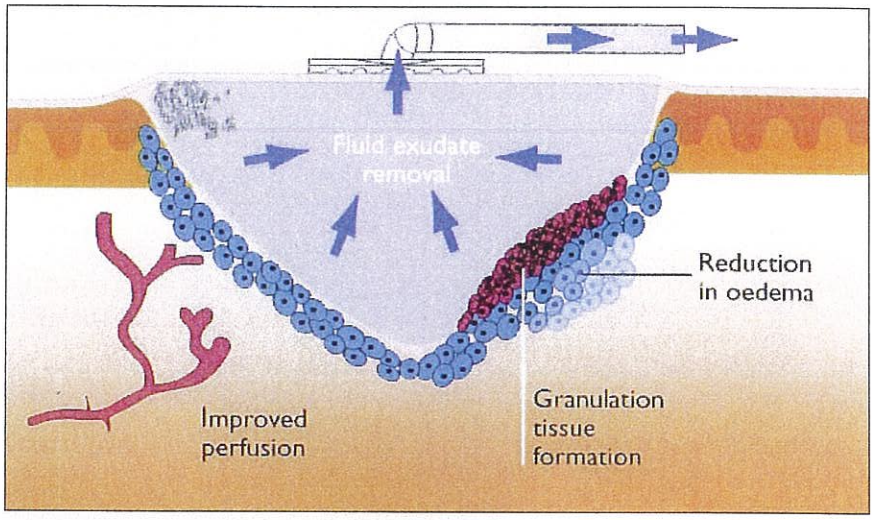

Figure 4.
Principles of action of the V.A.C. therapy device (reproduced by kind permission of KCI Europe).

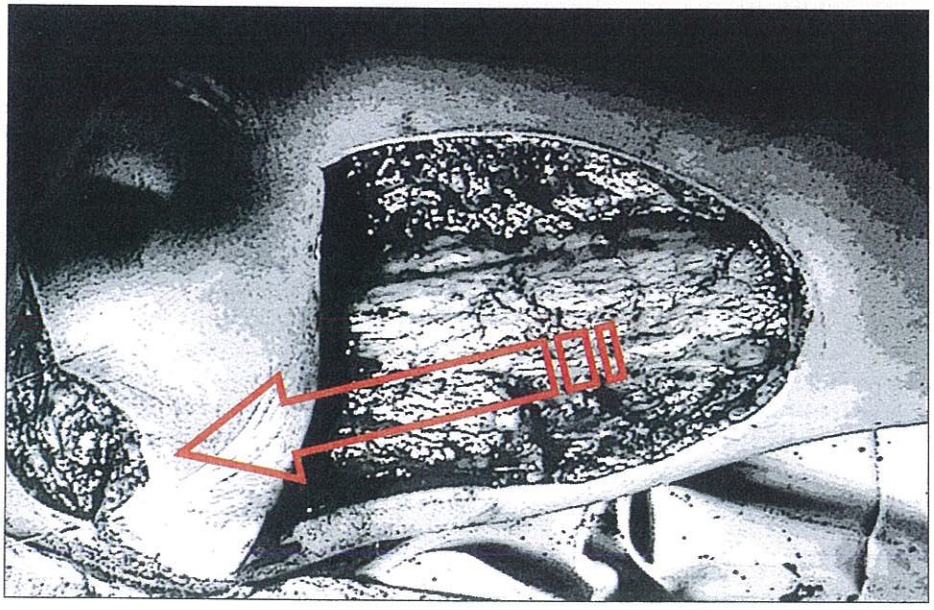

Figure 5.
To allow for further surgical options in case of relapse, a fasciocutaneous axially vascularized flap (here: posterior thigh flap) is always the method of first choice in our treatment algorithm.

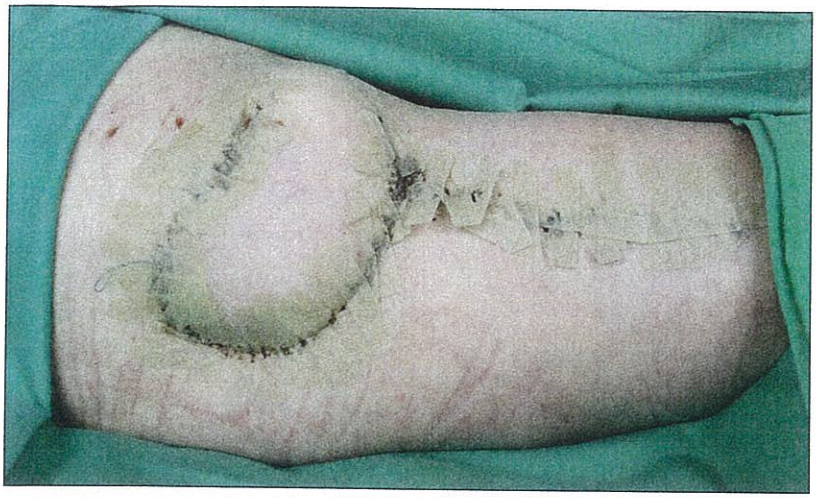

Figure 6.
After insertion of the posterior thigh fasciocutaneous flap the donor site can be primarily closed. Note that the tip of the flap has been de-epithelialized and buried to fill up the cavity of the ulcer.

of the patients, whereas in the historic control group without VAC pre-treatment the rate was 7.9%. One of the patients with partially secondary wound healing was irradiated in the flap area.

Discussion

Whereas for chronically- or terminally-ill patients with long-standing or recurrent ulceration a conservative approach is best suited to deal with a pressure ulcer, aggressive surgical treatment remains in the best interest of the patient when the therapeutic aim of treatment is either to resolve an acute infection with septic conditions or to close the wound and reintegrate the patient into social life. Once the decision has been made to treat a pressure ulcer surgically the mainstay of any procedure is a thorough surgical debridement before surgical closure can be achieved. Very few pressure ulcers can or should be closed primarily following debridement due to unacceptably high complication rates. However, this period of wound bed preparation can be tedious and time consuming. Both factors contribute to some of the major socio-economic problems in pressure ulcer treatment. With the advent of negative topical pressure application following surgical debridement a significant enhancement of this wound bed preparation period has been noticed.

Although the exact mechanism is not yet known in detail, it is hypothesized that negative pressure contributes to wound healing by reducing the bacterial load and removing excess interstitial fluid thereby reducing oedema, increasing vascularity of the wound and creating force to draw the edges of the wound closer together.[6] Complications of flap reconstruction include haematoma, seroma, wound separation, flap necrosis, flap dehiscence and infection and these have contributed in part to the bacterial load of the ulcers. The technique of vacuum pre-treatment after surgical debridement and before a definitive wound closure with surgical flaps has resulted in a high flap survival rate (93%) and fewer immediate infection complications. Furthermore, in our experience, it has reduced the rate of seroma formation. We have yet to analyze thoroughly the long-term results of our reconstructed complex pressure ulcer wounds, but we expect this analysis to confirm the long-term efficacy of these reconstructions. In conclusion, the vacuum sealing technique represents an effective option in the management of chronic pressure ulcers and allows efficient and safe plastic surgical reconstruction.

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MANAGING PRESSURE ULCERS WITH NEGATIVE PRESSURE WOUND THERAPY: EXAMINATION OF A CONSENSUS PANEL GUIDELINE

Dr Mona M. Baharestani

This paper and all algorithmic figures are adapted from Gupta S, Baharestani M, Baronski S, et al. *Guidelines for managing pressure ulcers with negative pressure wound therapy.* Advances in Skin and Wound Care. *2004; 17 (2–Suppl): 2–16.*

Introduction

Given the plethora of active and passive local modalities available for the treatment of full-thickness pressure ulcers, it is not surprising that clinicians are often overwhelmed and unsure of which products are most clinically efficacious and cost-effective. Negative pressure wound therapy as delivered by Vacuum Assisted Closure (V.A.C.®) has consistently demonstrated both clinical efficacy and cost-effectiveness.[2] For example, in a retrospective study by Philbeck *et al.*[3] an average closure rate of 0.23 cm^2 in Stage III and IV pressure ulcers (n = 566) was reported, compared to 0.090 cm^2 among those having received conventional wound care. Pressure ulcers managed with NPWT were found to be 38% less costly to treat than those receiving conventional care.[3] Even more impressive are results from a 2002 prospective Japanese study in which a daily closure rate of 1.0 cm^2/day was reported among infected Stage IV pressure ulcers treated with NPWT.[4] Pressure ulcers and other chronic wounds treated with NPWT revealed a statistically significant decrease in depth of 66% versus 20% in those treated with normal saline wet to moist dressings ($p < .0001$) in a study by Joseph *et al.*[5] Histologically, 81% of ulcers treated with wet to moist dressings revealed inflammation and fibrosis, whereas NPWT treated ulcers (n = 645) exhibited granulation tissue as the chief characteristic.[5] Despite multiple documented clinical benefits, faster wound closure rates and cost-savings, clinicians in various practice settings remain ambiguous regarding use of NPWT in the treatment of pressure ulcers, although comfortable with V.A.C.® use in acute wounds.

Guideline Development

Acknowledging clinicians' uncertainty in pressure ulcer treatment of when to initiate NPWT, on whom, using which settings, which foam and what pressure and for how long, a consensus panel was assembled with the mission of addressing these questions through guideline development. This interdisciplinary panel comprised of three nurses and five physicians with expertise in wound management and use of NPWT critically reviewed all literature published on NPWT use in pressure ulcer treatment, as well as current best practices for pressure ulcer management. The pres-

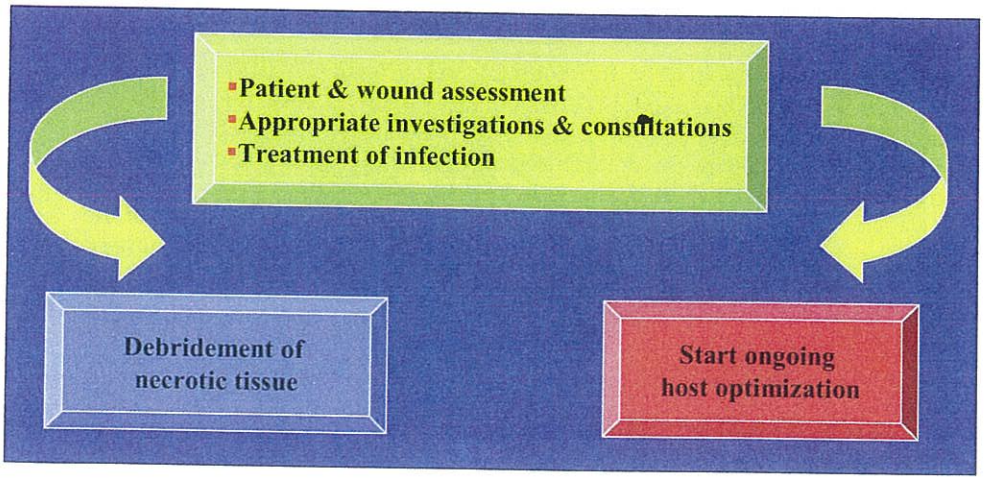


Figure 1
Management of a Patient with Pressure Ulcers using V.A.C.® Therapy

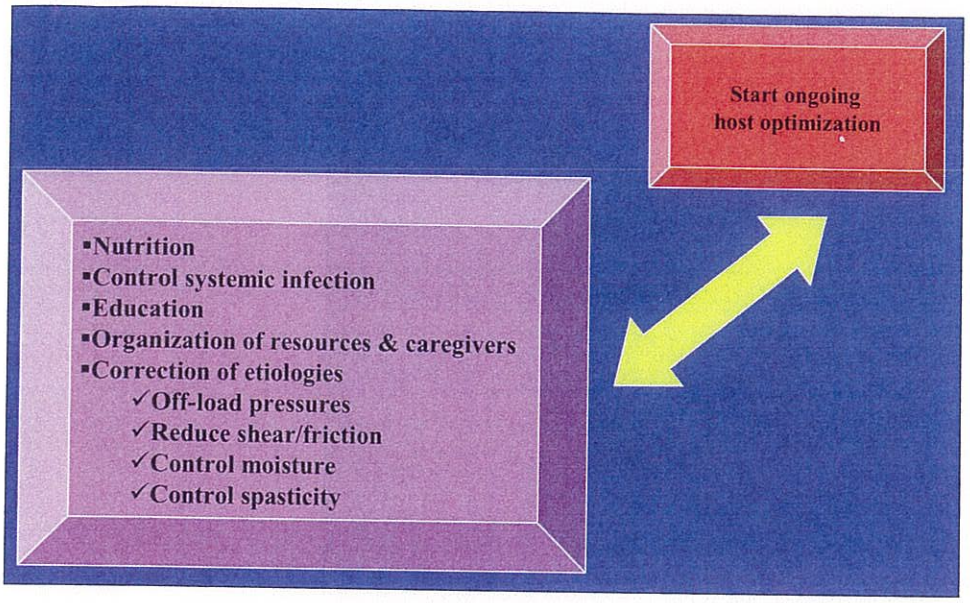


Figure 2
Management of a Patient with Pressure Ulcers using V.A.C.® Therapy

sure ulcer staging system utilized by this panel was that of the National Pressure Ulcer Advisory Panel (NPUAP).[6]

According to the Agency for Health Care Policy and Research (AHCPR)[7] now known as the Agency for Health Care Research and Quality (AHCRQ), guidelines are reflective of the current knowledge on effective and appropriate care. Furthermore, guidelines are aimed at assisting practitioners and patients in making decisions regarding specific conditions.[7]

Based on panel consensus and review of the literature, the fundamental algorithmic components of managing a patient with pressure ulcers using NPWT, as delivered by V.A.C.® therapy, are outlined in Figures 1 and 2. Use of NPWT in the surgical candidate is described in Figure 4. Figure 5 provides a treatment algorithm for NPWT in non-surgical candidates, while Figure 6 outlines patient and wound characteristics that are not favourable for V.A.C.®

In the development of a treatment algorithm for the management of patients with pressure ulcers using V.A.C.® therapy, the following key questions were answered by the panel[1]:

1. *What are the indications for NPWT in patients with pressure ulcers?*
   - Full-thickness pressure ulcers (Stage III & IV) (Figure 3)
   - An ulcer size large enough to allow foam contact with the base and for safe extraction
   - Poor or inadequate granulation tissue
   - Presence of undermine or tunnelling
2. *What wound characteristics do not favour use of NPWT?*
   - Inadequately debrided, fibrotic or desiccated wound beds
   - An ulcer size too small to allow for foam contact with base and for safe foam extraction
   - Inadequate haemostasis
   - Inadequate perfusion to support healing

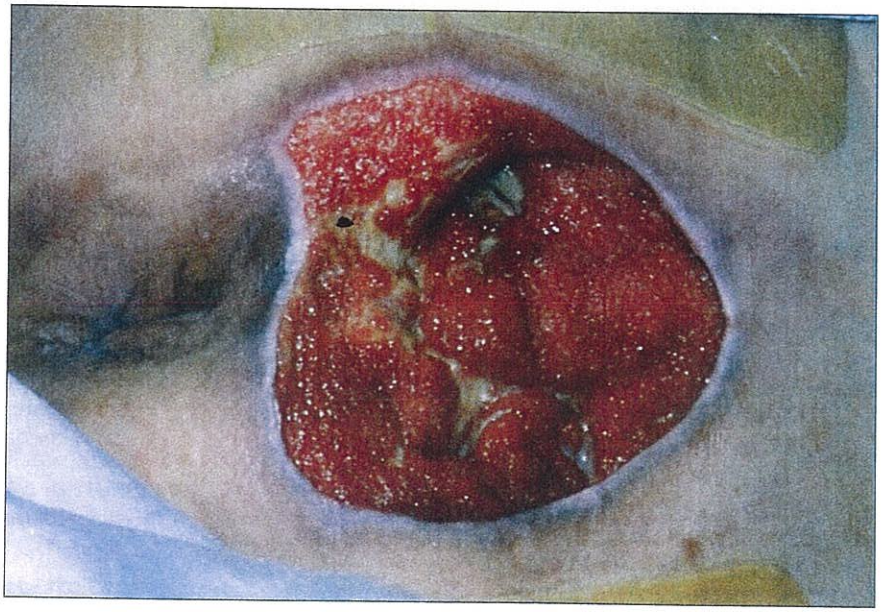


Figure 3
Stage IV Pressure Ulcer

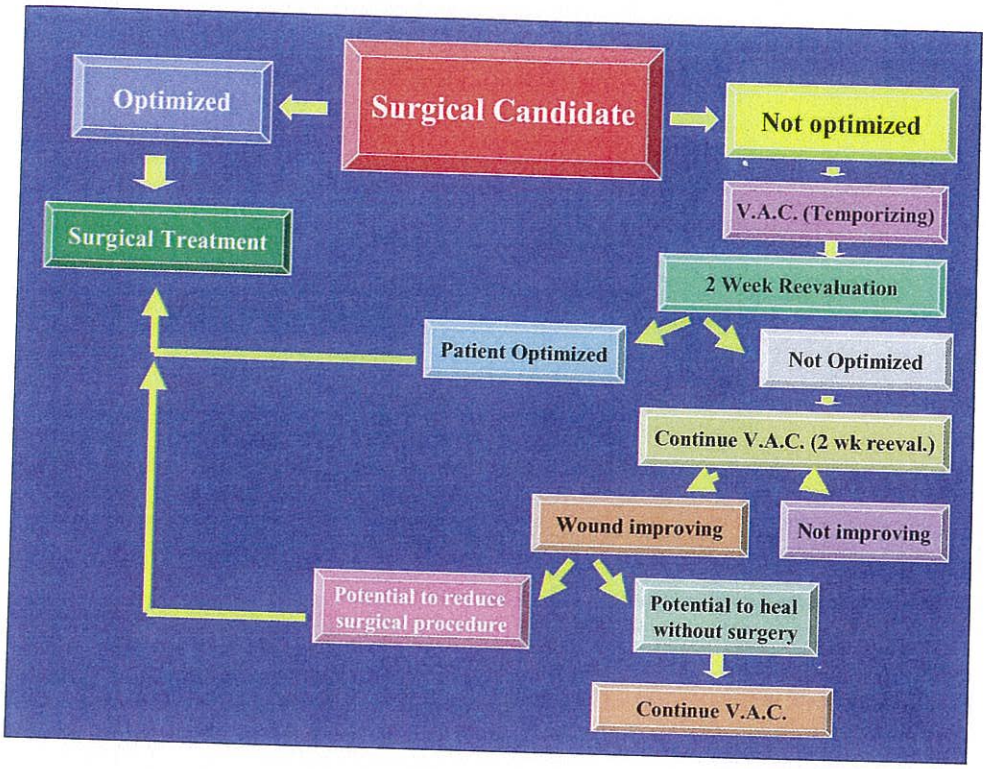


Figure 4

3. What patient characteristics do not favour use of NPWT?

- Inadequate patient adherence with pressure off-loading and other components of the treatment protocol
- Inadequate financial or caregiver resources
- Untreated malnutrition
- Intolerance of pain resulting from V.A.C.® therapy despite alterations made in technique
- Allergy to adhesive drape materials
- Inability to maintain an airtight seal
- Bleeding disorders impacting ability to achieve haemostasis
- Malignancy within the wound bed is cited by the manufacturer KCI, Inc. as a contraindication to the use of V.A.C.®[8] But, it was the consensus of the panel that NPWT can be used in palliative care when the management of pain and exudate control are treatment goals.

4. What wound size is most appropriate for NPWT use?

- As long as the ulcer meets the criteria outlined in question 1, then the wound size does not matter. For small pressure ulcers, clinicians must weigh the cost-benefit ratio of use of NPWT to that of other treatment modalities

5. How often should the wound be monitored?

- Monitor the ulcer with every dressing change
- In the absence of a heavy bioburden, the panel recommends that dressings be changed every 72 hours or sooner if indicated. KCI, Inc.'s recommendation is dressing changes every 12–24 hours for infected wounds and every 48 hours for noninfected wounds.[8]

6. What are the optimal settings for NPWT use in pressure ulcers?

- A target pressure of 125mm Hg is recommended based on the seminal research by Morykwas *et al.*[9] Pressure settings may need to be titrated from lower pressures of 75–100mm Hg as tolerated for those who are elderly, malnourished, on anticoagulant therapy, have blood dyscrasias, or are intolerant of pain related to V.A.C.® application.
- A continuous mode setting should be utilized for the first 48 hours of treatment and continued in the following cases:
  - ✓ Presence of undermine
  - ✓ Significant discomfort with intermittent cycling
  - ✓ Anatomical sites in which maintenance of an airtight seal would be problematic
  - ✓ Heavy wound drainage

7. Which foam dressings should be used?

- Granufoam (Polyurethane foam)
  For stimulation of granulation tissue
- Versafoam (Polyvinyl alcohol foam)
  - ✓ For controlled ingrowth of granulation into the foam
  - ✓ Wounds in which the goal is increased re-epithelialization
  - ✓ Tunnelled areas
  - ✓ Patients who are unable to tolerate Granufoam secondary to pain

8. What should be done if the patient is experiencing pain?

- Decrease pressure settings
- Switch to Versafoam

Figure 5

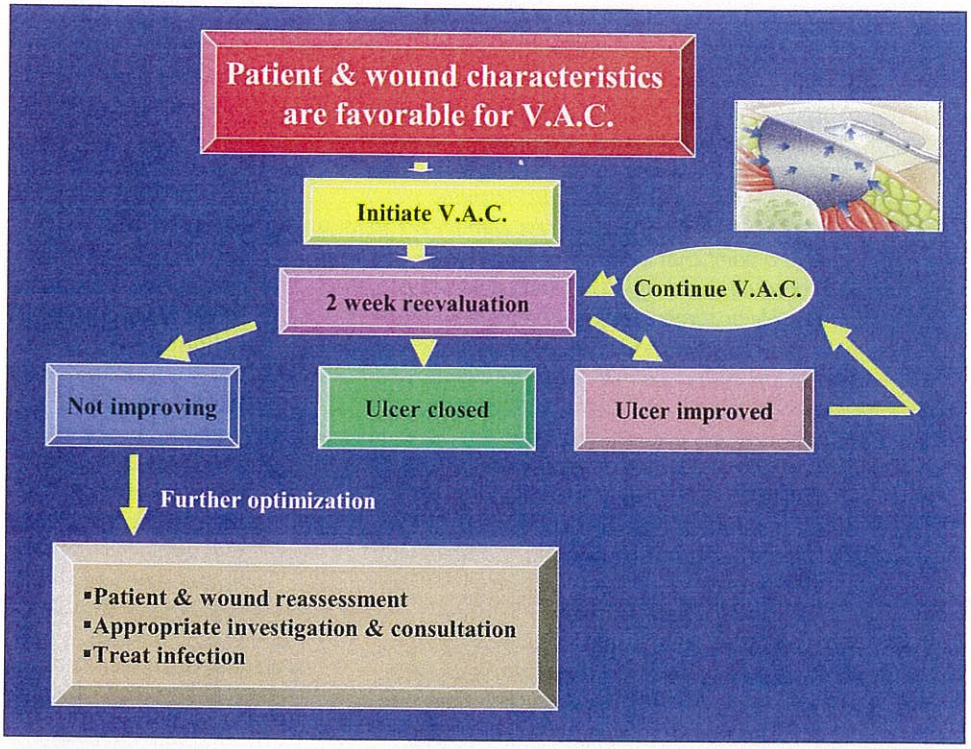
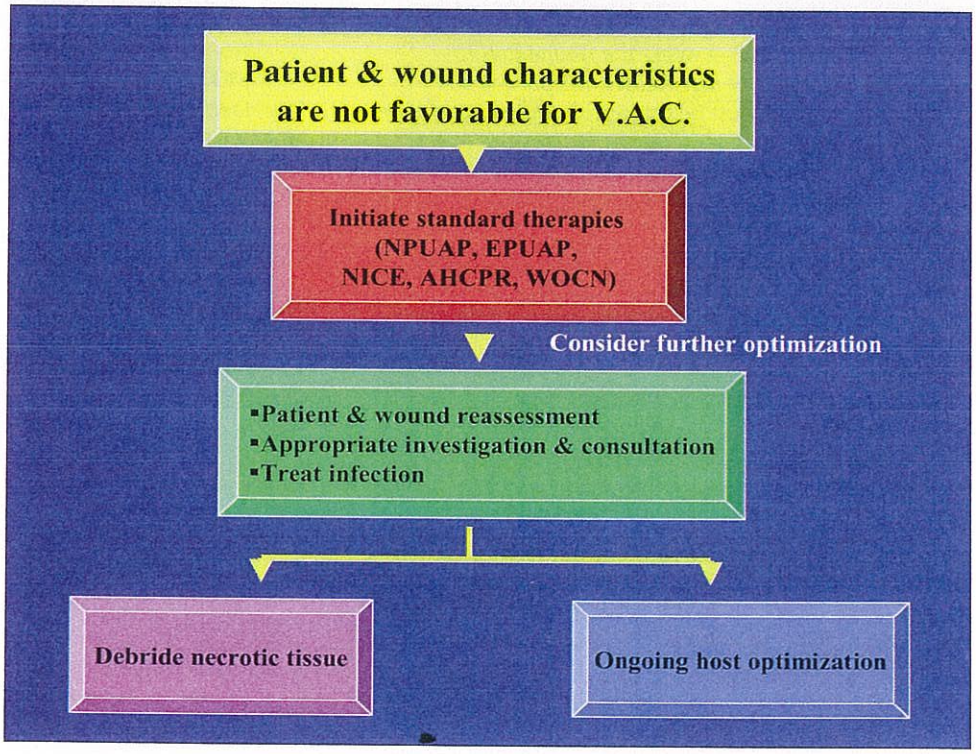


Figure 6



- Line the ulcer base with a nonadherent meshed interface dressing
- Premoisten the foam prior to removal
- Allow the patient to assist with dressing changes where feasible
- Utilize topical anaesthetics or systemic analgesics
- Provide skin protection of peri-ulcer skin and dermal wound margins
- Reassess the frequency of dressing changes (refer back to question 5)

9. *Does osteomyelitis affect NPWT use?*

- Patients receiving appropriate systemic antibiotics for the treatment of osteomyelitis can be effectively treated with NPWT[8]
- Untreated osteomyelitis is a contraindication to NPWT use[8]

10. *What are the treatment end points?*

- The treatment endpoints are contingent upon whether the patient is a candidate for surgical

closure. V.A.C.® treatment goals may include:

✓ Preparation for surgical closure (Figure 4)
  ❖ *NPWT serves as a means to temporize the patient, allowing for nutritional maximization, antibiotic administration and stabilization of coagulopathies while further pre-operative wound bed preparation occurs. In many cases, the wound may progress with NPWT to such a point that a less complicated surgical procedure than originally planned becomes possible or surgery may not be required at all. If no progress is made with NPWT, reassessment of both the patient and wound must be performed with appropriate intervention implemented, followed by reconstructive surgery or institution of another adjunctive modality.*

✓ Promotion of flap healing

✓ Closure by secondary healing for patients who are not surgical candidates. (Figure 5) NPWT can be utilized until there is:
  ❖ *A fully granulated wound surface*
  ❖ *Decreased volume and the wound surface is essentially up to skin level at which time the clinician needs to consider the clinical efficacy and cost-effectiveness of continued NPWT versus another product*
  ❖ *If within 2–4 weeks the wound fails to improve or deteriorates, the patient and wound must be reassessed and pressure ulcer best practice guidelines for pressure ulcer management should be followed* (Figure 6)
  ❖ *Resolution of tunnels and undermined areas*

11. What is the duration of NPWT treatment?

- NPWT can be continued for as long as the wound is exhibiting progress without an unfavourable patient response

Conclusions

With the results of more than twenty randomized controlled NPWT studies forthcoming, coupled with wound etiopathogenesis specific treatment guidelines, clinicians will have a more structured and scientifically rigorous foundation upon which to make patient specific treatment decisions.

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Verbandsanlage an anatomisch schwierigen Lokalisationen und bei ausgedehnter Wundfläche

Dressing technique in anatomicaly difficult regions and extensive wound area

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Zusammenfassung

Die Anlage „normaler" V.A.C.®-Verbände oder mittlerweile auch „normaler" V.A.C.®-Instill-Verbände ist nach einer gewissen Lernkurve gut durchzuführen. Je nach Spektrum der behandelnden Abteilung ist die Dimension der Wunde(n) und deren Lokalisation oft sehr unterschiedlich. Als Plastische Chirurgie haben wir über die letzten Jahre extensive Weichteilinfektionen oder posttraumatische/postoperative Defekte der Körperoberfläche mit beiden V.A.C.®-Verbänden therapiert bzw. für weitere rekonstruktive Maßnahmen vorbereitet.

Die Größe und auch die Nähe zu besonderen anatomischen Gegebenheiten, wie Anus, Anus praeter, enterokutanen Fisteln, Vagina, Skrotum, Penis, Axilla, Hals, Hand/Finger, Fuß/Zehen, machen die Verbandsanlage oft zu einer besonderen Herausforderung. Auch wenn die Anlage gelungen ist, stellt die dauerhafte Dichtigkeit oft den limitierenden Faktor dar und macht oft eine Neuanlage vor dem elektiven Wechsel notwendig. Wir möchten mit diesem Beitrag verschiedene Anleitungen und Tricks für die Beherrschung eben dieser Fälle durch Pflege- und Ärzteschaft geben.

Neben finanziellen Zwängen und dem Wunsch nach bestmöglichen Ergebnissen steht für alle an der Therapie Beteiligten die Patientenzufriedenheit und der Behandlungskomfort mit im Vordergrund.

Schlüsselwörter

V.A.C.®, V.A.C.®-Instill, Verbandsanlage, Weichteildefekt, Anleitung

Summary

Applying the V.A.C.® and V.A.C.®-Instill-System is quiet easy to learn after a certain training curve. Depending on the spectrum of the department, the quality of wounds is very different, in means of depth or area and particular where the defects are located (anatomically difficult regions). As a department of plastic surgery we came to treat patients with extensive soft tissue infections and posttrauma or postoperative defects with both systems. The close proximity to certain orifice, such as artificial or anatomical anus, vagina, scrotum, intestinocutaneous fistula, penis, axilla, throat, hand/fingers, feet/toes can be a challenge for applying the dressing. Even if the sealing was succesfull in the first line, the limiting factor is its durability and the changing ahead of schedule is often indispensable. By this paper we want to contribute some instructions and tricks for care workers and doctors to come by with these special indications.

Financial constraints of the medical system and the quest for the best possible patient outcome forces us to optimize the treatment even in purpose of patient contentment and treatment comfort.

Keywords

V.A.C.®, V.A.C.®-Instill, dressing, soft tissue defect, instruction

Einleitung

Der Einsatz der Unterdrucktherapie in der Behandlung akuter und chronischer Wunden hat im deutschsprachigen Raum über die letzten 12 Jahre in vielen Kliniken Einzug gehalten und wird bei unterschiedlichsten Indikationen angewandt. Dabei war gerade in den letzten Jahren festzustellen, dass die Kontraindikation von Gestern oft die Indikation von Morgen wurde und in einigen Fälle sogar zu einem Paradigmenwechsel geführt hat (1, 2).

Der Einsatz geht mittlerweile vom offenen Thorax und Abdomen, über die Anlage von Verbänden über Blut- und Lymphgefäßen, Gefäßprothesen bis hin zur Instillationstherapie beim Implantat- und Protheseninfekt sowie ausgedehnten akuten schnell progredienten Weichteilinfektionen wie beispielsweise der nekrotisierenden Fasziitis. Die Techniken der Verbandsanlage haben sich über die letzten Jahre weiterentwickelt und im Laufe der Indikationserweiterung den speziellen Herausforderungen der jeweiligen Lokalisation und den speziellen Bedürfnissen der Therapieform angepasst. Nach der richtigen Indikation und dem inevitablem radikalen Débridement, stellt neben dem möglichst genauem Einpassen der Schwämme in die Wundfläche/-höhle, die eingestellte Sogstärke und die Dichtigkeit der Verbände die entscheidenden Größe für eine erfolgreiche Therapie dar. Nachfolgend möchten wir auf die Verbandsanlage an anatomisch schwierigen Körperregionen eingehen. Hierbei steht, neben dem Verbandskomfort für den Patienten, vor allem die Anlage langfristig dichter Verbände im Vordergrund. Gerade die Hand mit den Interdigitalfalten, die Axilla, die Inguinal- oder Perianalregion, die Nähe zu enterokutanen Fistel oder einem Anus praeter stellen hierbei eine besondere Herausforderung für die Langlebigkeit der Verbände dar.

Durch die Einführung der V.A.C.®-Instill kommt eine zusätzliche temporäre Flüssigkeitsansammlung im Verband zustande, welche schnell die Grenzen der Verbandsdichtigkeit überschreiten kann. Frustrane Versuche schwierige Verbänden am Bett abzudichten werden oft von der Neuanlage im OP gefolgt und stellen häufig und gerade bei Infektionen mit multiresistenten Keimen ein logistisches Problem für den OP-Ablauf mit langen Wartezeiten für die Patienten und das pflegerische und ärztliche Team dar. Hier wird klar das der Anlage des V.A.C.®-Verbandes im Op, auch wenn sie den Abschluss des operativen Geschehens darstellt, nochmals besondere Aufmerksamkeit geschenkt werden sollte.

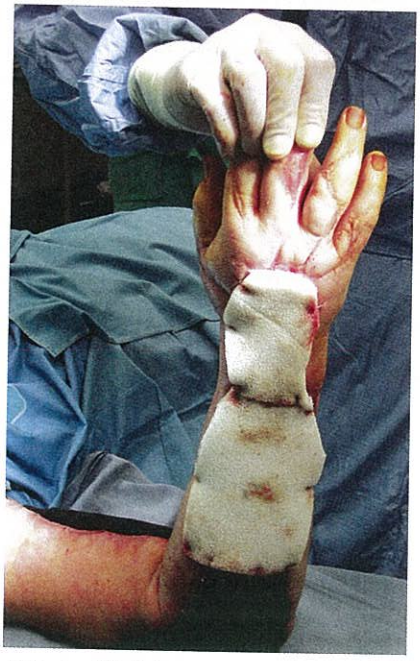


Abb. 1 : PU-Schwamm zur weiteren Konditionierung PVA zur Spalthautfixation

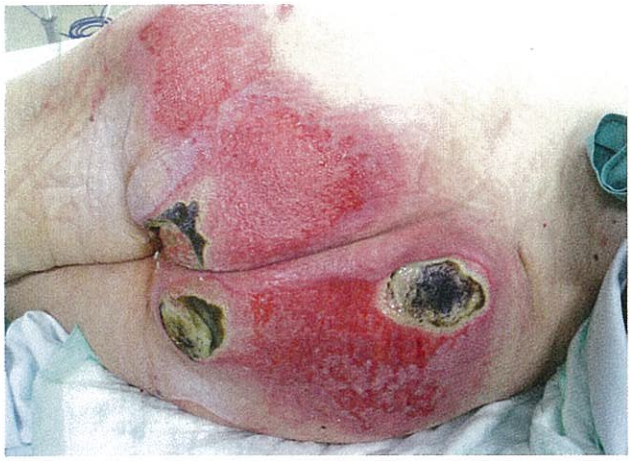


Abb. 2: Dekubitus I-IV,

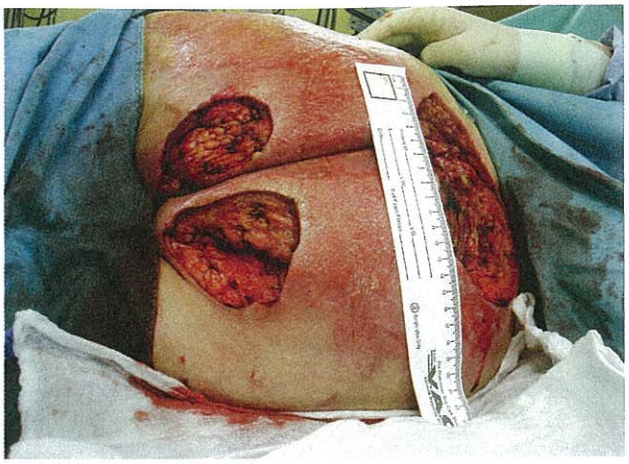


Abbildung 3: nach dem radikalen Débridement

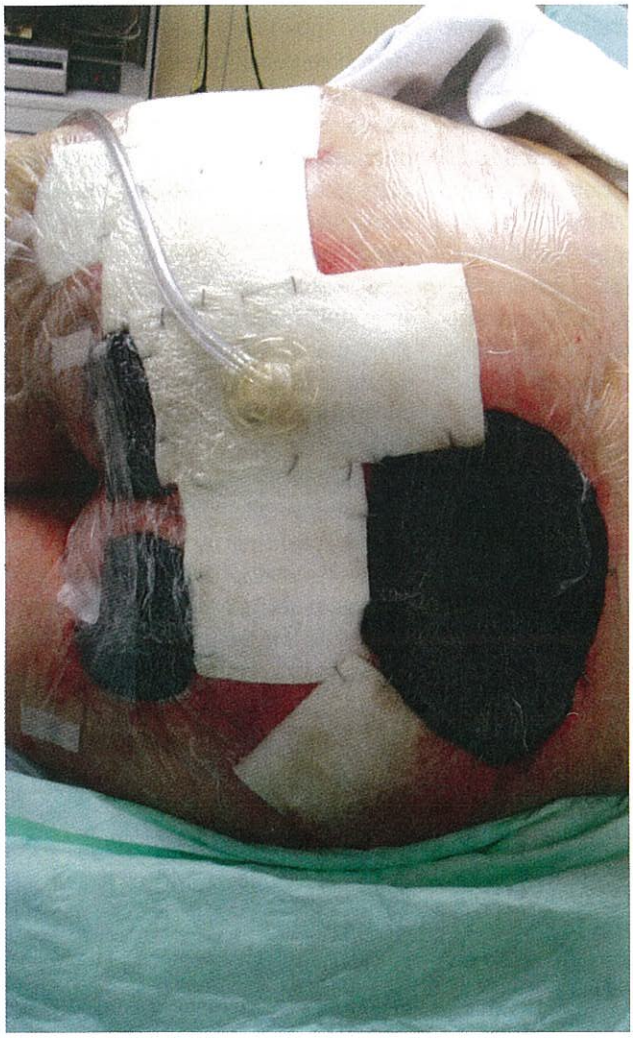


Abbildung 4: Verband mit PU und PVA-Schwamm

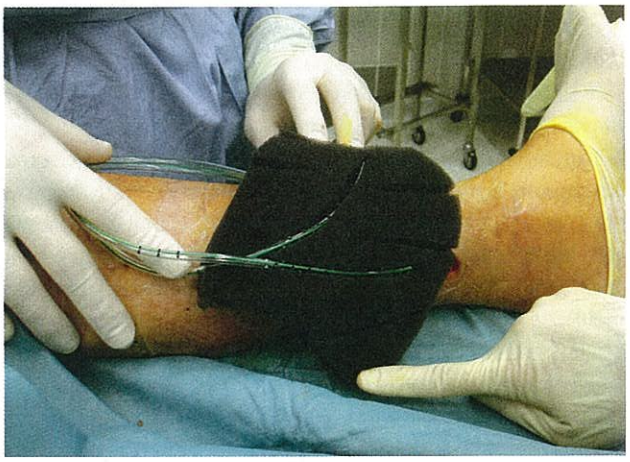


Abb. 5: längs eingekerbter PU-Schwamm zur besser Anpassung an die Unterschenkelzirkumferenz (+V.A.C.®-Instill-Drainagen)

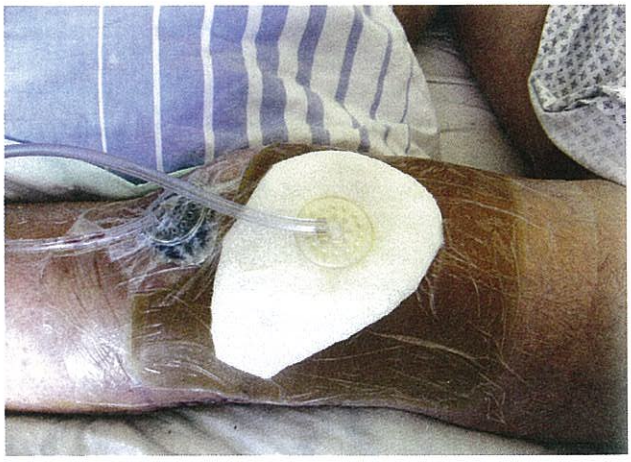


Abb. 6: Wundrandschutz mit Commfeel®

Material und Methoden

In den letzten 5 Jahren wurde die überwiegende Mehrheit unserer Patienten mit großen Wunddefekten, im Sinne einer Interimslösung oder zur Konditionierung bis zur definitiven plastischen Deckung, einer Unterdrucktherapie zugeführt. Der Algorithmus unserer Klinik sieht dabei mindestens zwei Verbandswechsel pro Woche vor, bei instabilem Zustand der Wunde(n) auch häufiger. Diese werden standardmäßig im OP-Saal durchgeführt. Die Verbandsneuanlage bzw. der Verbandswechsel erfolgen erst nach einem radikalen Débridement auf dann vitalem Wundgrund. Eine sorgfältige Blutstillung sollte unbedingt durchgeführt werden und vermeidet ein vorzeitiges „verkloten" der Schwämme durch Blutbestandteile (Aggregationen/Eiweiße) und damit einen vorzeitigen Verbandswechsel oder eine insuffiziente Therapie.

Neben dem meistgebrauchten V.A.C.® GranuFoam® (PU), wurde bei MRSA infizierten Wunden der GranuFoam Silver® eingesetzt (3). Waren im Wundareal empfindliche Strukturen wie Nerven oder vulnerable Gefäße freigelegt worden, wurde oft der WhiteFoam® (PVA) verwendet. Wenn die Wunde Areale in

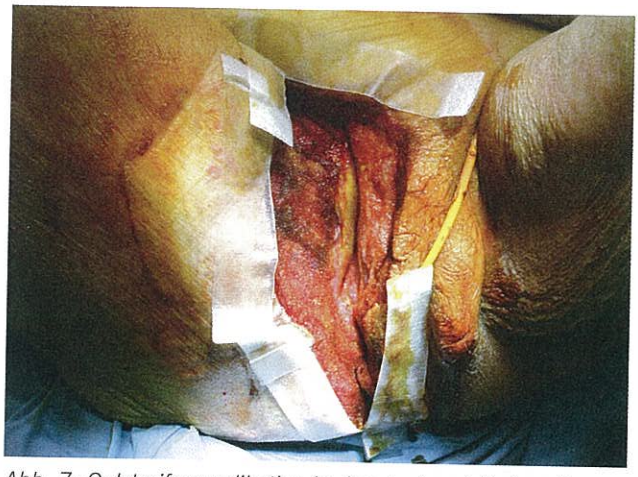


Abb. 7: Gelstreifenapplikation im Inguinal und Perianalbereich

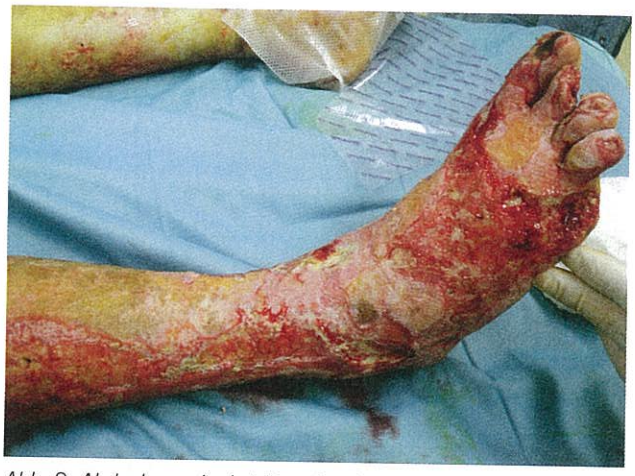
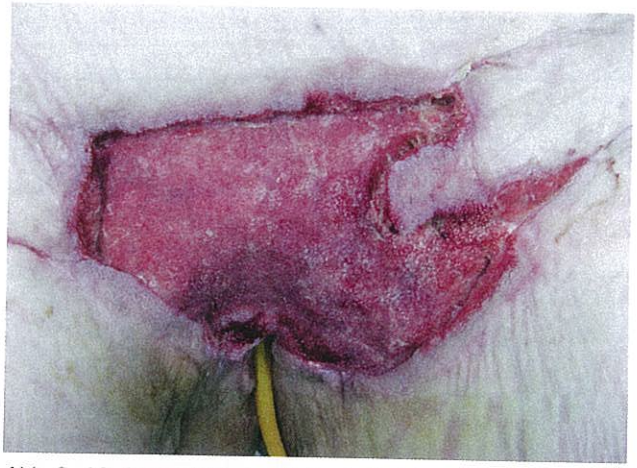


Abb. 8: Abdeckung der intakten Areale mit Silikongaze und Ausschneiden der Defekte, danach kann der gesamte Fuß mit einem PU-Schwamm „eingepackt" werden



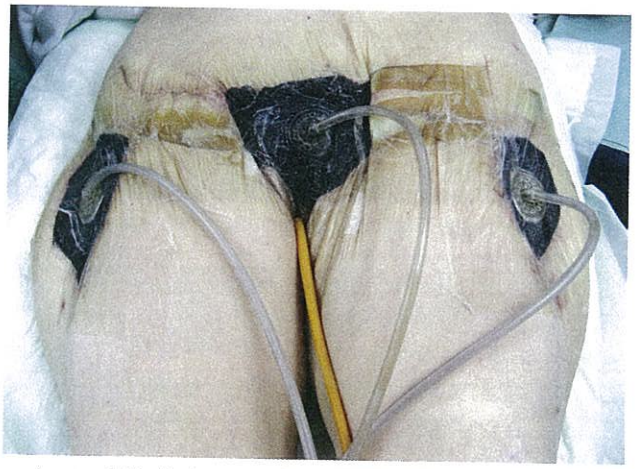


Abb. 9, 10: Suprapubischer Befund, der bis an das Harnröhren Ostium heranreicht. Katheter wird in Sandwichtechnik mit eingeklebt

unterschiedlichen Wundstadien aufwies, wurde auch eine Kombination aus GranuFoam® und WhiteFoam® durchgeführt (Abbildung 1-4). V.A.C.®-Instill-Verbände wurden mit PU- oder PVA-Schwamm und 16 Charrière Redondrainagen angelegt. Die Fixierung der Schwämme mit Klammergeräten am Wundrand stellt gerade bei zirkulären Verbandsanlagen oder für die Modellierung der Schwämme während des Einpassens eine enorme Erleichterung dar. Wenn Schwämme über die Zirkumferenz der Extremitäten gelegt wurden, hat sich zur besseren Anpassung das Einkerben mit einem Skalpell als hilfreich erwiesen (Abbildung 5).

Wenn landkartenartige Befunde vorlagen, bei denen ein Anpassen der Schwämme deutlich erschwert war, so hat sich das Aufbringen dünner Hydrokolloidplatten als Wundrandschutz, welche entlang des Wundrandes abgeschnitten wurden, als zeitsparende und effektive Methode herausgestellt. Der Schwamm konnte dann über den Wundrand auf das Hydrokolloid überstehen ohne eine Granulation oder Schädigung der intakten Haut zu verursachen, nicht selten bewirkt dies auch einen raschen Ausgleich von Niveauunterschieden (Abbildung 6).

Der Hydrogelstreifen wurde gerade im Bereich der Achsel, der Inguinal- und Perianalregion oder wenn nur schmale Brücken mit intakter Haut zum Aufkleben der Folie zur Verfügung standen bzw. wenn eine starke Sekretion aus der Wunde bzw. dem Wundrand bestand aufgeklebt oder mit in den Verband integriert (Abbildung 7). Zur Verbandsanlage in der Axilla, sollte der Arm maximal eleviert sein. Der Schwamm und die Folie ließen sich nun gut anpassen und aufkleben und behindert den Patienten später nicht bei der Mobilisierung.

Sollte die umliegende Haut mit Paraffin oder anderen fettreichen Salben bzw. Folienkleberresten kontaminiert sein, empfiehlt sich die Säuberung mit Wundbenzin um ein sicheres Anhaften der Folie zu ermöglichen. Wenn sich in großflächigen Befunden inselartige, bereits abgeheilte Areale befanden, so wurden diese unter dem Schwamm mit beispielsweise einer Silikonwundauflage abgedeckt (Abbildung 8).

Für langstreckige Befunde an den Extremitäten, welche sich über mehrere distale Gelenke erstreckten, wurde häufig das V.A.C.® GranuFoam® Hand Dressing eingesetzt. Die beiliegenden Schwämme wurde nicht als Handschuh verwendet, sondern wie der GranuFoam® angepasst und aufgelegt. Die beiliegende tütenförmige Folie hat sich als praktische und langfristig dichte Versiegelung herausgestellt und ist ausreichend, um auch einen Verband von den Zehen bis zum proximalen Unterschenkel zu versiegeln und abzudichten. Zudem gelingt eine schnelle Verbandsanlage, da das Kleben der Folieneinzelteile entfällt.

Die Anlage von Verbänden in der Nähe oder um enterokutane Fisteln oder einem Anus praeter (AP) stellt immer wieder eine Herausforderung dar. Besonders high output Dünndarmfisteln limitieren die Haltbarkeit des Verbands erheblich

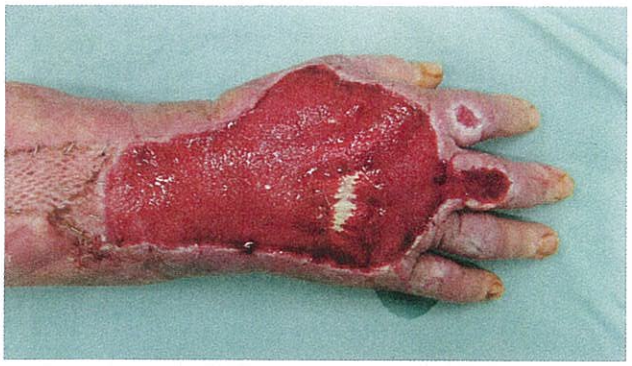


Abb. 11

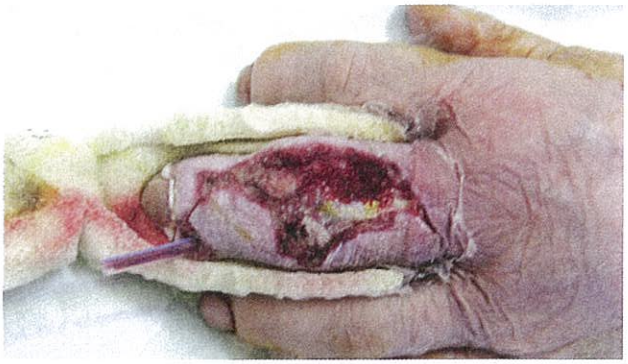


Abb. 14

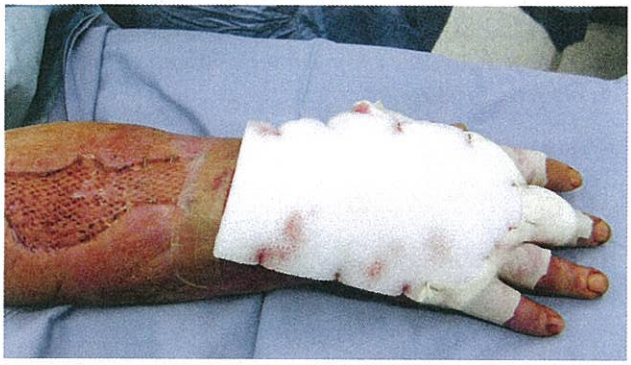


Abb. 12

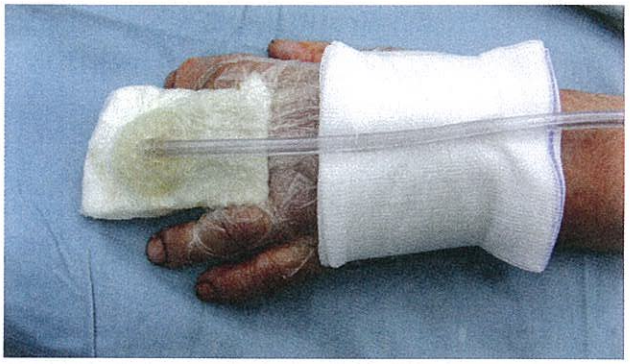


Abb. 15

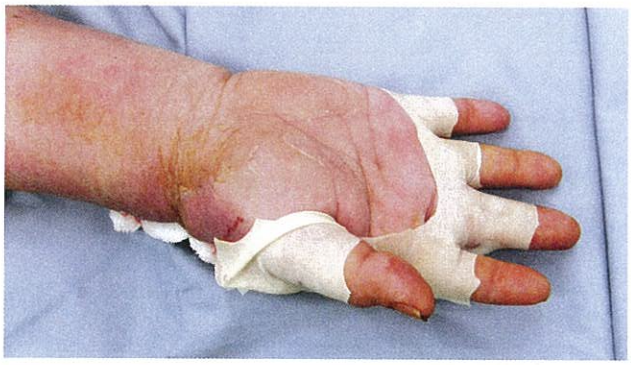


Abb. 13

Abb. 11-13: Handrücken- und Fingerdefekt nach nekrotisierender Fasziitis. Modifizierte Handschuhtechnik und PVA-Schwamm

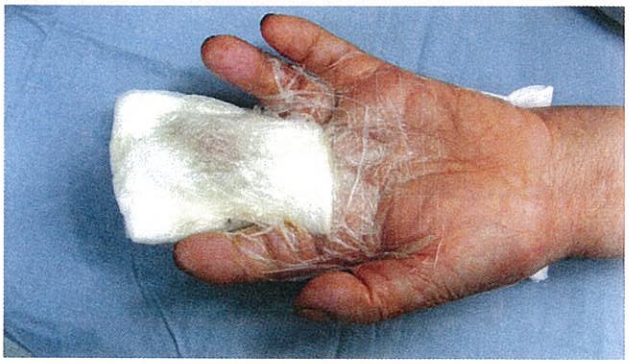
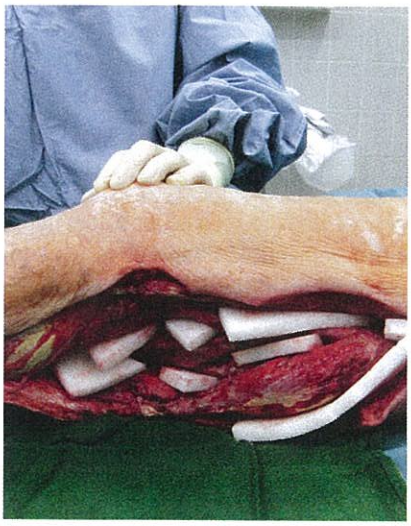
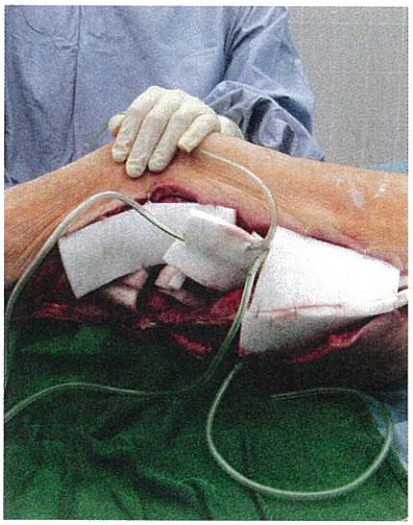


Abb. 16

Abb. 14-16: Schwere Fingerphlegmone, PVA-Sandwich-Verband





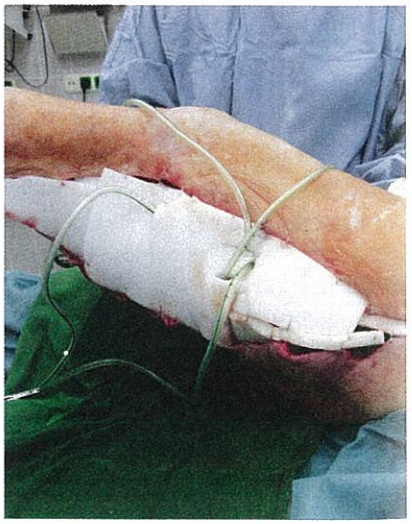


Abb. 17-19: V.A.C.®-Instill-Verband bei einer nekrotisierenden Fasziitis. Zuläufe zentral, Abläufe lateral plaziert, in die jeweiligen Kompartimente

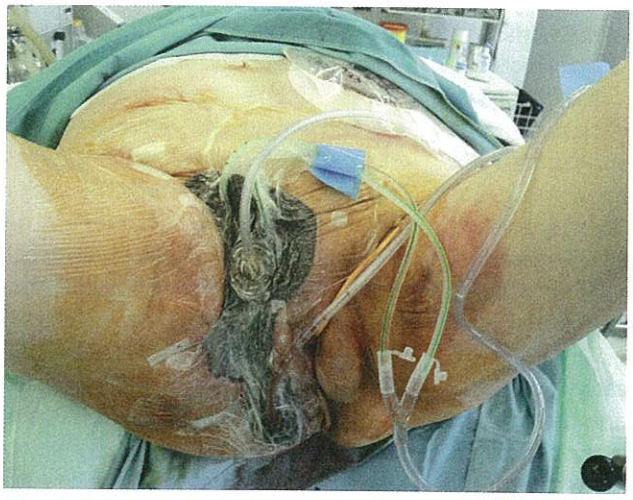


Abb. 20: Fournier´sche Gangraen mit V.A.C.®-Instill-Verband. Evakuation der Flüssigkeit kaudal, Zulauf von kranial

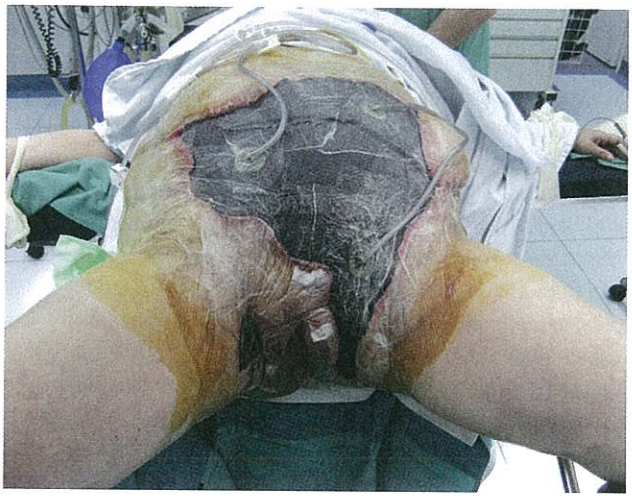


Abb. 21: Fournier´sche Gangraen mit Beteiligung der abdominellen Weichteile. Bei Verbänden dieser Größe mehr als ein T.R.A.C.-Pad®

und führen schnell zu Undichtigkeiten bzw. zu verstopften Schwämmen oder Schläuchen. In der Literatur und auf den Kongressen der letzten Jahre wurden verschiedenste Vorgehensweisen dargestellt (4, 5). Als sehr praktikabel hat sich die Methode der isolierten Integration gezeigt. Hierfür wird direkt über der Öffnung ein Loch in den Schwamm geschnitten, das um ca. 0,5 cm größer als der AP oder der Fisteldurchmesser ist. Die Innenseite des Schwamms wird dick mit Stomapaste abgedichtet. Nach der Versiegelung mit Folie wird über die Öffnung ein Stomabeutel platziert, welcher nicht in den Sog einbezogen sein sollte. Gelegentlich kann auch ein Stomaausgleichsring an der Basis hilfreich sein.

Die Pin´s eines Fixateur externe, Katheter im Genitalbereich oder Drainageschläuche können einfach mit der Sandwichtechnik abgedichtet werden. Gelegentlich kann es notwendig sein bei Befunden, die unmittelbar ans Anoderm oder an den Übergang zur Mukosa der Vagina heranreichen, eben genannte Körperöffnungen zu Überkleben und mit in den Verband zu integrieren. Hier muss im Vorfeld eine Harnableitung über einen Katheter sichergestellt bzw. zur Stuhlableitung ein protektiver, temporären Anus praeter angelegt worden sein (Abbildungen 9 und 10).

Die Anlage der Verbände im Finger/Hand oder Zehen/Vorfußbereich kann ebenfalls erschwert sein und häufig mit Undichtigkeit imponieren. Oft sind die intakten Finger miteingeklebt und nicht mehr für eine Physiotherapie zugängig.

Im Handbereich hat sich die modifizierte Handschuhtechnik als hilfreich erwiesen (6). Hierfür wurden sterile latexfreie oder Vinylhandschuhe verwendet. Wenn die Defekte am Handrücken oder der volaren Hand vorlagen und die Mittel- und Endglieder nicht involviert waren, wurde der Teil der Handschuhe um die Grundglieder und im Bereich der MCP-Gelenke belassen. Der Rest wurde ausgeschnitten. Der Verband konnte dann unkompliziert mit Schwamm und KCI Folie weitergeklebt werden (Abbildungen 11-13). Es sollte so wenig wie möglich Handschuh belassen werden, da doch eine gewisse Mazeration der unterliegenden Haut aufgrund der fehlenden Semipermeabilität des Handschuhs stattfindet. Bei isolierten Defekten an den Fingern wurde der gesamte Finger mit PVA-Schwamm umschlossen (Abbildungen 14-16). Im Zehenbereich sollte bei mehreren Zehen und Übergang der Wunde auf den Vorfuß eine größere Versiegelung stattfinden. Dabei sollte ein Mazerationsschutz in die intakten Interdigitalräume eingelegt werden.

Die Anlage von Instill-Verbänden setzt eine noch subtilere Klebetechnik voraus. Gerade im inguinalen Bereich ist der Einsatz von Gelstreifen zwingend. Die Zuläufe sollten am cranialen Pol des Verbandes angelegt werden. Sind beide Zirkumferenzen einer Extremität betroffen so sollte jeweils ein Zulauf eingebracht werden. Die Zulaufdrainage sollte nie unmittelbar in der Wundfläche aufliegen sonder maximal in den letzten 3-4 mm des wundnahen Schwammes eingebettet sein um Drucknekrosen bei kollabiertem Schwamm zu vermeiden. Die Ablaufdrainage bzw. der T.R.A.C.-Pad® sollten die instillierte Flüssigkeit aus den kaudalen Anteilen der Wunde evakuieren. Je nach Größe der Wunde sollten mehrere Abläufe geschaffen werden (Abbildungen 17-20).

Wenn im Randbereich der Wunde Unterminationen oder Wundtaschen bestehen und eine stärkere Sekretion der Wunde vorliegen, so sollten Redondrainagen in den Schwamm eingezogen werden, welche die Flüssigkeit in Richtung T.R.A.C.-Pad® weiterleiten, da doch gelegentlich eine Flüssigkeitsretention bei der Verbandsentfernung in diesen Bereich zu sehen war.

Bei Patienten mit extensiven Verbänden an Körperstellen, die während der Umlagerung stärker strapaziert werden, ist es hilfreich kurzzeitig einen Sog von -200 mmHg anzuwenden, um eine Dislokation der Schwämme oder ein Abreißen der Folie zu vermeiden. Auf die gewünschte Sogstärke kann unmittelbar danach zurückgekehrt werden. Bei Gefäßbeteiligung oder einem Blutungsrisiko sollte jedoch auf ein erhöhtes Risiko verzichtet werden.

Diskussion

Mit den o.g. Mitteln ist in aller Regel ein für die Therapiedauer bis zum nächsten Wechsel dichter und suffizienter Verband anzulegen. In Bezug auf die Sogstärken hat sich über die letzten Jahre eine leichte Tendenz zu eher niedrigeren Drücken ≤125 mmHG ergeben. Die Diskussion welcher Schwamm für welche Indikation besser geeignet ist, wird oft kontrovers geführt. Eine gesicherte Evidenz über prospektive Studien liegt gegenwärtig noch nicht vor. Viele Kliniken verwenden ausschließlich den PU-Schwamm,

da dieser eine breitere Einsatzmöglichkeit bietet und zusammen mit Silikongazen nahe zu jede Indikation abdeckt. Bei bestimmten Fragestellungen bietet der PVA-Schwamm jedoch seine spezifischen Vorteile. Er kollabiert nicht so stark und ist zur Einlage in unterminierte Wundränder oder dünne Fisteln oder subkutan auslaufenden Wundanteile gut geeignet.

Letztendlich sollte jeder Anwender das Material einsetzen mit dem er sich am sichersten fühlt und die meiste Erfahrung besitzt, sofern die Indikation dem aktuellen Stand entspricht.

Die in vitro Untersuchungen von Willy et al. (7) über die Fortleitung des Soges im PU- oder PVA-Schwamm und deren unterschiedlichen Oberflächendrücke zeigen keinen Unterschied bis 30 cm vom T.R.A.C.-Pad® und einem Sog von -125 mmHg. Wir setzen deshalb bei einem Verbandsdurchmesser >60 cm einen zusätzlichen T.R.A.C.-Pad® ein (Abbildung 21). Zur Granulationsförderung zeigt laut Morykwas et al. und Wackenfors et al. der intermittierende Modus einen signifikanten Vorteil gegenüber der kontinuierlichen Besaugung (8,9), lediglich die On-Off-Intervallfolgen unterscheiden sich in den Studien 2 min. ON-5 min. Off gegenüber 10 min ON-10 min. OFF. Für den Einsatz der verschiedenen Instillationsflüssigkeiten liegen bedauerlicherweise ebenfalls keine evidenzbasierten Daten vor. Etabliert hat sich jedoch die Anwendung mit Polihexanid-Lösung. Die Anwendung sollte bei normalem Eiweißernährungsstatus eine Dauer von 14 Tagen nicht überschreiten, da eine Eiweißdenaturierung an der Wundoberfläche erfolgen kann (8). Diese ist ohne Nachteil für die Wundbehandlung, kann jedoch vermieden werden. Bezüglich des Einsatzes von Antibiotika liegen nur Erfahrungsberichte vor (9). Unsere letzten Anwendungen von Gentamycin oder Tobramycin waren bei MRSA positiven Wundinfekten positiv. Hier sollte aber eine dezidierte Indikationsfindung vorliegen und eine Rücksprache mit den Mikrobiologen bezüglich der einzusetzenden Antibiotika gehalten werden. Auch muss eine Exploration hinsichtlich antibiotika-assozierter Allergien erfolgt sein, da in der Literatur oft starke anaphylaktische Reaktionen beschrieben sind.

Insgesamt bleibt festzuhalten, dass die Therapie mit den V.A.C.®-Systemen gut auf eine intuitive Art und Weise zu erlernen ist. Ein gewisser Einfallsreichtum und die Freude an Herausforderungen sind die stärkste Triebfeder um entstehende Probleme mit schwierigen Verbände zu bewältigen.

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Einsatz von Hyaluronan in der V.A.C.®-Therapie bei tiefen Wundhöhlen unter dem besonderen Aspekt der Lymphozele

Hyaluronan treatment in vacuum-assisted closure-therapy of deep wound cavities particulary in lymphoceles

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Zusammenfassung

Lymphozelen sind mühsam zu behandelnde Komplikationen nach chirurgischen und anderen interventionellen Eingriffen. Bis anhin war die Standardtherapie nicht einheitlich. Neben Empfehlungen der Prophylaxe durch schonende Operationstechniken unter Respektierung der Anatomie der Lymphgefäße oder das prophylaktische Verkleben mit Fibrinkleber hat sich in der Behandlung zunehmend die Vakuumtherapie durchgesetzt. Bis anhin wurde der Einsatz von Hyaluronsäure im Rahmen der V.A.C.®-Therapie insbesondere auf dieses Krankheitsbild und andere tiefe Wundhöhlen nicht beschrieben. Wir zeigen den positiven Einfluss von Hyaluronan in Kombination mit einer V.A.C.®-Therapie bei sekundär heilenden Lymphozelen und anderen tiefen Wundhöhlen.

Schlüsselwörter

Lymphozele, Hyaluronan, Hyaluronsäure, Vakuumbehandlung

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B. Loos
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Optimierung der Vakuumtherapie bei ausgedehnten Wundtaschen

Optimizing Vacuum Therapy in Extensively Undermined Wounds

Zusammenfassung

Einleitung: Ausgedehnte Wundhöhlen und Wundtaschen stellen ein bekanntes Problem in der chirurgischen Behandlung dar. Durch eine Modifikation der Vakuumtherapie soll die Abheilung solcher Problemwunden beschleunigt werden. **Material und Methoden:** Anhand ausgewählter Fallbeispiele mit Wundheilungsstörungen oder extrem ausgedehnten Wunden nach Ablederung oder Abszessbildung wird die Anwendung der lokalen Unterdrucktherapie zur Verklebung der Wundränder bei gleichzeitiger Sekretableitung angrenzender Wundtaschen mit zusätzlichen Drainagen beschrieben. **Ergebnisse:** Bei insgesamt 5 Patienten konnten durch die hier beschriebene Vakuumverbandsanordnung erfolgreich Wundränder dauerhaft an den Wundgrund im Defektbereich fixiert und die angrenzenden Wundtaschen zur Abheilung gebracht werden. **Schlussfolgerung:** Großflächige Ablederungen sowie Wundheilungsstörungen nach ausgedehnter Gewebemobilisation oder Gewebeentnahme im Rahmen der Defektdeckung in der Plastischen Chirurgie können mit der Vakuumtherapie behandelt werden. Während die langfristige konventionelle komplette Auskleidung von Wundhöhlen mit PU-Schwämmen effektiv und im Einzelfall unerlässlich ist, kann aber bei geeigneten großflächigen subkutanen oder epifaszialen Wunden durch Applikation von topischem Unterdruck eine Kompression der Wundränder auf den Wundgrund erreicht werden. Um eine Abkapselung der umgebenden Wundtaschen mit behindertem Sekretabfluss zu vermeiden, kann die Optimierung der Vakuumtherapie durch das gleichzeitige Einlegen von Re-

Abstract

Introduction: Extensively undermined wound cavities represent a common surgical problem. By a modified vacuum therapy the healing of such wounds can be accelerated. **Materials and methods:** Based on our experience in selected cases with wound healing disorders or extremely undermined wounds following degloving injuries or abscess formations the application of topical negative pressure therapy to fix wound margins to the wound ground while at the same time allowing exudates emission with additional drainages is described. **Results:** In 5 patients we were able to demonstrate the efficacy of vacuum dressing system described here with successful and lasting adaptation of the wound margins to the defect. All wounds were brought to permanent healing. **Conclusion:** Extensive tissue degloving and wound healing disorders after excessive tissue mobilization during plastic surgical defect coverage can be treated successfully with topical negative pressure therapy (TNP). Whereas longterm complete conventional polyurethane foam lining of wound cavities is an effective method and may be necessary in special situations, the application of TNP can lead to a firm adhesion of wound margins in extensive subcutaneous or epifascial wounds to the undersurface. To avoid exudate formation in the adjoining tissue TNP can be effectively optimized by the placement of drainge tubes into the surrounding tissue.

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donschläuchen in die Wundtaschen hinein als ein wirksames Verfahren dienen.

Schlüsselwörter
Vakuumtherapie · Wundheilungsstörungen · Serom · Dekubitalulkus

Key words
Vacuum therapy · wound healing disorders · wound exudate · decubital ulcer

Einleitung

In der plastischen Chirurgie stellen ausgedehnte Wundhöhlen nach Gewebetransplantationen eine Herausforderung in der klinischen Praxis dar. Therapieerfolge können hierbei mit der Vakuumtherapie erreicht werden [3, 4, 6, 8–10]. Die so genannte V.A.C.®-Therapie (V.A.C.®, vacuum-assisted wound closure) beruht auf der Applikation eines definierten, kontrollierten Unterdrucks über einen Polyurethan- (PU) oder Polyvinylalkoholschwamm (PVA) auf die Wundoberfläche [1]. Der kontinuierliche Abtransport von Wundsekret und Zelldetritus führt zu einer Reduktion des interstitiellen Wundödems mit konsekutiver Verbesserung der Mikrozirkulation und Wundheilung [5, 7].

Besonders problematisch erweist sich die Behandlung tiefer ausgedehnter subkutaner oder epifaszialer Wundtaschen bei gleichzeitig oft nur geringem Hautdefekt (Abb. **1a**). In derartigen Wunden kann die Applikation von topischen Unterdruck auf die Wundfläche zu einer Kompression der Wundränder auf den Wundgrund führen, woraus eine Abkapselung der Wundtaschen resultiert. Der behinderte Sekretabfluss kann wiederum zu einer vermehrten Ansammlung von Wundsekret und Zelldetritus in den Wundhöhlen führen und den Wundheilungsprozess negativ beeinflussen sowie das Infektionsrisiko erhöhen (Abb. **1b**). Auch das sorgfältige Auskleiden der Wundtasche mit dem PU-Schwamm kann sich hierbei als ineffektiv erweisen, da dieser durch die Unterdruckapplikation kollabiert, die Wundhöhle verschließt und den Sekretabtransport aus den weiter entfernt liegenden Wundtaschen verhindern kann.

Abhilfe kann durch das gleichzeitige Einlegen von Redonschläuchen geschaffen werden, welche in die Wundtaschen eingelegt und durch den Schwamm hindurch ausgeleitet werden. Über den Schwamm und die Traq-Pad-Einheit kann hierdurch die Drainage erfolgen und eine rasche Verkleinerung der Ausdehnung der subkutanen Wundtaschen durch Verklebung der Wundoberflächen erzielt werden (Abb. **1c**).

Fallbeispiel 1

Bei einer 47-jährigen Frau kam es nach einer modifizierten Abdominoplastik im Rahmen eines autologen Brustaufbaus mittels freier mikrochirurgischer TRAM-Lappenplastik im Bereich der Lappenentnahmestelle zu einer Wundheilungsstörung. Nach ausreichender Demarkierung erfolgte die Resektion der 5 × 8 cm großen Nekrosezone. Es zeigte sich dabei, dass es im Areal der Wundheilungsstörung auch zu keiner vollständigen Verklebung der Wundoberflächen der Abdominoplastik gekommen war. So bestand eine ca. 10 × 20 cm große subkutane/epifasziale Wundtasche perifokal um die Nekrosezone. In den entstandenen Defekt und die Wundtasche wurde zunächst ein Polyurethan schwamm eingelegt und mit der Vakuumtherapie bei einer kon tinuierlichen Sogapplikation von – 125 mm Hg begonnen. Nac 4-tägiger Vakuumtherapie wurde ein Verbandswechsel durch geführt (Abb. **2a**). Zu diesem Zeitpunkt berichtete die Patienti über einen leichten Spannungsschmerz im Unterbauch. Im Auf fangkanister hatten sich ca. 50 ml Sekret angesammelt. Bei Ent fernung des Schwammes entleerte sich ca. 600 ml seröses Sekre (Abb. **2b**). Durch die Vakuumapplikation und Kollabieren de PU-Schwammes war es zu einem Anpressen der Wundränder auf die Wundoberfläche gekommen, so dass sich konsekutiv ab gekapselte Wundhöhlen ausgebildet hatten. Dies führte zu eine Blockade des kontinuierlichen Sekretabtransports über die Va kuumtherapie und zur Ausbildung eines subkutanen Flüssig

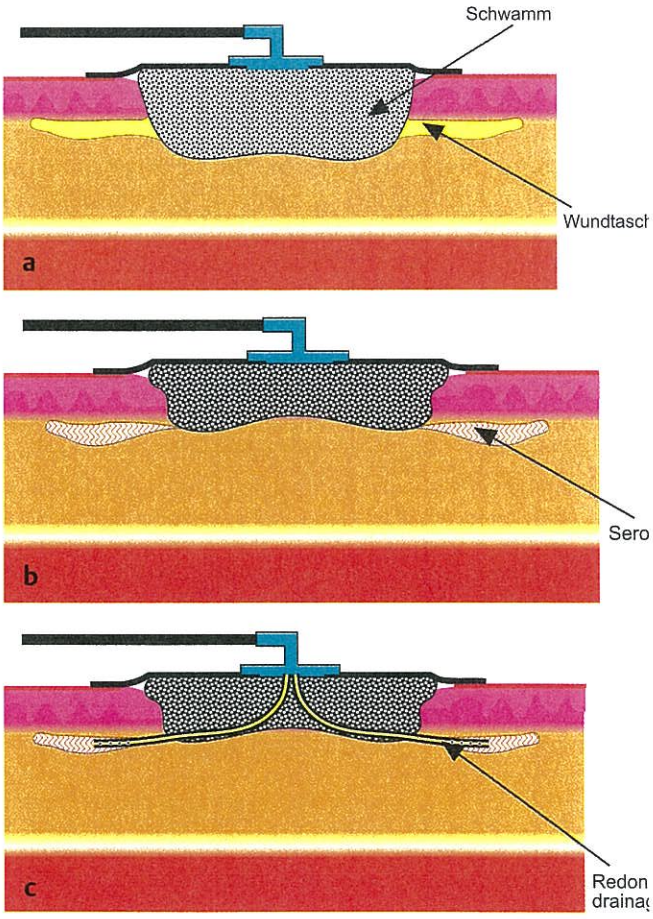


Abb. **1**
a, **b** Schematische Darstellung der Entstehung eines Sekretverhalt unter Vakuumtherapie. Durch die Vakuumapplikation kommt es zu Kollabieren des Schwammes und damit zur Retraktion der Wundfl chen. Im Sinne der Wundhöhlentamponade kann es dabei zur Ausb dung eines Sekretverhaltes kommen.
c Durch das Einlegen von Redondrainagen in die Wundtaschen kan die Entstehung eines Sekretverhaltes vermieden werden.

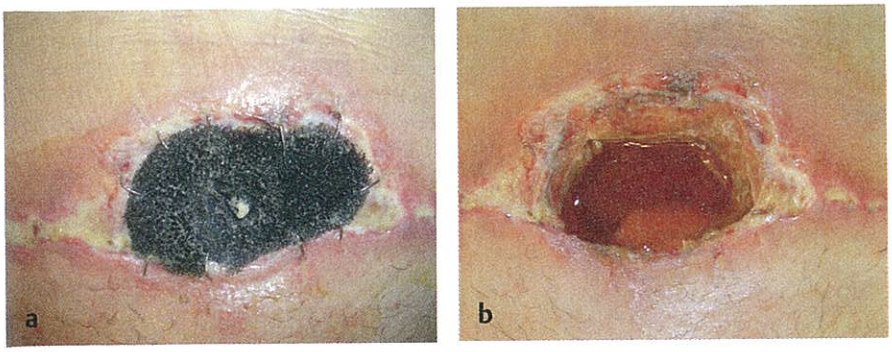


Abb. **2** (Fallbeispiel 1)
a Wundsituation vor Entfernung des PU-Schwammes.
b Durch Wegnahme des Unterdruckes kommt es zur Entleerung von serösem Wundsekret. Die gesamte Wunde ist durch nachlaufendes Wundsekret gefüllt.

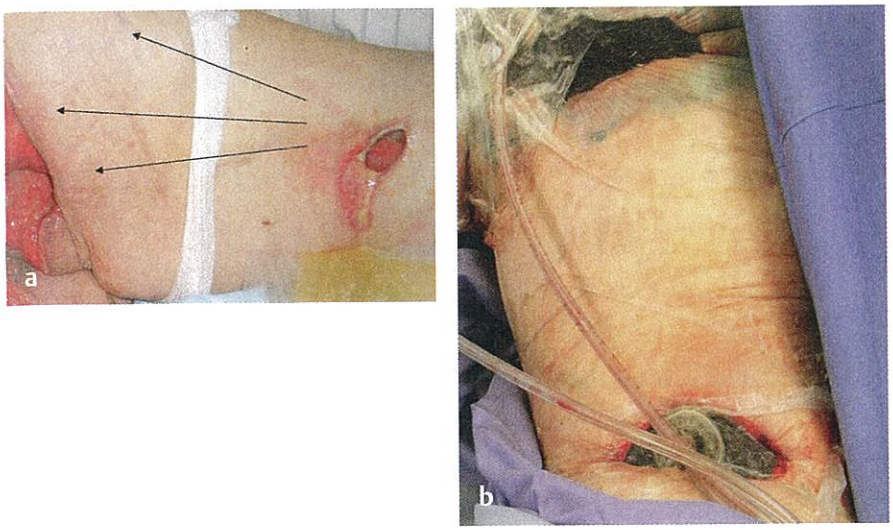


Abb. **3** (Fallbeispiel 2)
a Komplette Ablederung der Oberschenkelinnenseite durch Infektion bei extrem ausgedehnten multiplen Dekubitalulkus, hier von der Kniekehle bis zum Gesäß links im Bild reichend (siehe Pfeile)
b Versiegelung aller Ulzera nach vorheriger Einlage von Redonschläuchen in die subkutanen Wundhöhlen.

keitsverhaltes. Nach Entfernung des Unterdrucks wurden die Wundflächen nicht mehr zusammengepresst und das Serom konnte sich entleeren. Die Wunde heilte nach Verklebung der Wundränder und frühzeitiger Sekundärnaht am Entnahmedefekt problemlos ab (Abb. **4c**).

Fallbeispiel 2

Bei einer 72-jährigen bettlägrigen Patientin bestanden bei weit fortgeschrittener Multipler Sklerose mehrere ausgedehnte Dekubitalulzera III.–IV. Grades über dem Os sacrum und dem Tuber ischiadicum beidseits mit subkutaner Taschenbildung bis zur Lendenwirbelsäule bei einer Gesamtwundfäche von ca. 15 × 35 cm. Zusätzlich bestand eine großflächige Ablederung der gesamten Oberschenkelrückseite vom Gesäß bis zur Kniekehle reichend nach subkutaner Abszessausbildung und hierdurch bedingter Ablederung der Weichteile mit Perforation des Abszesses auf der distalen Oberschenkelrückseite (Abb. **3a**).

Technik

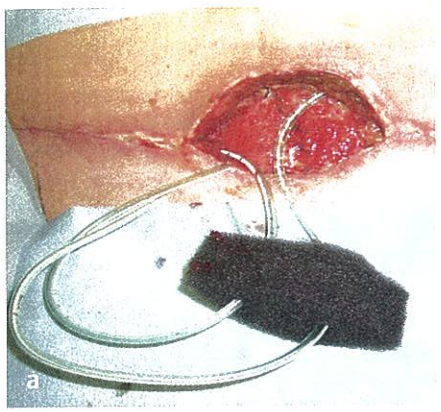
In beiden Fallbeispielen wurden zur Vermeidung einer Sekretansammlung nun mehrere 14er-Redondrainagen in die Wundhöhlen eingelegt (Abb. **1c**, **3b**, **4a**). Nach Anpassung des Polyurethanschwammes an die Wundgeometrie wurden die Redondrainagenschläuche in den Schwamm eingeleitet und überstehende Anteile abgeschnitten (Abb. **4b**). Eine hermetische, luftdichte, wasserdampfdurchlässige Versiegelung der Wunde erfolgte mittels einer transparenten und keimdichten Polyurethanfolie. Nach Anbringen der Traq-pad-Einheit wurde die kontinuierliche Vakuumtherapie bei einer Sogstärke von – 125 mm Hg fortgesetzt (Abb. **1c**). Bei dem nächsten V.A.C.®-Wechsel nach 5 Tagen zeigte sich, dass es neben einer Bildung von Granulationsgewebe zu keiner klinisch und sonographisch nachweislichen erneuten Serombildung gekommen war und sich die Wundoberflächen miteinander verklebt hatten.

Im ersten Fallbeispiel konnte daher nach 10-tägiger Vakuumtherapie bei reizlosen Wundverhältnissen die Sekundärnaht des Defekts erfolgen (Abb. **4c**).

Auch im zweiten Fallbeispiel konnte durch die Vakuumtherapie neben einer Induktion von Granulationsgewebe durch die Verwendung der Redonschläuche eine Verklebung der gesamten Oberschenkelrückseite mit dem Untergrund erreicht werden (Abb. **5a**). Nach 14-tägiger Vakuumtherapie und Präkonditionierung des Transplantlagers konnten die bestehenden Defekte durch mehrere Lappenplastiken verschlossen werden (Abb. **5b**).

Diskussion

Die Vakuumtherapie ist zu einer etablierten Behandlungsmethode insbesondere in gegenüber konventionellen Therapien resistenten Problemwunden geworden. Gute Ergebnisse können auch bei ausgedehnten subkutanen Wundflächen erzielt werden.



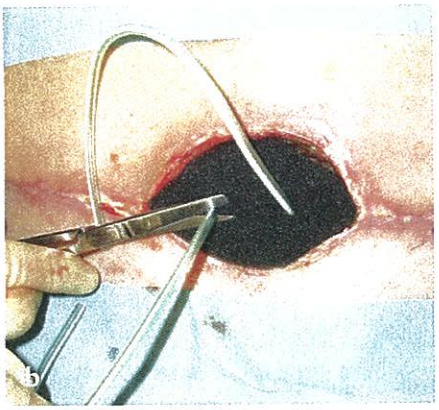
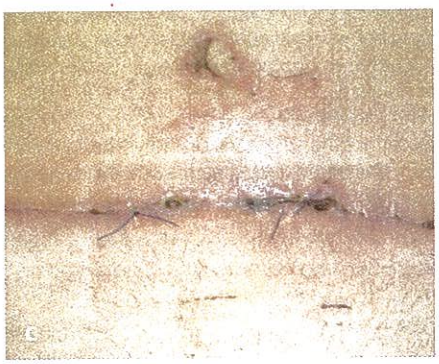
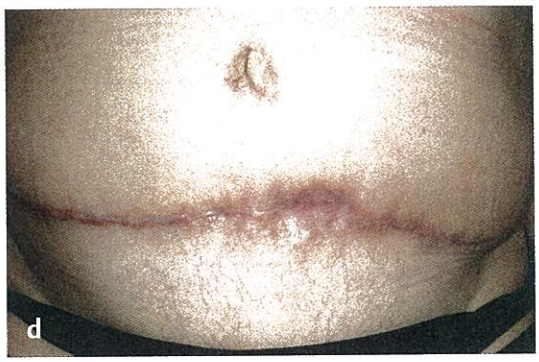
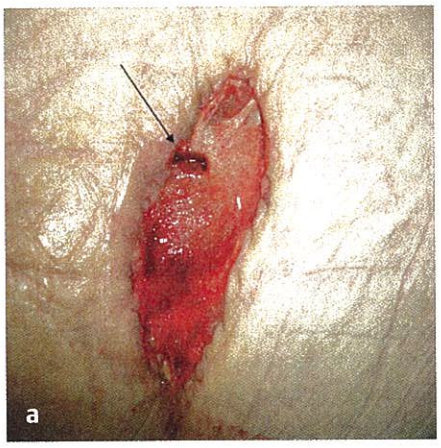


Abb. **4** (Fallbeispiel 1)
a Einlegen von Redondrainagen in die Wun taschen und Ausleitung durch den Polyure- thanschwamm.
b Die Redondrainagen werden auf Niveau d Schwammes abgeschnitten und das Wunda real in üblicher Art mit der entsprechenden Folie versiegelt. Über die Traq-Pad-Einheit kommunizieren die Redondrainagen mit de V.A.C.®-Therapieeinheit.
c Frühzeitige Sekundärnaht nach Ankleben Wundränder und
d Ausheilung der ehemaligen Defektwunde







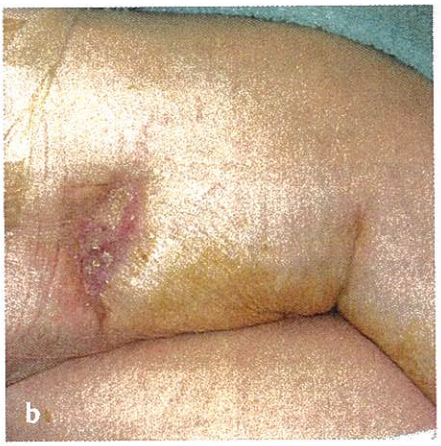


Abb. **5** (Fallbeispiel 2)
a Wundsituation im Bereich der Oberscher kelinnenseite nach 5-tägiger Vakuumthera mit deutlicher Granulationsgewebebildung Durch das Einlegen der Redonschläuche kö te ein Herabnähen der Wundränder auf de Wundgrund erfolgen, ohne dadurch einen Flüssigkeitsverhalt zu provozieren. Die Lag des Redonschlauches ist noch deutlich zu sehen (siehe Pfeil).
b Situs nach Abschluss der Vakuumtherapi und Defektdeckung mit einfachem Spalth transplantat und Vakuumfixierung.

Bisher erfolgte die Behandlung durch sorgfältiges Auskleiden der ausgedehnten Wundhöhlen und nachfolgender sukzessiver Verkleinerung des Schwammes, um eine zunehmende Verklebung der Wundflächen in mehreren Schritten zu erreichen. Nicht zu unterschätzen ist hierbei allerdings die Gefahr, dass beim Verbandswechsel kleinere Schwammreste ungewollt in tiefen Wundtaschen verbleiben könnten. Oftmals ist allerdings aufgrund der anatomischen Gegebenheiten ein vollständiges Auskleiden der Wundhöhlen unmöglich und es würde die Entstehung von Flüssigkeitsverhalten, wie im Fallbeispiel 1 dargestellt, begünstigen. Dies kann von vorneherein durch das zusätzliche Einlegen von Redondrainagen in die Wundhöhlen verhindert werden. Vorteilhaft erweist sich hierbei, dass die Ausbildung eines subkutanen Sekretverhaltes im Sinne einer Wundhöhlentamponade vermieden werden kann, ohne dass die gesamte Wundhöhle zeitaufwändig mit einem Schwamm ausgekleidet werden muss. Somit kann ein frühzeitiges Verkleben der Wundflächen erzielt werden. Die Vakuumtherapie stellt daher auch bei gedehnten subkutanen Problemwunden bzw. -wundtasc nach ausgedehnten Gewebemobilisationen (bsp. Lappenent men beim Gewebetransfer, Ablederungen oder Infektionshöl eine sichere und adäquate Behandlungsmethode dar, die zu e Verkürzung der Abheilungszeit beitragen kann.

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V.A.C.®-Therapie zur Optimierung eines mehrzeitigen Vorgehens bei der Sanierung komplexer Druckgeschwüre

B. Reichert

Optimizing Delayed Reconstruction of Complex Pressure Sores by V.A.C.® Therapy

Originalarbeit

Zusammenfassung

Die Verwendung der V.A.C.®-Therapie hat zu einer deutlichen Verbesserung in der Behandlung der tiefreichenden Dekubitalulzera geführt, weil neben der günstigen Einwirkung auf das Wundmilieu eine sichere Keimbarriere gebildet wird und die Wartezeit bis zur definitiven plastisch-chirurgischen Rekonstruktion verkürzt werden kann. Durch die sichere Folienfixierung kann eine akzidentelle Ablösung mit entsprechend nachteiligen Folgen einer Wundexposition verhindert werden. Dieser Aspekt stellt besonders in der Nähe der Analöffnung bei immobilen und multimorbiden Patienten einen wesentlichen Vorteil dar. Gerade in dieser Region bestehen aber auch technische Grenzen der Anwendung. Komplexe Defektwunden nach mehrfachen Voroperationen können oft nicht mehr klassisch versorgt werden. Langfristige Wundkonditionierungen sind erforderlich, stellen unter DRG-Bedingungen für vollstationäre Einrichtungen aber eine wesentliche Belastung dar. Für diese Patienten sind sektorenübergreifende Strukturen zu entwickeln, die eine kompetente Anwendung der V.A.C.®-Therapie ermöglichen. So werden mehrzeitige Sanierungen über große Zeitintervalle wieder realisierbar.

Schlüsselwörter
Dekubitus · Druckgeschwür · V.A.C.®-Therapie

Abstract

V.A.C.®-therapy has improved the treatment of extended
sure sores, because of its beneficial effect on the wound su
and the safe microbial barrier. Definitive reconstructive su
can be performed earlier. Using modern aids fixation of the
ce will be possible even in difficult locations as the perianal
This is important for immobile and multimorbid patients. O
other hand, this area still shows limitations of the method.
current cases it is difficult to use classical methods of r
struction. Long-term-treatment is necessary, which is ecor
cally difficult. It is important for hospitals to cooperate with
cialised wound therapeutics so that these patients can be
missed earlier. This may allow reconstructive procedures,
if this takes several hospital stays over a long period of time

Key words
Decubitus ulcer · pressure sore · vacuum assisted closure

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Bibliografie
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Einleitung

Dekubitalulzera stellen viele medizinische Disziplinen vor stetig wachsende Herausforderungen. Zwar sind einschlägige Risikofaktoren bekannt (niedriger ASA- oder NYHA-Score, schlechter Ernährungszustand, typische Hautveränderungen bei immobilen Patienten an prädisponierter Lokalisation u. a.). Gleichwohl steigt die Inzidenz aber mit der Zunahme der Lebenserwartung, sowie aufgrund einer immer effektiver agierenden Intensivmedizin kontinuierlich an [1, 11, 15, 16].

Die Entstehung von Druckulzera wird durch externe (Druck, Reibung, Scherkräfte, Feuchtigkeit) und interne Faktoren (Fieber, Unterernährung, Anämie, Endothelschäden) begünstigt. Typischerweise können drei Patientenkollektive unterschieden werden:

In der ersten Gruppe (Kollektiv A) fassen wir Menschen zusammen, die hauptsächlich aufgrund von Sensibilitätsstörungen Druckschäden entwickeln. Besonders häufig finden sich in dieser Gruppe der neurologisch auf spinaler oder peripherer Höhe geschädigten Patienten rollstuhlfahrende Paraplegiker. Sie sind häufig jung und aktiv und nutzen jede technische Hilfestellung, um ein weitgehend normales Privat- und Berufsleben führen zu können. Diese Lebensweise führt allerdings zu einem deutlich gesteigerten Risiko der Entwicklung von Dekubitalulzera, weil über den Sitzbeinhöckern erhöhte Druckbelastungen bestehen und begünstigt durch Immobilisation und Asensibilität in diesem Bereich über lange Zeiträume und ohne Schmerzempfindung wirken können. Wenn diese Patienten frühzeitig qualifiziert behandelt werden, kann dadurch eine Fortsetzung dieser Lebensgestaltung ermöglicht werden. Von größter Bedeutung hierbei ist neben einer belastbaren Defektrekonstruktion die Anpassung der Lebensführung, die den tatsächlichen Gegebenheiten des ortsständigen Gewebes Rechnung tragen muss. Werden die zwingend erforderlichen Vorbeugemaßnahmen missachtet, entstehen Rezidive, die immer schwerer chirurgisch sanierbar sein werden. Schlimmstenfalls sind diese Patienten dann nicht mehr rollstuhlfähig.

Hiervon abzugrenzen sind diejenigen Patienten, die aufgrund außergewöhnlicher Lebensumstände kurzfristig immobil wurden und dabei Druckschäden entwickelt haben (Kollektiv B). Dazu zählen traumatisierte oder intoxikierte, durch kardiovaskuläre Ereignisse akut erkrankte Patienten oder auch Personen, die durch unterschiedlichste Umstände längerfristig intensivtherapiert werden müssen. Auch nach langdauernden Operationen werden Druckschädigungen sichtbar. In all diesen Fällen sind häufig günstige Langzeitergebnisse zu erzielen, weil eine Rezidive begünstigende Immobilisation oder Asensibilität nicht grundsätzlich weiterbesteht. Sofern allgemeine Operabilität gegeben ist, wird auch hier die Indikation zur Durchführung aufwändiger chirurgischer Verfahren großzügig gestellt werden können.

Diese Einschätzung trifft für Patienten im Kollektiv C allerdings seltener zu. Hier finden wir die permanent immobilen, pflegebedürftigen Menschen. Charakteristisch ist für dieses Kollektiv, dass immer wieder ganz bewusst auf Versuche, eine definitive Defektversorgung zu erzielen, verzichtet werden muss, weil die eingeschränkte Operabilität Grenzen setzt, das ortsständige Gewebe nach vorangegangenen chirurgischen Sanierungsversuchen nicht mehr rekonstruktiv nutzbar ist, oder die postoperativ zu fordernde optimierte Lagerung und Pflege absehbar nicht geleistet werden wird. Bei diesen Patienten muss also nach einem initialen chirurgischen Debridement zeitgerecht nach alternativen Behandlungsmöglichkeiten gesucht werden. Freie Lappenplastiken wurden für solche Patienten zwar bereits vorgeschlagen [17], werden nach unserer Erwartung aber nur in Einzelfällen anwendbar sein. Wenn ideale Behandlungsmöglichkeiten nicht mehr genutzt werden können und alternativ auf Verfahren der zweiten und dritten Wahl ausgewichen werden muss, kommt einer intermittierenden Lokaltherapie mit geeigneten Methoden eine besondere Bedeutung zu.

Allgemein gebräuchliche Stadieneinteilungen für Dekubitalulzera unterscheiden Schweregrade in Analogie zu Verbrennungsverletzungen und suggerieren damit, dass eine von extern wirkende Noxe initial die äußersten Hautschichten betrifft, und erst mit längerer oder intensiverer Einwirkung auch tiefere Gewebezonen schädigt (Tab. **1**). Tatsächlich aber entstehen Schäden durch langdauernde Druckeinwirkungen vor allem im unmittelbar an das Skelett angrenzenden Gewebe. Mit bis zu 70 mm Hg wird hier der kapilläre Mindestperfusionsdruck von 32 mm Hg deutlich überschritten, während an der Haut selbst gleichzeitig „nur" Druckwirkungen von 30 mm Hg gemessen werden [14]. Hieraus erklärt sich die klinisch bekannte Beobachtung, wonach bei Penetration der Haut oftmals bereits ausgedehnte und sehr tiefreichende Unterminierungen und Nekrosehöhlen bestehen. Daher schlägt mittlerweile auch die NPUAP eine Ergänzung ihrer Stadieneinteilung durch die Bezeichnung „Tiefe Gewebsschädigung unter intakter Haut" vor [2]. Besonders diese kritischen und komplexen Wunden bedürfen einer qualifizierten chirurgischen Versorgung. Während oberflächliche Läsionen häufig noch durch moderne Wundtherapeutika in Verbindung mit optimierten Lagerungshilfen und angepasster Nutrition erfolgreich konservativ behandelt werden können, gelten für die tief liegenden Dekubitalulzera ab Stadium III seit langem bekannte chirurgische Behandlungsprinzipien [5, 6, 16, 20]:

- Exzision des Ulkus mitsamt umgebender Narbe und unterminierender Bursa
- Glättung darunter liegender knöcherner Unebenheiten
- Auffüllen von Hohlräumen mit vitalem Gewebe
- Defektdeckung durch Lappenplastiken.

Hierfür werden Muskel- oder Hautmuskellappen bevorzugt, weil sie über eine definierte Blutversorgung verfügen und dadurch trotz Debridements fortbestehende bakterielle Kontaminationen kontrollieren können [12]. Konturdefekte lassen sich

Tab. **1** Stadieneinteilung der Dekubitalulzera (nach National Pressure Ulcer Advisory Panel [www.npuap.org])

Stadium I	nicht abblassendes Erythem
Stadium II	oberflächliche Ulzeration (z. B. Blase, Abrasion)
Stadium III	Ulzeration bis zur Faszie, ggf. Unterminierung der Umgebung
Stadium IV	ausgedehnte Destruktion mit Beteiligung von Muskel, Knochen, Sehne usw.

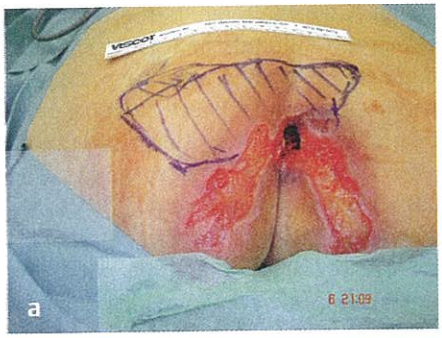

Abb. **1a** PL (w., 84). Sakrales Dekubitalgeschwür Grad IV nach Knie-TEP. Die Schraffierung markiert den Bereich der Unterminierung („Pseudobursa").

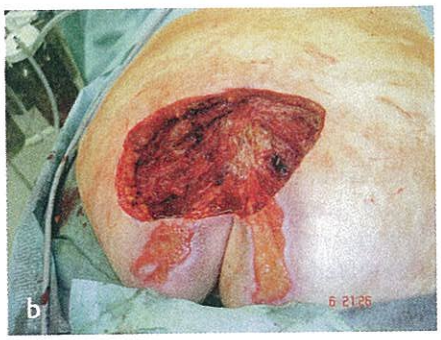

Abb. **1b** Aufgrund septischer Komplikationen erfolgt ein notfallmäßiges Debridement.

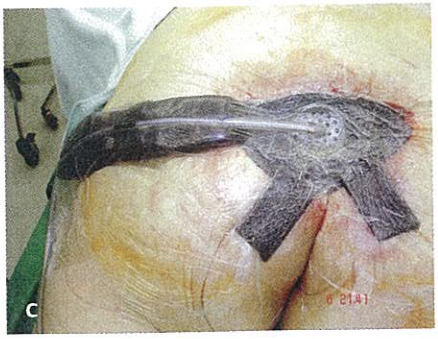

Abb. **1c** Zunächst intermittierende V.A.C.®-Therapie.

ausgleichen, die bei späterer Belastung auftretenden Druckkräfte werden günstig verteilt, und das Rezidivrisiko dadurch gemindert [7]. Werden solche Lappenplastiken allerdings durchgeführt, ohne dass das geforderte vorherige radikale Wunddebridement ausreichend sicher erfolgt ist, ist mit einem deutlich gesteigerten Risiko kritischer Wundheilungsstörungen zu rechnen. Hier hat sich ein mehrzeitiges Vorgehen bewährt, bei dem über mehrere operative Sitzungen das gewünschte Ergebnis einer suffizienten Wundsäuberung mit ausreichender Evidenz erreicht wird. Während dieser Behandlungsphase haben wir zur Wundbedeckung die V.A.C.®-Therapie verwendet. Nur in Ausnahmefällen, die aufgrund anderer Kriterien für die standardisierte Versorgung nicht geeignet erschienen, wurde die V.A.C.®-Therapie zur definitiven Behandlung eingesetzt.

Patienten und Methode

Seit 2004 wurden 26 Patienten mit Dekubitalulzera der Stadien III und IV behandelt. 18 Patienten waren permanent pflegebedürftig und immobil (Kollektiv C), jeweils 4 Patienten aktive Paraplegiker (Kollektiv A) oder nur vorübergehend immobilisiert (Kollektiv B). Bei 17 Patienten bestanden sakrale, bei 4 Patienten ausschließlich ischiale Defekte, in 7 Fällen fanden sich Druckulzera andernorts. Bei 5 Patienten bestanden parapelvine Ulzera an mehreren Lokalisationen. Nur 8 Patienten kamen zur ersten chirurgischen Versorgung, in 71% der Fälle handelte es sich um ausgedehnte Rezidive, zwei Patienten mussten zweimal stationär behandelt werden. Je Behandlungsfall waren durchschnittlich 5,3 Eingriffe erforderlich, 3,7 erfolgten vor den eigentlichen Rekonstruktionsoperationen. In 23 Fällen (82%) wurde in dieser Phase eine Vakuumversiegelung durchgeführt, um die radikal exzidierte Wunde zu schützen und eine sichere Keimbarriere zu schaffen (Abb. **1a–c**). Bei einer durchschnittlichen stationären Behandlungsdauer von 47,1 Tagen wurde im Mittel 14 Tage mit V.A.C.® therapiert. In einem Fall wurde ein prolongierter Verlauf beobachtet, weil nach insuffizientem Debridement unter Vakuumversiegelung septische Komplikationen auftraten.

Ergebnisse

Die Beurteilung der erzielten Resultate erfolgte anhand einer semiquantitativen Evaluation der Behandlungsunterlagen unter Berücksichtigung der Abschlussuntersuchung (Tab. **2**). Befunde zu späteren Zeitpunkten konnten wir nur in Ausnahmefällen erheben (Abb. **2**).

Sehr gute, gute oder mäßig zufriedenstellende Behandlungsergebnisse konnten wir in 68% (19 von 28 Behandlungsfällen) erzielen (Abb. **2**). Bei zwei Patienten konnten wir trotz chirurgisch günstiger Verhältnisse eine Abheilung nicht erreichen, bei zwei weiteren Patienten mussten wir bei eingeschränkter Operabilität Rekonstruktionen parapelviner Defekte mit freien Hauttransplantaten vornehmen, bei drei anderen Patienten wurde diese Methode zur Versorgung von Defekten an Knöchelregion oder Ferse eingesetzt. Je einmal kamen hier Suralis- und Peronäus-brevis-Lappen zum Einsatz. Zwei Patienten verstarben während der stationären Behandlung. Die schwerwiegendste lokale Komplikation war eine Lappennekrose, welche wir in einem Fall beobachten mussten.

Bei 20 Patienten mit parapelvinen Ulzera erfolgten Defektdeckungen durch myokutane Lappenplastiken (17 bilaterale Glutäus-maximus-Transpositionslappen; 9 Hamstring-Flaps; 3 Tensor-fasciae-latae-Lappen; 1 Grazilis-Lappen). Bei einem Patienten wurde ein ausgedehntes und mehrfach voroperiertes Dekubitalulkus mit femoralen Filet-Lappen (Total Thigh Flap) versorgt.

Tab. **2** Rekonstruktionsergebnis

sehr gut	stabile, normal belastbare Oberfläche
gut	intakte, temporär belastbare Oberfläche
mäßig	intakte, wenig belastbare Oberfläche
unbefriedigend	fortbestehende Defektwunde

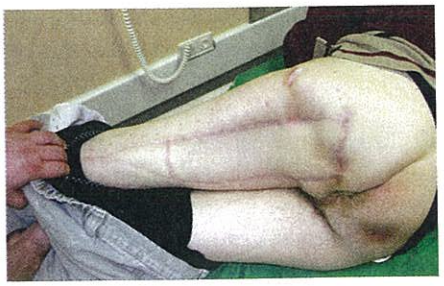

Abb. **2** WH (m., 56). Ein Jahr nach mehrzeitigem Debridement eines Grad-IV-Sitzbeinulkus, intermittierender V.A.C.®-Therapie und Rekonstruktion durch Hamstring-Flap.

Diskussion

Druckgeschwüre wurden ursprünglich als Gangraena per decubitum bezeichnet und damit auf eine liegende Position (decumbere) zurückgeführt. Denkt man an die typischerweise bei rollstuhlfahrenden Paraplegikern auftretenden Sitzbeinulzera, so wird deutlich, wie unsinnig die Beschränkung auf einen solchen Zusammenhang ist. Der angloamerikanische Begriff „pressure sore" ist umfassender, zumal damit auch die noch nicht ulzerierte Form einer Druckschädigung beschrieben werden kann.

Zu den früher gültigen Prinzipien der chirurgischen Behandlung chronischer und komplexer Wunden zählte neben dem chirurgischen Debridement die Anwendung lokal antiseptisch oder antibiotisch wirkender Externa oder auch die Verwendung biologisch wirksamer Substanzen wie Kollagenasen. Tägliche Verbandswechsel, nicht selten nur unter Narkosebedingungen durchzuführen, waren wesentlicher Bestandteil dieser Konzepte. Ausgehend von diesem Standard ist ein Behandlungsverfahren, welches eine mehrtägige Wundbedeckung erlaubt, schon allein deshalb attraktiv.

Bei der V.A.C.®-Therapie profitieren die lokalen Gewebsverhältnisse vom kontinuierlichen Abtransport von Wundsekret. Der offenporige Schwamm gibt den von der Pumpe aufgebauten Unterdruck gleichmäßig auf die gesamte Wundoberfläche weiter. Die heute verwendeten Geräte und Materialien sind technisch ausgereift und erlauben bei korrekter Handhabung eine mehrtägige Anwendung. Auch die nach Debridement tiefreichender Dekubitalulzera verbliebenen Defekte lassen sich so behandeln. Nachteilig ist, dass der Wundgrund unter einem Vakuumverband nicht beurteilt werden kann. Umso höher ist die Bedeutung eines radikalen Debridements einzuschätzen. Die Vakuumversiegelung einer nicht ausreichend debridierten Wunde ist sicherlich nicht zweckmäßig.

In der sicheren Abgrenzung der Wunde gegenüber der Umwelt, wie sie die V.A.C.®-Therapie erlaubt, sehen wir einen zweiten wesentlichen Vorteil der Methode. Bei Dekubituspatienten bleiben auch debridierte Wunden meist in Kontakt mit Auflageflächen, werden also weiterhin Druck- und Scherbelastungen ausgesetzt. Konventionelle Verbände lassen sich hier nur schlecht fixieren, bilden durch Verformungen neue Druckprobleme und Superinfektionen können nur schwer vermieden werden. Sofern es gelingt, einen V.A.C.®-Verband sicher zu applizieren, ist dieser in allen hier genannten Belangen deutlich überlegen. Einschränkungen sehen wir bei Dekubitalulzera vor allem bei sakralen oder ischialen Defekten in der Nähe der Analöffnung. Hier kann die zusätzliche Verwendung von Gelstreifen bei der Sicherstellung der erforderlichen Folienabdichtung helfen. Bei trochantären Läsionen finden wir dagegen immer eine ausreichend breite Zone gesunder umgebender Haut, auf der die Folie sicher fixiert werden kann.

Nach unserer Ansicht konnten wir seit Einführung der V.A.C.®-Therapie in die Behandlungsphase zwischen Debridement und definitiver plastisch-chirurgischer Defektrekonstruktion neben einer eindeutigen Verbesserung der Wundkonditionierung bei gleichzeitiger Steigerung des Patienten- und Pflegekomforts auch eine Senkung postoperativer Komplikationsraten nach der eigentlichen Lappenplastik erreichen.

Die bislang publizierten Anwendungsbeobachtungen der V.A.C.®-Therapie bei Dekubitalulzera haben nachzuweisen versucht, dass schon die alleinige Anwendung dieser Methode vorteilhaft sei: Smith berichtete 2004, dass die Vakuumversiegelung verglichen mit Alginat- oder Hydrokolloidverbänden die beste Wirksamkeit bei Druckulzera aufwies [18]. Bei 281 Patienten wurden die Heilungsverläufe dokumentiert, der stabile Wundverschluss untersucht und die Heilungsdauer betrachtet. Dabei zeigten nur die mit der Vakuumversiegelung behandelten Ulzera in all diesen Kategorien positive Effekte.

Ford et al. führten an 28 Patienten mit 41 Dekubitalulzera der Stadien II und höher eine randomisierte Studie durch und verglichen nach einem sechswöchigem Behandlungsintervall die Ergebnisse bei 20 Patienten mit V.A.C.®-Therapie mit denen von 15 Patienten, die nach den Vorgaben des Healthpoint Systems mit Hydrogelverbänden therapiert wurden [9]. In beiden Gruppen wurde eine vollständige Abheilung bei zwei Patienten beobachtet. Auch bei der Verringerung der Ulkusdimensionen ergaben sich keine signifikanten Unterschiede. Lediglich bei drei Patienten mit histologisch gesicherter Osteomyelitis zeigte sich unter der V.A.C.®-Therapie eine signifikante Verbesserung.

Aus diesen Berichten kann eine pauschale Empfehlung, die V.A.C.®-Therapie als alleinige Behandlungsoption zu propagieren, nicht abgeleitet werde. Wir setzen die Methode nur in denjenigen Fällen mit einer solchen Intention ein, bei denen wir die üblichen plastisch-chirurgischen Rekonstruktionsverfahren nicht mehr verwenden können.

Schließlich darf nicht unerwähnt bleiben, dass die beschriebenen Behandlungsprinzipien unter den Bedingungen pauschalierter Vergütungssysteme kritisch betrachtet werden müssen. Einerseits decken die derzeit geltenden Grundlagen für die Bemessung von Fallpauschalen die tatsächlichen Erfordernisse mehrzeitigen operativen Vorgehens mit entsprechendem materiellen und zeitlichen Mehraufwand nicht ab. Hier muss dringend auf entsprechende Anpassungen hingewirkt werden. Andererseits müssen sektorenübergreifend neue Strukturen geschaffen werden, die eine frühzeitigere Entlassung aus der stationären Fachabteilung erlauben, ohne dass dadurch ein erhöhtes Komplikationsrisiko begünstigt wird. Da auch tragbare Absaugpumpen zur Verfügung stehen, könnte hier ein neues Anwendungsgebiet auch und gerade für die V.A.C.®-Therapie eröffnet werden.

Grundsätzlich aber gilt, dass wir unsere Behandlungsergebnisse nur verbessern können, wenn in der Behandlung Kompetenzen aus allen relevanten Gebieten (Pflege, Lagerung, Infektionsbekämpfung, Ernährung, chirurgische Therapie) zusammengeführt werden [8, 13, 19]. Dabei werden moderne Methoden der Verlaufskontrolle zukünftig eine wertvolle Bereicherung darstellen [4, 10]. Die Inzidenz von Dekubitalulzera werden wir allerdings nur dann senken können, wenn neben einer exakten Risikoabschätzung auch eine effektive Prävention betrieben wird [3].

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Clinical Outcome After Poststernotomy Mediastinitis: Vacuum-Assisted Closure Versus Conventional Treatment

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Background. The conventional treatment for poststernotomy mediastinitis usually involves surgical revision, closed irrigation, or reconstruction with omentum or pectoral muscle flaps. Recently, vacuum-assisted closure has been successfully used in poststernotomy mediastinitis. The aim of the present study was to compare the clinical outcome and survival in 101 patients undergoing vacuum-assisted closure therapy or conventional treatment for poststernotomy mediastinitis.

Methods. One hundred one consecutive patients underwent treatment for poststernotomy mediastinitis: vacuum-assisted closure therapy (January 1999 through December 2003, n = 61) or conventional treatment (July 1994 through December 1998, n = 40). Follow-up was made in April 2004 and was 100% complete. Actuarial statistics were used to calculate the survival rates.

Results. The 90-days mortality was 0% in the vacuum-assisted closure group and 15% in the conventional treatment group ($p < 0.01$). The failure rate to first-line treatment with vacuum-assisted closure and conventional treatment were 0% and 37.5%, respectively ($p < 0.001$). There was no statistically significant difference in the recurrence of sternal fistulas after vacuum-assisted closure therapy or conventional treatment: 6.6% versus 5.0%, respectively. Overall survival in the vacuum-assisted closure group was significantly better ($p < 0.05$) than in the conventional treatment group: 97% versus 84% (6 months), 93% versus 82% (1 year), and 83% versus 59% (5 years).

Conclusions. Our findings support that vacuum-assisted closure therapy is a safe and reliable option in poststernotomy mediastinitis with excellent survival and a very low failure rate compared with conventional treatment.

(Ann Thorac Surg 2005;79:2049-55)

Poststernotomy mediastinitis after cardiac surgery is a devastating, and potentially life-threatening, complication. The incidence is relatively low, 1% to 3% [1, 2], but the mortality rate varies between 19% and 29% according to recent studies [1, 3]. Several wound-healing strategies have been established for the treatment of poststernotomy mediastinitis. Conventional forms of treatment usually involve surgical revision with open dressings or closed irrigation, or reconstruction with vascularized soft tissue flaps such as omentum or pectoral muscle. These wound-healing techniques may be used as a single-line therapy or as a combination of procedures, but there is a considerable lack of consensus regarding the optimal surgical management. Conventional treatment has disadvantages such as destabilization of the thoracic cage, prolonged immobilization, or substantial surgical trauma that might be deleterious in a compromised patient [4].

Recently, several studies have reported promising results with the use of vacuum-assisted closure (VAC) therapy in poststernotomy mediastinitis after open heart surgery [5–10]. In these patients, the VAC technique has been successful, either as a single-line therapy [11] or as a procedure for providing optimal conditions for second-line treatment with tissue flaps [12]. We use VAC as a single-line therapy followed by sternal rewiring without the use of tissue flaps.

We have treated 101 patients with culture-verified poststernotomy mediastinitis since July 1994. Conventional treatment was used between 1994 and 1998, and VAC was used between 1999 and 2003. Comparisons of early outcome between VAC therapy and conventional treatment are scarce [13, 14] and, no long-term studies have been performed comparing the clinical outcome of these therapies. The aim of the present study was to compare the failure rate and survival after single-line VAC therapy or conventional treatment in patients with poststernotomy mediastinitis.

Patients and Methods

Between July 1994 and December 2003, 101 consecutive patients were treated for culture-verified poststernotomy mediastinitis at the Department of Cardiothoracic Surgery in Lund, Sweden. During this period the incidence of poststernotomy mediastinitis was 0.9%

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Table 1. Patient Characteristics

	VAC Therapy		Conventional Treatment		
Variable	n	%	n	%	*p* Value
Number of patients	61		40		
Sex					
Male	44	72	38	95	0.004
Female	17	28	2	5	0.004
Surgical procedure					
CABG	40	66	33	83	0.073
Other procedures	21	34	7	17	0.073
Diabetes mellitus	26	43	12	30	0.190
Obesity (BMI ≥ 30)	23	38	12	30	0.419
LVEF < 0.30	14	23	4	10	0.116
COPD	12	20	4	10	0.164
Emergency surgery	9	15	1	3	0.084
Renal failure[a]	7	11	2	5	0.313
Immunosuppression	4	7	0	0	0.150
	Mean	SD	Mean	SD	
Age (y)	67.3	10.1	68.9	7.8	0.368
EuroSCORE	7.6	3.8	5.0	2.9	<0.001

[a] Serum creatinine > 200 μmol/L.

BMI = body mass index; CABG = coronary artery bypass graft; COPD = chronic obstructive pulmonary disease; LVEF = left ventricular ejection fraction; SD = standard deviation; VAC = vacuum-assisted closure.

(101 patients of 11,348 sternotomy procedures). The incidence was stable throughout the 10-year period; however, referrals for cardiac surgery increased during the relevant period. Forty patients diagnosed with poststernotomy mediastinitis underwent conventional treatment (open dressings, closed irrigation, pectoral muscle flaps, or omentum flaps) between July 1994 and December 1998.

In January 1999 the surgeons at our cardiothoracic surgery department changed their standard therapy in cases of poststernotomy mediastinitis from conventional treatment to VAC therapy. Since then, VAC has been used as single-line treatment before sternal rewiring in 61 consecutive patients with poststernotomy mediastinitis. During the initial phase, before VAC therapy had become fully established, 3 patients were treated with conventional techniques at the surgeon's discretion, and these patients were included in the conventional treatment group.

The preoperative variables, including the EuroSCORE [15], were prospectively collected in the department's database before surgery (Table 1). EuroSCORE was used to assess the grade of surgical complexity and preoperative status. In addition, information on risk factors considered relevant to poor wound healing, such as diabetes mellitus, obesity, and systemic immunosuppressive therapy [1, 16], was collected from the patients' medical records. The presence of bilateral mammary artery grafts was not included because this technique was practiced rarely at our department.

Poststernotomy mediastinitis was defined according to the guidelines of the US Centers for Disease Control and Prevention (CDC) [17]. Diagnosis required at least one of the following criteria: (1) an organism was isolated from culture of mediastinal tissue or fluid; (2) evidence of mediastinitis was seen during operation; or (3) one of the following conditions, chest pain, sternal instability, or fever (>38°C) was present and there was either purulent discharge from the mediastinum or an organism isolated from blood culture or culture of drainage of the mediastinal area. However, no patient presenting signs of infection but with negative substernal tissue cultures was included in the study. All patients in this report required surgical revision with removal of the sternal wires. Patients with sterile dehiscences or superficial sternal wound infections were not included. The patients were also classified according to the criteria proposed by El Oakley and Wright (Table 2) [18]. This classification differentiates between time of presentation and preoperative risk factors and ranged from type I to type V in the study population. Type I is mediastinitis within 2 weeks after operation in the absence of risk factors. Type II is mediastinitis presenting at 2 to 6 weeks after operation in the absence of risk factors. Type IIIA is mediastinitis type I in the presence of one or more risk factors. Type IIIB is mediastinitis type II in the presence of one or more risk factors. Type IVA is mediastinitis type I, II, or III after one failed therapeutic trial. Type IVB is mediastinitis type I, II, or III after more than one failed therapeutic trial. Type V is mediastinitis presenting for the first time more than 6 weeks after operation.

Table 2. Poststernotomy Mediastinitis Classification

	VAC therapy		Conventional treatment	
El Oakley Class	n	%	n	%[b]
I	12	20	10	25
II	7	11	3	8
IIIA	13	21	7	18
IIIB	26	43	7	18
IVA	1[a]	2	9	23
IVB	0	0	2	5
V	2	3	2	5

[a] Failure to respond to conventional treatment (revision + rewire). VAC was initiated until a second rewiring was performed uneventfully. [b] The sum of the percentages exceed 100% because of rounding-off errors.

VAC = vacuum-assisted closure.

Antibiotic Therapy

Our standard perioperative antibiotic regime during the relevant period was isoxazolyl penicillin 2 g, three doses on the day of operation and the first postoperative day. When poststernotomy mediastinitis was diagnosed, the antibiotic therapy usually commenced with vancomycin intravenously and continued until the results of the tissue cultures became available. The entire panorama of pathogens is presented in Table 3. Thereafter, the antibiotic therapy was adjusted according to bacterial sensitivity and strain. The antibiotic regimen was similar in the VAC group and the conventional treatment group.

Table 3. Culture-Verified Mediastinal Pathogens

	VAC Therapy		Conventional Treatment	
Bacterial Strains	n	%[a]	n	%[a]
CoNS	34	56	27	68
S aureus	8	13	2	5
E cloacae	4	7	1	3
Klebsiella oxytoca	3	5	0	0
Propionibacterium acnes	2	3	0	0
E coli	1	2	0	0
Bacterioides fragilis	1	2	0	0
Klebsiella pneumoniae	1	2	2	5
CoNS + *S aureus*	3	5	2	5
CoNS + *E coli*	2	3	0	0
CoNS + *Proteus mirabilis*	1	2	1	3
CoNS + *Pseudomonas aeruginosa*	1	2	0	0
CoNS + *Enterococcus faecalis*	0	0	3	8
CoNS + *Enterobacter aerogenes*	0	0	1	3
S aureus + *Citrobacter freundii*	0	0	1	3

[a] The sum of the percentages exceeds 100% because of rounding.

CoNS = coagulase-negative staphylococci strains; *S aureus* = *Staphylococcus aureus*; *E cloacae* = *Enterobacter cloacae*; *E coli* = *Escherichia coli*.

Vacuum-Assisted Closure Therapy

Between January 1999 and December 2003, 61 patients underwent VAC as a single-line therapy followed by sternal rewiring. All patients underwent initial surgical revision with removal of all sternal wires. Substernal tissue cultures were sent for microbiologic investigation and determination of the antibiotic resistance pattern. The wound was stepwise revised during VAC changes with a sharp spoon and necrotic bone was removed when necessary, but extensive sternectomy was avoided. The VAC system was established in the sternal wound according to the method previously described by our group [11]. The majority of patients was extubated immediately after VAC therapy initiation and left the intensive care unit after 2 to 3 hours. The patients in the VAC group underwent 3.4 ± 2.3 surgical procedures (median 3; range, 2 to 17). These procedures included initial revision with removal of the sternal wires and application of VAC therapy, changes of polyurethane foam, and the final rewiring of the sternum.

Conventional Treatment

Between July 1994 and December 1998, 40 consecutive patients were diagnosed as having poststernotomy mediastinitis. The patients in this group underwent initial surgical revision with complete debridement of the presternal tissue and sternal edges, similar to the VAC group. This revision included removal of fibrins, necrotic tissue, and sternal wires.

The surgical procedure performed (rewiring, open dressings, closed irrigation, pectoral flaps, or omentoplasty) depended on the clinical condition of the patient and the surgeon's preference. The vascularized soft tissue flaps were performed in cooperation with a plastic surgeon when needed. The different combinations of surgical procedures in the conventionally treated patients are presented in Table 4.

Open dressings (wound packing) consisted of moist saline gauzes in the mediastinum for 1 or several days. Dressings were changed several times daily in combination with surgical revision. The procedure was concluded with a sterile drape covering the wound and bypass grafts to prevent desiccation. When the wound was considered clean and there was a bed of fresh granulation tissue, the sternum was rewired or, when necessary, additional wound-healing measures were applied (Table 4).

Closed irrigation was initiated with two or three drains in the mediastinum in combination with two thin catheters for irrigation. The sternum was closed in a standard manner with interrupted steel wires. The fascia and skin were closed in separate layers. The wound was irrigated with normal saline solution, without antibiotics, until the infection was considered under control. The drainage tubes were removed in the ward several hours after irrigation had ceased.

Pectoralis flaps were performed as bilateral advancement flaps on the basis of lateral pectoral arterial blood supply. The sternum was adapted with steel wires when possible, depending on the degree of sternal necrosis.

Table 4. Conventional Surgical Wound-Healing Therapies (40 Patients)

1st Therapy	2nd Therapy	3rd Therapy	n	90-Days Mortality
Rewire			5	0
Rewire[a]	Open dressings	Rewire	1	0
Rewire[a]	Open dressings	Omentoplasty	2	1
Open dressings			1	0
Open dressings	Closed irrigation		3	0
Open dressings	Pectoralis flap		4	2
Open dressings	Omentoplasty		6	1
Open dressings	Rewire[a]	Pectoralis flap	2	0
Open dressings	Pectoralis flap	Omentoplasty	1	0
Closed irrigation			7	0
Closed irrigation	Pectoralis flap		1	0
Closed irrigation	Open dressings	Pectoralis flap	1	0
Closed irrigation	Open dressings	Omentoplasty	1	0
Pectoralis flap			2	1
Pectoralis flap	Open dressings	Omentoplasty	1	1
Omentoplasty			1	0
Omentoplasty	Open dressings	Pectoralis flap	1	0

[a] Initial revision + rewiring was followed by a second wound rupture.

Thin drainage tubes were placed under the muscle flaps and in the mediastinum. Subcutaneous tissue and skin were sutured with interrupted sutures. The thin drainage tubes were removed in the ward when only small amounts of fluid were evacuated.

Omentoplasty was performed through an upper midline incision. The omentum flap was mobilized and passed through a hole in the peritoneum to the mediastinum anterior to the pericardium. If possible, the sternum was rewired during omentoplasty. The subcutaneous tissue and skin were then closed over the omental flap with interrupted sutures.

Follow-Up

The study protocol was approved by the ethics committee for clinical research at Lund University, Lund, Sweden. The follow-up was performed in April 2004 and included 337.8 patient-years (VAC group: 145.4 patient-years; conventional treatment group: 192.4 patient-years), and no patient was lost to follow-up (Fig 1). Information about the patients was collected from the computerized database at our department and, when needed, collected retrospectively from the patients' medical records. The cause of death during follow-up was provided by the National Board of Health and Welfare. Length of stay was calculated according to Domkowski and coworkers [10], ie, after the onset of mediastinitis if it occurred during the same period of hospitalization as the initial cardiac surgery, or the period of hospitalization as a result of separate admission for mediastinitis.

Data Analysis

The survival functions for the conventional treatment group and the VAC group were calculated using the Kaplan-Meier method. The survival functions were then compared using the (nonparametric) log-rank test, Breslow's test, and Tarone-Ware test. The two-sample Student's t test was used to evaluate continuous variables. For categorical variables, for which the normal approximation was valid, the two-sample proportion test was used. For other categorical variables, Fisher's exact test was applied. A p value less than or equal to 0.05 was considered statistically significant.

Results

The patients' preoperative characteristics demonstrated a significantly higher EuroSCORE and significantly more women in the VAC group. All variables are presented in Table 1.

The 90-days mortality was significantly lower in the VAC group than in the conventionally treated group: 0% (0 patients) versus 15% (6 patients; $p < 0.01$). The 6

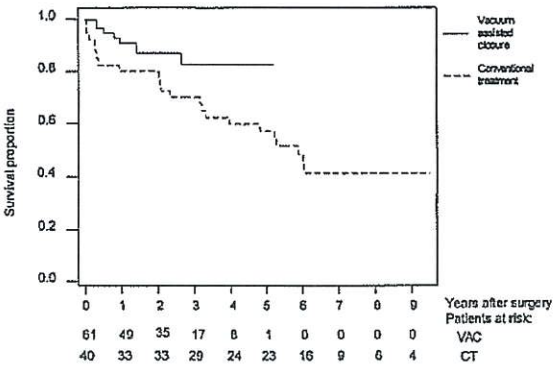

Fig 1. Actuarial survival in the vacuum-assisted closure group (VAC) and conventional treatment (CT) group.

patients in the conventionally treated group all died of multiorgan failure caused by severe sepsis. The numbers of failures to respond to first-line VAC treatment were 0% (0 patients) in the VAC group and 37.5% (15 patients) in the conventional treatment group ($p < 0.001$; Table 4). The patients with failures to first-line and second-line treatment in the conventional treatment group were classified as El Oakley class type IVA and Type IVB, respectively (Table 2). All 61 patients in the VAC group underwent sternal rewiring without tissue flap surgery. In the conventional treatment group, tissue flaps were performed in 57.5% (23 patients; Table 4). There was no significant difference between the VAC group and the conventionally treated group when comparing the rate of polymicrobial infections (Table 3).

There was no significant difference in time from cardiac surgery to diagnosis of poststernotomy mediastinitis between the VAC group and the conventional treatment group: 16 ± 10 days (range, 3 to 71 days) versus 17 ± 16 days (range, 3 to 97 days), respectively. There was no significant difference in treatment duration between VAC and conventional treatment: 12 ± 9 days (range, 2 to 66 days) versus 10 ± 14 days (range, 1 to 53 days), respectively. The total length of stay in the VAC group and conventional treatment group was 25 ± 17 days (range, 7 to 103 days) and 25 ± 20 days (range, 1 to 87 days), respectively (not significant).

There was no significant difference in recurrent sternal fistulas between VAC therapy and conventionally treated patients: 4 patients (6.6%) and 2 patients (5.0%), respectively. The patients were readmitted to our department, and the fistulas were debrided under general anesthesia. The fistulas were obliterated completely, without sternectomy, after removal of the sternal wires followed by VAC therapy or conventional treatment in combination with antibiotic therapy.

Overall survival was significantly better ($p < 0.05$) in the VAC group than in the conventional treatment group: 96.9% ± 1.0% (n = 59) versus 84.4% ± 5.6% (n = 35) at 6 months, 92.9% ± 3.3% (n = 49) versus 82.4% ± 6.0% (n = 33) at 1 year, and 82.7% ± 6.6% (n = 1) versus 58.7% ± 7.6% (n = 23) at 5 years (Fig 1). There were 7 late deaths in the VAC group and 16 late deaths in the conventional group. None of the late deaths was caused by ongoing infection in either group.

Comment

Poststernotomy mediastinitis was initially treated with surgical revision, with or without multiple open dressing changes, followed by sternal rewiring or secondary healing. Previous authors have reported a mortality of 45% with this approach [19]. One major disadvantage of open dressings is thoracic instability, which requires mechanical ventilation. Prolonged immobilization increases the risk of additional complications such as pneumonia, thrombosis, and muscular weakening. An important step was made when continuous saline solution and antibiotic irrigation was developed by Bryant and colleagues in 1969 [20]. This technique offers a stable sternum, but previous studies have reported unsatisfyingly high rates of failure [13, 21] and mortality [22].

Another established method is the use of vascularized soft tissue flaps. The use of pectoral muscle flaps was initially described by Jurkiewicz and colleagues [23]. Recent studies have reported varying results with pectoral muscle flaps in poststernotomy mediastinitis [24–26]. Other authors have advocated the technique using omentum flaps first described by Lee and coworkers [27] for closure of mediastinal defects [28]. Reconstruction with soft tissue flaps has a relatively low mortality rate according to some reports [24, 28], but may be associated with flap-related morbidity [29].

Vacuum-assisted closure is a novel approach in wound-healing management [30]. During the application of this subatmospheric form of treatment, several advantageous features of conventional treatment are combined. Vacuum-assisted closure allows open drainage that continuously absorbs exudate with simultaneous stabilization of the chest and isolation of the wound. This therapy stimulates granulation tissue formation in combination with an increased blood flow in the adjacent tissue [31]. Furthermore, VAC therapy approximates the wound edges and provides a mass filling effect with a low degree of surgical trauma, without establishing a new wound (eg, abdominal wound in omental flaps).

In the present study, we retrospectively compared VAC therapy in poststernotomy mediastinitis with other wound-management strategies previously used at our department. We have used VAC therapy exclusively as a single-line therapy before sternal rewiring without the use of soft tissue flaps [11]. This wound-healing strategy requires an objective measure to assess the correct time at which to rewire the sternum without recurrent infections. Our group has previously demonstrated that sternal rewiring after VAC therapy can be successfully guided by C-reactive protein levels [32]. These previous findings were confirmed in the present study because we did not observe any 90-days mortality or any failure to first-line treatment in the VAC group. In the conventional treatment group the in-hospital mortality was 15%, and the failure rate to first-line treatment was 37.5%. Furthermore, we did not identify any significant difference in recurrent sternal fistulas between the VAC therapy and conventional treatment groups, 6.6% and 5.0%, respectively.

Our present study constitutes the largest series of patients used to compare single-line VAC therapy with conventional treatment. Catarino and coworkers [13] performed an early, small, retrospective study on a series of patients to compare VAC therapy with continuous irrigation. They demonstrated a significantly greater number of treatment failures with continuous irrigation compared with VAC therapy. Domkowski and colleagues [10] conducted an observational study using VAC therapy as a single-line treatment or as a bridge to tissue flap surgery with very low early mortality (3.7%). However, in this study they included both superficial and deep sternal wound infections. In a recent study, Fleck and coworkers [33] presented lower rates of recurrent mediastinitis

using VAC followed by delayed primary closure or pectoralis muscle flaps compared with primary closure. Doss and colleagues [14] reported results with VAC and conventional wound management, but they used VAC as a bridge to tissue flap treatment in 20% of their patients. Doss and coworkers [14] also reported a shorter length of stay and treatment duration after VAC therapy. In our study, we did not observe any significant difference in length of stay or treatment duration between VAC therapy and conventional treatment. One explanation may be that differences in the health-care systems affect the routines regarding discharge to the patient's home or transfer of patients to the referring hospital. Furthermore, treatment duration varies considerably among different surgical techniques, and therefore, results in different studies should be interpreted with caution.

Another important finding in the present study was the significantly better long-term survival in the VAC group (Fig 1). A possible explanation of this observation may be that an effective wound treatment counteracts the negative long-term effects of a severe infection, such as poststernotomy mediastinitis. Previous studies have reported that mediastinitis is an independent factor with negative influence on long-term survival after coronary artery bypass graft surgery [1, 2, 34]. The reason for this negative prognostic effect is not fully understood, but a severe systemic infection with septic episodes might cause irreversible effects on vulnerable organs such as the heart, kidneys, and bypass grafts.

There are obvious limitations on the results of this study because of its retrospective and nonrandomized design. A randomized study might add further information, but the ideal design is not always feasible in a surgical setting because of practical or ethical reasons. Although partially biased by the fact that the two groups compared date from different periods, this study indicated a significant improvement in overall survival after VAC therapy. However, the number of women was significantly higher in the VAC group, which may disturb this observation. Furthermore, the conventional group included several techniques for poststernotomy mediastinitis management. In our opinion, this heterogeneity reflects surgical reality as there is no consensus regarding the optimal management of poststernotomy mediastinitis.

In conclusion, the present study demonstrates that properly applied VAC therapy is a safe and reliable option in poststernotomy mediastinitis, with excellent survival and very low failure rate compared with conventional treatments.

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Interim Analysis of a Prospective, Randomized Trial of Vacuum-Assisted Closure Versus the Healthpoint System in the Management of Pressure Ulcers

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Twenty-eight patients with 41 full-thickness decubitus ulcers were randomized to compare the Vacuum-Assisted Closure device (VAC) with the Healthpoint System (HP) of wound gel products in promoting ulcer healing. A total of 22 patients with 35 full-thickness ulcers completed the 6-week trial of treatment, during which time 2 patients (10%) in the VAC group (N = 20) and 2 patients (13%) in the HP group (N = 15) healed completely. The mean percent reduction in ulcer volume was 42.1% with HP and 51.8% with VAC ($p = 0.46$). The mean number of PMNs and lymphocytes per high-power field *decreased* in the VAC group and *increased* in the HP group ($p = 0.13$, $p = 0.41$ respectively). The mean number of capillaries per high-power field was greater in the VAC group ($p = 0.75$). There were 15 cases of biopsy-proven osteomyelitis underlying the ulcers; three (37.5%) improved with VAC and none improved with HP ($p = 0.25$). VAC promotes an increased rate of wound healing and favorable histological changes in soft tissue and bone compared with HP.

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Pressure ulcers are responsible for substantial patient morbidity and mortality. Currently, approximately 500,000 patients have pressure ulcers.[1] The relative risk of dying is significantly higher for nursing home patients with pressure ulcers when compared with those residents without ulcers.[2] In the United States alone, approximately $1.3 billion per year is spent on the management of these difficult ulcers.[3] Spinal cord injury, advanced age, malnutrition, excessive moisture, and friction are notable risk factors for ulcer formation.

The first line of attack is prevention. Superficial or early-stage ulcers are treated with topical barriers, which keep exposed dermal surfaces moist, thus promoting reepithelialization. Full-thickness ulcers (stage III and IV) frequently require chemical or surgical debridement and may be complicated by osteomyelitis. In appropriate cases, local flaps may be used to expedite wound closure. Yet, there has been no proof to date of any benefit in ulcer recurrence with the performance of flap procedures. The incidence of ulcer recurrence may be as high as 90% in some cases.[4] The successful management of partial and full-thickness ulcers is hindered by the lack of a consistent and cost-effective wound treatment modality.

The Vacuum-Assisted Closure device (VAC), pioneered by Argenta and Morykwas,[5] offers an innovative approach to the management of pressure ulcers that potentially reduces the morbidity and mortality of chronic "unsalvageable" wounds. A Food and Drug Administration (FDA)-approved treatment, VAC is thought to promote wound healing in four ways: the removal of third-space edema, thus enhancing oxygen and nutrient delivery to

Table 1. Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
Presence of stage III or IV ulcer for 4 or more weeks	Fistulas to organs or body cavities
Albumin ≥ 2.0	Malignancy in the wound
Age 21–80	Pregnant or lactating female
Ulcer volume after debridement = 10–150 ml	Hashimoto thyroiditis
	Graves disease
	Iodine allergy
	Systemic sepsis
	Electrical burn
	Radiation exposure
	Chemical exposure
	Cancer
	Connective tissue disease
	Chronic renal or pulmonary disease
	Uncontrolled diabetes
	Corticosteroids or immunosuppressive agents
	Cardiac pacemaker
	Ferromagnetic clamps
	Recent placement of orthopedic hardware

cells; the continuous application of negative pressure, thus removing debris, decreasing bacterial colonization, and promoting the formation of granulation tissue; the promotion of angiogenesis; and the evacuation of wound inhibitory factors.[5] Joseph and coworkers[6] found that VAC is superior to normal saline dressings in the management of chronic wounds.

The Healthpoint System (HP) offers a second innovative approach to the management of pressure ulcers. It consists of three FDA-approved gel products—Accuzyme, Iodosorb, and Panafil—each targeted to optimize a particular macroscopic phase of wound healing.[7] Accuzyme, a papain–urea debridement ointment, is best suited for necrotic wounds. Iodosorb gel and Iodoflex pads consist of 0.1 to 0.3 mm hydrophilic beads containing 0.9% cadexomer iodine. Iodosorb is identical structurally to Iodoflex, the latter being indicated for larger, deeper ulcers. When applied to an infected wound bed with liquefaction necrosis, the beads soak up bacteria and cellular debris by capillary action, thus reducing inflammation, odor, and edema, while concomitantly releasing iodine, which imparts antimicrobial properties to the dressing. Moberg[8] found that Iodosorb is more effective than normal saline dressings as treatment for decubitus ulcers. Panafil—a papain–urea–chlorophyllin–copper ointment—is ideal for clean, granulating wounds.

A formal randomized study comparing VAC and HP as treatments for pressure ulcers has yet to be conducted to date. The objectives of this study were to determine whether VAC is superior to HP in promoting the healing of full-thickness ulcers and to evaluate the effects of each treatment regimen on ulcers with underlying osteomyelitis.

Patients and Methods

The study was approved by the institutional review board at Boston University School of Medicine. Twenty-eight patients with 41 wounds were recruited from the plastic surgery clinic and inpatient physician referral at Boston Medical Center. Patients were between the ages of 18 and 80 years with one to three full-thickness ulcers present for a minimum of 4 weeks. Enrolled patients had an albumin level more than or equal to 2.0 g per deciliter. Ulcer volume after debridement was between 10 and 150 ml. The Table provides a complete list of inclusion and exclusion criteria.

After giving informed consent, each patient underwent a series of pretreatment tests, which included a complete blood cell count, erythrocyte sedimentation rate, albumin level, photograph of the wound site, soft-tissue biopsy, plaster wound impression, and measurement of wound dimensions. Patients also underwent bone biopsy, bone culture, and magnetic reso-

nance imaging (MRI) if osteomyelitis was suspected based on wound and bone characteristics, a white blood cell count of more than 15,000, and an erythrocyte sedimentation rate of more than 120 mm per hour.[9,10] Bone biopsies were performed with either a Jamshidi needle (Pharmaseal; Allegiance Health Care) or a rongeur, depending on the depth of the ulcer. Patients with osteomyelitis proven by bone biopsy or by MRI received a 6-week course of systemic antibiotics appropriate to bone culture findings. Patients underwent ulcer debridement as necessary, followed by random assignment to 6 weeks of treatment with either VAC or HP. Randomization was based on a table of random letters, V or H, generated before the trial began. Patients who randomized to HP and whose wounds showed substantial exudate received Iodosorb or Iodoflex; those patients whose ulcers were clean and granulating received Panafil. Because all wounds were debrided surgically as appropriate, Accuzyme was not used.

VAC dressings were changed Mondays, Wednesdays, and Fridays (manufacturer recommends dressing changes every 48 hours). HP dressings were changed once or twice daily, depending on the degree of wound drainage. Strict pressure reduction with the appropriate beds and positioning was instituted. Patients returned to the plastic surgery clinic at Boston Medical Center at 3 and 6 weeks for evaluation of wound healing. The 3-week evaluation included a photograph of the wound site, a plaster wound impression, and measurement of wound dimensions. The 6-week evaluation included a series of posttreatment tests, consisting of a photograph of the wound site, a soft-tissue biopsy, a plaster wound impression, and measurement of wound dimensions. If a bone biopsy and MRI were performed as part of pretreatment testing, then these tests were repeated at 6 weeks.

Blinded clinic staff, including nurses, medical students, and interns, measured wounds and obtained plaster impressions. Plaster impressions, soft-tissue biopsies, and bone biopsies were coded by a number. Volume displacements of plaster impressions were determined by a medical student. Soft-tissue biopsies were analyzed quantitatively for the number of PMNs, lymphocytes, and capillaries per high-power field (hpf). Bone biopsy results were analyzed for inflammation, fibrosis, and evidence of acute or chronic osteomyelitis. MR images were evaluated for signal intensity changes suggestive of osteomyelitis.

We compared patient demographics using Fisher's exact test. We used Student's *t*-test to compare mean changes in dimension, volume, and histopathological data.

Results

Of 28 enrolled patients with 41 full-thickness pressure ulcers, 22 patients with 35 wounds completed the trial (3 patients were lost to follow-up, 1 patient was deemed noncompliant with treatment and was removed from study participation, 1 patient died of coronary artery disease, and 1 patient died of respiratory arrest secondary to Guillain–Barré syndrome). The average patient age was 41.7 years in the VAC group and 54.4 years in the HP group. The ulcer distribution was as follows: 9 ischial, 17 sacral, 4 lateral malleolar, 1 trochanteric, and 4 calcaneal. Two ulcers (10%) in the VAC group (N = 20) and 2 ulcers (13%) in the HP group (N = 15) healed completely during the treatment period. Follow-up ranged from 3 to 10 months. One lateral malleolar ulcer in a patient with diabetes, hypertension, and vascular insufficiency was treated with VAC and complicated by sepsis, requiring amputation. There were no other treatment complications. Six wounds in the VAC group (30%) and 6 wounds in the HP group (40%) underwent flap surgery.

Three patients with 3 wounds completed one 6-week trial of treatment followed by a second 6-week trial of the opposing treatment. In this cohort, the mean reduction in ulcer volume was 57% with VAC and 25% with HP. Overall, the mean percent reduction in volume was 51.6% with VAC and 42.1% with HP ($p = 0.46$; Fig 1). The mean reductions in length, width, and depth respectively were 36.9 cm, 40.0 cm, and 33.6 cm in the VAC group compared with 18.7 cm, 19.0 cm, and 31.0 cm in the HP group ($p = 0.10$, $p = 0.11$, $p = 0.90$ respectively; Fig 2). The mean changes in PMNs, lymphocytes, and capillaries respectively were −37.0/hpf, −6.2/hpf, and −5.1/hpf in the VAC group compared with 22.7/hpf, 45.0/hpf, and

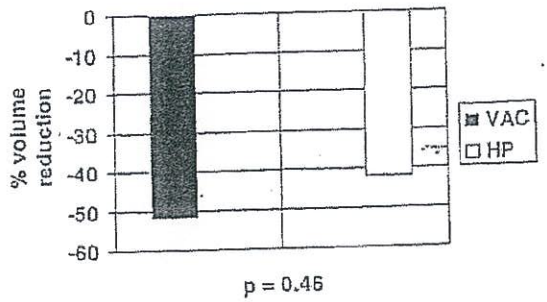

Fig 1. Mean percent change in wound volume over the course of 6 weeks. p = 0.46. VAC = Vacuum-Assisted Closure; HP = Healthpoint.

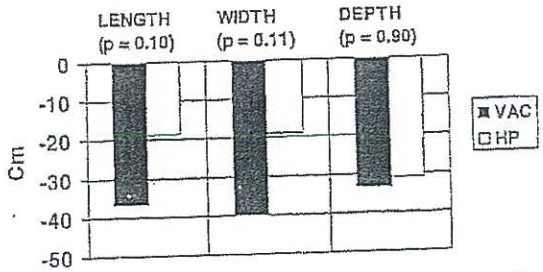

Fig 2. Mean change in wound dimensions over 6 weeks. VAC = Vacuum-Assisted Closure; HP = Healthpoint.

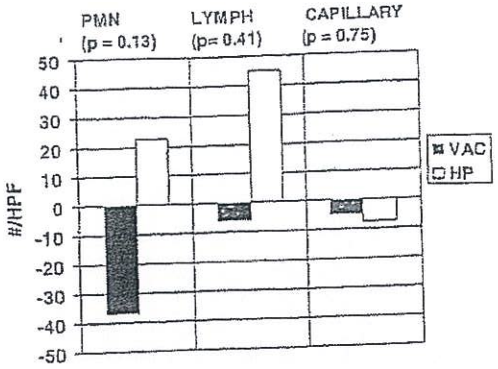

Fig 3. Mean change in PMNs, lymphocytes (LYMPH), and capillaries per high-power field (HPF) over the course of 6 weeks. VAC = Vacuum-Assisted Closure; HP = Healthpoint.

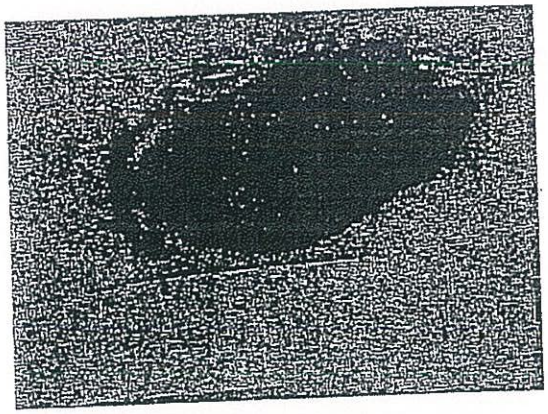

Fig 4. Stage IV ischial ulcer at 0 weeks.

−7.6/hpf in the HP group ($p = 0.13$, $p = 0.41$, $p = 0.75$, respectively; Fig 3).

Fifteen of 35 wounds were suspicious for osteomyelitis and underwent bone biopsy and MRI. There were 3 positive bone biopsy specimens and 10 positive MR images. Three wounds in the VAC group showed improved osteomyelitis, two by bone biopsy and one by MRI ($p = 0.25$). In the HP group, there was no improvement in osteomyelitis by bone biopsy or by MRI.

Patient Reports

Patient 1

J.G. is a 41-year-old man who has incomplete C4/C5 quadriplegia resulting from a motor vehicle accident in 1974. He resides in a private apartment, spends most of his time on a waterbed, and is visited by his nurse every day. He presented to the plastic surgery clinic with a stage IV left ischial ulcer of 4-month duration, measuring 4 × 3 × 6 cm, and with an initial wound volume of 42.6 ml (Figs 4 and 7). The wound was malodorous, with purulent exudate and necrotic debris. His serum albumin level was 3.7 g per deciliter. Ischial bone biopsy was negative for osteomyelitis. Soft-tissue biopsy showed fibroconnective tissue with mild acute and chronic inflammation. The wound was debrided to viable tissue. J.G. was randomized to receive VAC treatment.

At the 3-week follow-up visit, his wound measured 3 × 2 × 4 cm, with a volume of 10 ml (Figs 5 and 7). Bone was no longer exposed. The wound had no odor, showed beefy granulation tissue, and had minimal exudate.

At the end of the 6-week trial, his wound measured 2 × 1.5 × 2 cm, with a volume of 6 ml (Figs 6 and 7). The wound continued to show beefy granulation tissue with minimal serosanguinous drainage. Soft-tissue biopsy showed granulation tissue with no inflammation. VAC was continued after the study. The total time to complete wound healing was 8 weeks.

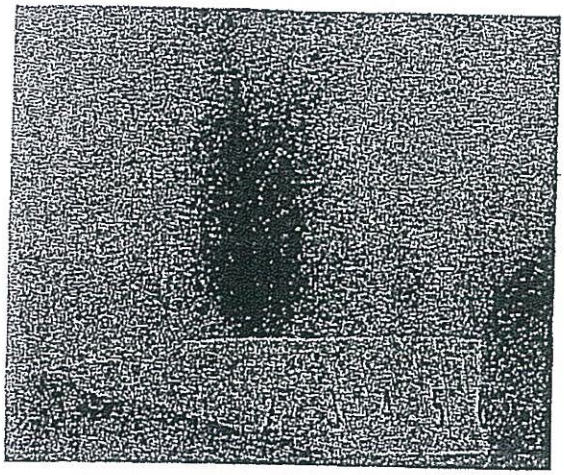

Fig 5. After 3 weeks of VAC treatment.

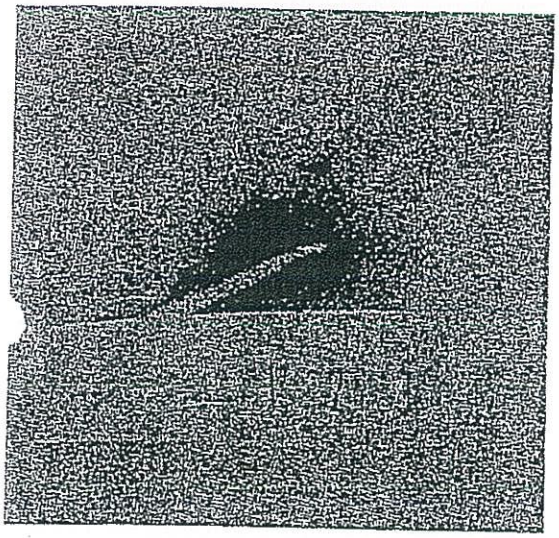

Fig 6. After 6 weeks of VAC treatment.

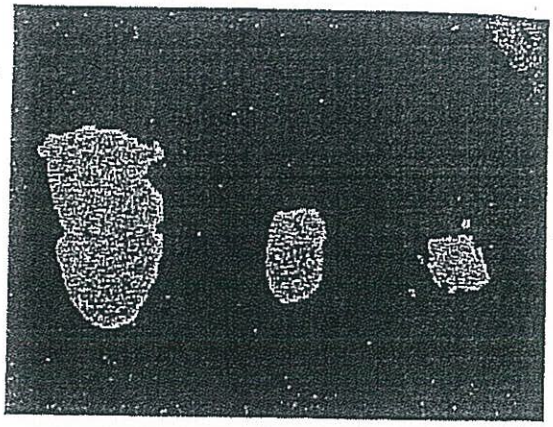

Fig 7. Plaster casts at 0, 3, and 6 weeks.

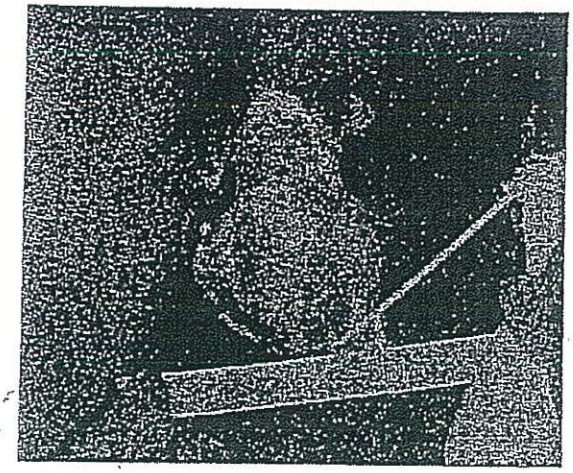

Fig 8. Stage IV sacral ulcer at 0 weeks.

Patient 2

B.T. is a 50-year-old woman who has T12 paraplegia resulting from an aneurysm repair in September 2000. She resides in a private apartment and is visited by her nurse every day. She presented to the plastic surgery clinic with a stage IV sacral ulcer of 1-month duration, measuring 9 × 11 × 2 cm, with an initial volume of 90 ml (Figs 8 and 11). The wound had patchy areas of granulation tissue, very little fibrinous exudate, and mild serosanguinous drainage. Her serum albumin was 2.8 g per deciliter. Soft-tissue biopsy ·wed chronic inflammation. Bone biopsy ·wed no evidence of osteomyelitis. B.T. was randomized to receive HP treatment.

At the 3-week follow-up visit, her wound measured 6 × 8 × 1.5 cm, with a volume of 30 ml (Figs 9 and 11). Physical examination revealed beefy granulation tissue.

At the end of the 6-week trial, her wound measured 4 × 4 × 1.5 cm, with a volume of 14 ml (Figs 10 and 11). The wound continued to show beefy granulation tissue. Soft-tissue biopsy showed increased inflammation compared with the previous biopsy. HP was continued after the study. The total time to complete healing was 10 weeks.

Discussion

For as long as the field of medicine has existed, doctors have grappled with the management and treatment of chronic wounds.[11] Despite advances in conservative and surgical wound

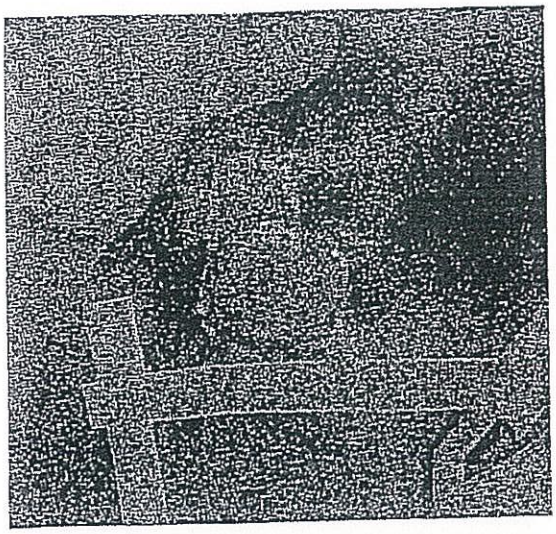

Fig 9. After 3 weeks of treatment with the Healthpoint System.

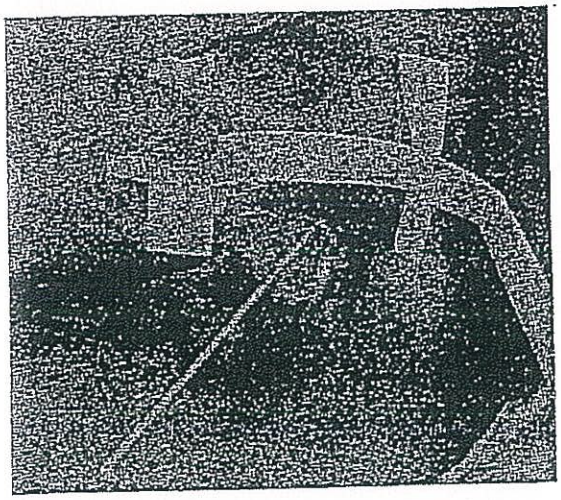

Fig 10. After 6 weeks of treatment with the Healthpoint System.

care management, such as flap surgery, split-thickness skin grafts, hydrocolloid dressings, iodine-based gels, and recombinant human platelet-derived growth factor, chronic wounds continue to plague more than 2.8 million people in the United States with an estimated annual cost of $3 billion.[5,12,13]

In this ongoing study, we evaluated the management of chronic full-thickness ulcers by comparing two unique treatment modalities. We observed increased rates of wound healing with VAC compared with HP. VAC appears to be superior in reducing inflammation at the wound

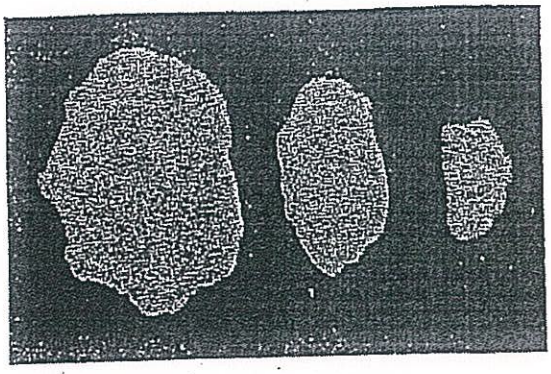

Fig 11. Plaster casts at 0, 3, and 6 weeks.

site: The mean number of PMNs and lymphocytes *decreased* in the VAC group and *increased* in the HP group. An additional soft-tissue finding was the presence of increased numbers of capillaries in the VAC group, suggesting that VAC promotes the formation of granulation tissue to a greater extent than HP. Our finding of three cases of improved osteomyelitis with VAC opens the possibility that VAC may be an effective adjunct to systemic antibiotic treatment for osteomyelitis. We hypothesize that the negative pressure of the vacuum device facilitates antibiotic absorption from surrounding capillaries into bone, thus reducing infection.

Conclusions

VAC promotes an increased rate of wound healing, probably secondary to favorable inflammatory soft-tissue changes and enhanced granulation tissue formation, compared with HP. In addition, VAC may prove useful in the management of osteomyelitis underlying complicated pressure ulcers. An ongoing trial of VAC versus HP directed by Dr. Dennis Orgill is currently underway at Brigham and Women's Hospital in Boston, MA.

Presented at the annual meeting of the Northeastern Society of Plastic Surgeons; Ritz–Carlton Hotel, Philadelphia, PA; October 4–6, 2001.

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Open Discussion

Christian N. Ford, BA

Maurice Nahabedian, MD (Baltimore, MD): How many of these wounds actually healed?

Mr Ford: There were a total of four wounds that healed completely—two in the VAC group and two in the Healthpoint group. That was within 8 to 10 weeks.

Dr Nahabedian: Why do you think the others didn't heal?

Mr Ford: I'm not precisely sure what the reason was. We did institute appropriate beds and positioning for all patients on the study. It is difficult to say because ulcer recurrence is so high—on the order of 90%.

Dr Breitbart: I think VAC is a promising technology, and I think it is important to do these prospective studies because your results may have approached statistical significance and it may be worth doing a study with a larger patient volume.

Pressure Ulcer Prevalence and the Role of Negative Pressure Wound Therapy in Home Health Quality Outcomes

Tina Schwien, MN, MPH; Jeff Gilbert, MS, CPHIMS; and Christine Lang

Home health agencies, challenged to demonstrate quality while containing costs, are motivated to find best practices for managing patient and wound care. The effects of different wound therapies on frequency of hospitalization and emergent care, two prominent quality measures, have not been studied. A retrospective study was conducted to determine the prevalence of Stage III and Stage IV pressure ulcers in the home health population and to quantify the impact of negative pressure wound therapy in reducing acute care hospitalizations and emergent care in general, and wound infection or deteriorating wound status in particular. Data from 1.94 million OASIS start-of-care assessments in 2003 and 2004 were evaluated to estimate pressure ulcer prevalence and a retrospective matched group analysis compared patients using (n = 60) and not using (n = 2,288) negative pressure wound therapy. In 2003, 6.9% and in 2004, 7% of patients had pressure ulcers at start of care. Of these, 23% were Stage III or Stage IV and 31% were "not healing." In the matched analysis group, it was found that compared to comparison group patients, those receiving negative pressure wound therapy experienced lower rates of hospitalization (35% versus 48%, P <.05), hospitalization due to wound problems (5% versus 14%, P < .01), and emergent care for wound problems (0% versus 8%, P = .01). To offset potential limitations in generalizability and increase practical application of these results, further research is needed with a larger, nationally representative sample to compare other quality outcomes as well as the cost of providing negative pressure wound therapy to other specific wound care modalities.

KEYWORDS: home health, pressure ulcer prevalence, outcomes, negative pressure wound therapy

Ostomy/Wound Management 2005;51(9):47-60

Healthcare policy makers, providers, and payors must find the optimal balance between providing high quality care and managing expenses. The estimated federal spending for Medicare and Medicaid beneficiaries in 2005 is $648 billion; for 2011, projected costs are more than $1 trillion.[1] On-going discussions about methods to reduce the growth of healthcare expenditures are tempered by considerable concern about the negative impact of any cost-cutting initiatives on the quality of care provided.

In response to the projected growth in healthcare expenditures, the federal government introduced initiatives through the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)[2] to manage costs and promote quality. These initiatives include programs that promote innovative use of technology, pay-for-performance (P4P) models, disease and chronic care management, and enrollment in Medicare Advantage (Medicare's managed care option). Simultaneously, quality improvement strategies and initiatives have been set forth by federal agencies as well as independent organizations, including the Agency for Health Research Quality (AHRQ),[3] the National Quality Forum (NQF),[4] the Joint Commission on Accreditation

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for Healthcare Organizations (JCAHO),[3] the Institute of Medicine (IOM),[4] and the American Health Quality Association (AHQA).[5]

The Cost/Quality Focus in the Home Health Industry

Before MMA initiatives that specifically impact the cost/quality equation in the home health industry were introduced, the Centers for Medicare and Medicaid Services (CMS) presented home health providers with regulatory changes directed at managing cost and quality. In response to concerns about skyrocketing Medicare costs associated with rapid growth in the use of home health services by Medicare beneficiaries,[6] the CMS implemented the Home Health Prospective Payment System (PPS) in October 2000.[7] Under PPS, home health agencies receive a single payment for all care associated with an episode of care (up to 60 days) rather than receiving per-visit reimbursement as had been the case in the fee-for-service system. The amount of the PPS payment is determined at the start of a patient's episode based on the patient's clinical severity, functional dependence, and need for services. This bundled payment is designed to cover the costs of managing all aspects of patient care, including skilled care visits, support services, and supplies.

Shortly after implementing PPS, the CMS also embarked on a Quality Initiative directed at home health agencies that emphasized the need for ongoing quality improvement activities at the provider level.[8] The Quality Initiative has two primary components — Outcomes Based Quality Monitoring (OBQM)[9,12] and Outcomes Based Quality Improvement (OBQI).[13] The former initiative requires agencies to monitor 13 adverse events determined by the CMS and investigate the care of patients who experience adverse events in order to identify potentially problematic or inadequate care or care practices. The latter initiative requires providers to focus performance improvement activities according to results obtained in 41 clinical and utilization outcomes areas determined by the CMS. Outcomes Based Quality Improvement further dictates a systematic approach to care investigation, implementation of best practices, and continual tracking or monitoring of progress. In addition to the OBQM and OBQI reports provided to agencies, the CMS makes a subset of the measures available to the public[14]; all data are available to state surveyors. State survey agencies use the reports as ammunition to target home health agency evaluations and sometimes hand select agencies for more frequent review. If a home health agency does not perform well on OBQM measures in comparison to the national norm, it is at risk for increased scrutiny by the state, which could result in condition-level deficiencies that may lead to Medicare decertification.

The CMS uses data collected in the Outcome and Assessment Information Set (OASIS) to determine PPS episodic payments and calculate the OBQM and OBQI quality indicators.[9,10] The OASIS is a set of standardized assessments that agencies must complete periodically throughout each patient's length of treatment as part of the Medicare Conditions of Participation (CoP). Agencies transmit the data to the state survey agency for reconciliation with the fiscal intermediary and analysis of quality and utilization outcome measures.

To aid home health agencies in their quality improvement efforts, the CMS contracts with quality improvement organizations (QIOs) in each state to help agencies refine OBQI activities and care delivery systems.[15] Based on Title XI of the Social Security Act, Part B, QIOs are given a Statement of Work (SOW) to guide their work with home health agencies.[16] Changes in the SOW occur periodically and are referred to as "Rounds." In the current 7th Round, QIOs are charged with helping agencies implement and use the OBQI process.[17] In the 8th Round, scheduled to take effect August 2005, in addition to other subtasks

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KEY POINTS

- The prevalence of pressure ulcers in home health care, as determined by a retrospective evaluation of 1.94 million start-of-care OASIS assessments, was found to be similar to previously published data and remains around 7%.
- However, the authors of this study also found that many of these ulcers are Stage III and Stage IV and categorized as "not healing."
- Significant differences were found when comparing select quality outcomes between a small subset of patients who received negative pressure wound therapy (NPWT) and those who did not receive this therapy.

aimed at assisting providers, the CMS will require QIOs to shift their activities away from a broad OBQI process focus to improving a specific OBQI measure — acute care hospitalization.[20]

While quality is most commonly assessed independently from cost, as with OBQI and OBQM, cost and quality measurement can sometimes overlap. The Agency for Healthcare Research and Quality (AHRQ), a federal entity that provides Fact Books to establish national benchmarks and identify target areas for quality improvement, has suggested that higher rates of preventable hospitalizations can help identify areas for potential cost containment and quality improvement in various segments of the US healthcare system.[21] Based on analysis of data from the Healthcare Cost and Utilization Project (HCUP), National Inpatient Survey (NIS), and Prevention Quality Indicators (PQI), the AHRQ reports that for the year 2000 nearly 5 million admissions to US hospitals involved the treatment of a preventable condition, costing more than $26.5 billion. The AHRQ suggests that even a 5% reduction in preventable hospitalizations could result in cost-savings of more than $1.3 billion.

The Challenge of Wound Care

Owing to the financial pressure of PPS and increased scrutiny under the Quality Initiative, agencies are increasingly motivated to determine best practices for managing chronic wounds that minimize expenses related to visits and supplies while achieving/maintaining a high level of quality care.[22-24] Patients with wounds present a more acute challenge to the cost/quality balance because wound care supplies can be expensive and wound management in home care often involves chronic, slow-healing wounds.[25] Inconsistent wound assessment, documentation, and minimal use of adjunctive wound therapies for chronic wounds may contribute to increased costs because they can increase healing times and care visit frequency.[26] Improved outcomes for wound care patients, especially for those with complex wounds, sometimes depend on advanced clinical skills in wound care management which also can add to the financial challenge faced by home health agencies.[24] Providing advanced training to clinical staff or seeking out clinicians specializing in wound care can require an expensive investment in human resources. Given the current nursing shortage, recruiting and retaining nursing staff to manage these labor-intensive patients also can increase cost.

The inability to demonstrate quality outcomes for wound patients also can lead to increased scrutiny and discipline by state surveyors. Notably, emergent care for wound infection and deteriorating wound status are among the OBQM adverse events tracked by State surveyors.[11] A CMS-sponsored "State of Science in Wound Care Management" multimedia broadcast[27] emphasized that in order to reduce costs while striving for high quality outcomes, agencies need to adopt a wound management approach that is driven by outcomes rather than by nursing visits. In an outcomes-driven model, agencies focus on accurately assessing wound status, utilizing cost-effective wound care formularies and basic algorithms to determine appropriate therapy and to quickly identify wounds that are not responding to care and subsequently make appropriate changes. Cost-effective therapy was described as products or systems that promote optimal wound healing environments, control exudate, and provide a bacterial barrier for 2 to 3 days, thus reducing visit frequency.

Wound Care Technologies — Negative Pressure Wound Therapy

Various wound care technologies are available for treating complex chronic wounds. Ovington[25] reports that more than 50 manufacturers produce more than 350 different types of wound care therapies. Many of these modalities are grouped under one of the following categories: transparent film, hydrocolloid, foam, calcium alginate dressings, or negative pressure wound therapy (NPWT). Of these technologies, NPWT in particular may present an attractive wound management system for the home health industry to investigate for its potential impact on the cost/quality balance. Some positive clinical outcomes using NPWT have been reported[28-30] and in one study a reduction in hospitalization of surgical patients was observed.[31] Furthermore, NPWT is reimbursable under the Medicare Part B Durable Medical Equipment (DME) benefit[32]; therefore, it may be more cost effective than some other wound technologies to home health providers. The only NPWT verified by the CMS is Vacuum Assisted Closure® (V.A.C.® Therapy, Kinetic Concepts, Inc. [KCI], San Antonio, Tex.).

Negative pressure wound therapy is the application of subatmospheric pressure to promote wound healing. According to a recent NPWT review article,[1] NPWT is ideally suited for the management of large, Stage III and Stage IV ulcers with inadequate or poor granulation tissue and heavy exudate. Negative pressure wound therapy consists of a sterile, open-cell foam dressing placed in the wound and covered with an occlusive dressing. A computerized therapy unit connected to the foam via tubing applies intermittent or continuous subatmospheric pressure to the wound while drawing exudate away from the wound into a sealed canister. The main reported mechanisms of action are the provision of a moist wound healing environment, removal of fluids and infectious materials, assisted perfusion, decreased bacterial colonization, and enhanced formation of granulation tissue.[1] Negative pressure wound therapy requires infrequent dressing changes — for instance, once applied, per manufacturer recommendations, the system needs only be changed once every 48 hours unless the wound is infected. The therapy system is safe and easy to manage in the home care setting.

Purpose

The effect of available technologies on wound healing and other clinical measures is frequently discussed, but limited data exist on whether any of these wound care technologies are associated with OBQI or OBQM quality indicators such as acute care hospitalizations, emergent care for wound infection, or deteriorating wound status.

Given the financial challenges presented by PPS and the increased focus on demonstrating quality outcomes, more research is needed to determine whether wound care technologies, such as NPWT, are associated with positive quality outcomes. Furthermore, the number of controlled clinical studies regarding NPWT and pressure ulcers is limited. Although promising results have been observed, few statistically significant differences have been reported.[29-31] This suggests more research is needed to better understand the role of NPWT in the care of pressure ulcers. Information about the prevalence of advanced stage pressure ulcers managed in the home health care setting that may be appropriate for many wound care technologies is small and fragmented, thwarting potential knowledge and impact of effective therapies.

This retrospective study was conducted to: 1) determine the prevalence of Stage III and Stage IV pressure ulcers in the home health care population and 2) quantify the impact of NPWT in reducing acute care hospitalizations and emergent care in general, and wound infection or deteriorating wound status specifically.

Literature Review

Prevalence of pressure ulcers in home health. Although the prevalence of pressure ulcers across many healthcare settings warrants concern, drawing definitive conclusions from previous prevalence estimates is difficult. According to an Agency for Healthcare Policy Research (AHCPR, now AHRQ) panel of experts,[34] in addition to studies that focus specifically on the home health setting, previous estimates of data acquisition methods and pressure ulcer classification systems suffer from insufficient control and few estimates are based on databases that contain a large number of patients from multiple sites. Additionally, many of the previous estimates are based on nearly 10-year-old data and data not representative of a full year.

Among studies estimating the prevalence of pressure ulcers in the home health care setting, a variation exists between mean and between-agency estimates. For example, in a survey of 177 home health agencies involving 21,529 patients, Meehan, O'Hara, and Morrison[35] found a pressure ulcer prevalence of 6.8%, with between-agency estimates ranging from 0.5% to 35.7%. In a study of patients admitted to home care, Ferrell et al[36] found a pressure ulcer prevalence of 9.12%. When the worst ulcer for each subject was considered, the prevalence of Stage III and Stage IV pressure ulcers was 27%. In addition, more than one third of patients admitted with a pressure ulcer had two or more ulcers and 30% of patients admitted to home care without a pressure ulcer were at risk for developing one while on the service.

Quality outcomes associated with NPWT and pressure ulcers. Few studies have investigated whether NPWT is associated with quality outcomes — specifically, reduction in hospitalization or emergent care. In a retrospective analysis of 47 surgical patients with open foot wounds with significant soft tissue loss, Page et al[31] found that patients treated with NPWT had an 80% reduction in risk for one or more hospital admissions compared to patients treated with wet-to-moist dressings

after controlling for age, serum albumin, and wound size ($P = .02$). However, no statistically significant difference was noted for cumulative wound cavity filling or wound closure. All patients had surgically debrided, non-infected wounds when therapy was initiated. Patients were excluded if they had persistent wound infection, necrotic tissue in the wound bed, or an interruption in treatment or alternative therapies during the wound cavity filling time. No studies were identified that investigated whether NPWT was associated with reduced hospitalization for home health patients with pressure ulcers. Similarly, no studies were identified that investigated whether NPWT was associated with reductions in emergent care or infections or home health patients with pressure ulcers.

Page et al's[31] inclusion of hospital readmission as an outcome measure is unusual. Most studies examining the effect of NPWT have focused on wound reduction or other clinical measures of healing, such as wound cavity filling and wound closure. Although many NPWT pressure ulcer studies report promising results, statistically significant differences are not observed, suggesting more research is needed to better understand the effects of NPWT on pressure ulcers. For example, in a randomized control trial of 28 patients with full-thickness pressure ulcers, Ford et al[28] observed that patients treated with NPWT had an overall pressure ulcer volume reduction of 51.8% compared to 42.1% for patients treated with other wound care products, but the difference was not statistically significant ($P < 0.1$). Decreased inflammation and an increase in capillaries also was observed but these differences also were not significant ($P < 0.1$). In another randomized trial of 22 patients with pelvic pressure ulcers, Wanner et al[25] found no difference in time needed to decrease wound volume by 50% between patients treated with NPWT and patients treated with wet-to-dry or wet-to-wet dressings soaked with Ringer's solution. Although these results did not support their hypothesis that NPWT would improve wound healing, they concluded that NPWT was advantageous because its effectiveness was similar to traditional dressings but less expensive because the reduced frequency of dressing changes saved nursing staff time. In a case series of 10 patients with Stage IV pressure ulcers treated with NPWT, Isago et al[29] reported that after 4 to 7 weeks of therapy, wound areas had reduced an average 55% and depth reduced by an average of 61%. Because this study did not include a control group, ascertaining whether these results are significantly different from another type of wound care technology is not possible.

Methods

To calculate prevalence of pressure ulcers in the home health care setting, data from the Outcome Concept Systems (OCS) OASIS data warehouse were analyzed. Outcome Concept Systems is a Seattle-based data company that maintains the largest OASIS database outside of the CMS. As of May 2005, the OCS OASIS database contained approximately 13 million individual OASIS records, representing 5 million complete cases of home care. Although this is a proprietary database comprised of patient records that represent the population served by OCS home health agency clients, these clients are diverse in terms of their geographic, urban/rural, agency affiliation, size, and profit-status representation (see Table 1). The OASIS data set is administered consistently across all agencies in accordance with the Medicare Conditions of Participation (CoPs).

Data from 1.94 million start-of-care OASIS assessments completed between January 1, 2003 and December 31, 2004 were used to calculate pressure ulcer prevalence. Prevalence was calculated by stage and status of the most problematic pressure ulcer and further categorized four ways: 1) the pressure ulcer was the only wound reported, 2) a stasis ulcer also was present, 3) a surgical wound was also present, and 4) for all instances of pressure ulcer. The average number of visible pressure ulcers also was calculated by stage. The prevalence denominator was the number of start-of-care assessments completed during each timeframe for all patients, and for the more detailed analysis, for all pressure ulcer patients. Numerators were defined as a subset of the start-of-care assessments using the OASIS M0-items (see Table 2).

Acute care hospitalization and emergent care rates of home health patients with Stage III and Stage IV pressure ulcers using NPWT were compared to those using any other wound care therapy (comparison group) using the following methodology: NPWT was defined as the use of the only NPWT verified by the CMS. Outcome Concept Systems identified 390 home health agencies utilizing both NPWT and OCS data analysis services. These agencies were asked to submit data that could be used to link patient OASIS records to NPWT

TABLE 1
CHARACTERISTICS OF AGENCIES INCLUDED IN THE OCS OASIS DATABASE

Agency Characteristic	n (%)
Setting*	
Rural	129 (26.8%)
Urban	158 (32.8%)
Both	194 (40.3%)
Visits per year*	
Less than 20,000	215 (44.7%)
20,000 - 49,999	143 (29.8%)
50,000 - 99,999	68 (14.1%)
100,000 or more	55 (11.4%)
Affiliation*	
Hospital-based	204 (42.4%)
Not hospital-based	277 (57.6%)
Part of a chain or system	229 (47.6%)
Not part of a chain or system	252 (52.4%)
Not-for-profit	323 (67.2%)
Proprietary (for profit)	158 (32.8%)
Medicare Region†	
Region 1 - New England	36 (4.7%)
Region 2 - Northeast	52 (6.8%)
Region 3 - East	80 (10.5%)
Region 4 - South	199 (26.0%)
Region 5 - Central	115 (15.1%)
Region 6 - Southwest	97 (12.7%)
Region 7 - Midwest	20 (2.6%)
Region 8 - Mountain	21 (2.7%)
Region 9 - West	111 (14.5%)
Region 10 - Northwest	33 (4.3%)

* *N = 481*
† *N = 764*

TABLE 2
OASIS M0 ITEMS USED TO CALCULATE PREVALENCE NUMERATOR

OASIS Item	Description
M0440	Does this patient have a skin lesion or an open wound? This excludes "ostomies."
M0445	Does this patient have a pressure ulcer?
M0450	Current number of pressure ulcers at each stage
M0460	Stage of most problematic (observable) pressure ulcer
M0464	Status of most problematic (observable) pressure ulcer
M0468	Does this patient have a venous ulcer?
M0482	Does this patient have a surgical wound?

usage records. Of the 367 agencies contacted, 320 submitted data (some had gone out of business, were no longer OCS clients, or did not return calls). Patient matches were identified in 292 agency databases.

Patients were identified in the OCS database as NPWT patients when NPWT records could be linked to OASIS data through a set of unique patient identifiers. To enhance homogeneity of the study population and reduce the confounding effects of concomitant conditions, only patients that met the inclusion and exclusion criteria were selected (see Table 3). Comparison groups were created by dividing eligible patients into those receiving NPWT and those receiving any other wound care modality. The comparison group was tracked from start of care through end of care. The latter group was obtained only from agencies not utilizing NPWT. All other modalities were grouped because discerning with certainty the exact type of technologies used was not possible. Case matching resulted in 60 patients in the NPWT and 2,288 in the comparison group.

In all instances, care utilization rates were calculated for the following categories:

- acute care hospitalization (for more than 24 hours) for any reason
- emergent care (ER visit, emergency house call, or emergency visit to a clinic, doctor's office or outpatient clinic)
- acute care hospitalization for wound infection, deteriorating wound status, or new lesion/ulcer
- emergent care for wound infection, deteriorating wound status, or new lesion/ulcer.

Patients receiving NPWT were tracked during the time NPWT was applied plus 7 days following removal to take into account any wound infection or deterioration that may have related to NPWT.

Outcome Concept Systems staff, independent of KCI, conducted all analyses and data management. Microsoft Excel, SQL, and Access (Redmond, Wash.), and SPSS (Chicago, Ill.) software packages were utilized throughout the study to facilitate data imports, merges, and calculations. *T*-tests were used to determine statistical significance of between-group differences.

Results

Pressure ulcers. Pressure ulcers were relatively common among home health patients. In 2003 and 2004,

TABLE 3
INCLUSION/EXCLUSION CRITERIA FOR ALL PATIENTS IN NPWT AND COMPARE GROUPS

Inclusion Criteria

- Start of care and end of care between July 1, 2002 and September 30, 2004
- One Stage III or one Stage IV pressure ulcer
- Primary diagnosis of 707.0 decubitus chronic skin ulcer

Exclusion Criteria

- Patients who died at home
- Enteral or parenteral nutrition therapy
- High risk factors of heavy smoking, alcohol dependency, or drug dependency
- Poor or unknown overall prognosis
- Secondary diagnoses of uncontrolled diabetes, cancer, systemic infections, or related to malnutrition/anemias/proteinemia

134,147 out of 1,941,039 (6.8%) of home health care patients had pressure ulcers at start of care. Table 4 outlines prevalence measures by different strata. Most patients with pressure ulcers (98,779 out of 134,147, 74%) did not have other wounds, such as venous ulcers or surgical wounds at start of care. Further, out of 134,147 problematic pressure ulcers, 31,097 (23.2%) were reported as Stage III or Stage IV at start of care and 41,305 (31%) were reported as "not healing." The average number of visible pressure ulcers by stage also was calculated for all ulcers by stage. Of patients with pressure ulcers at start of care, the average number of visible ulcers was 1.58 in 2003 and 1.56 in 2004 (see Table 4 and Table 5). Patient characteristics in the NPWT group were similar to those in the comparison group (see Table 6).

A significantly lower percentage of NPWT patients (35%) experienced hospitalization when compared to the comparison group (48%, $P < .05$) (see Table 7 and Table 8). None of the NPWT patients needed emergent care for wound-related problems, compared to 189 (8%) of the comparison group ($P < .01$) and three (5%) of the NPWT group required hospitalization for a wound-related problem compared to 310 (14%) in the comparison group, ($P < .01$).

When stratified by pressure ulcer stage, many of these associations remained statistically significant. For example, seven (24%) of the NPWT patients with Stage III pressure ulcers experienced hospitalizations and one (3%) experienced hospitalizations for wound problems, compared to 756 (44%, $P < .05$) of patients in the comparison group with Stage III pressure ulcers who required pressure ulcer-related hospitalization and 194 (11%, $P < .01$) hospitalizations for wound-related problems. Similarly, a lower percentage of patients with Stage

TABLE 4
PREVALENCE OF PRESSURE ULCERS IN HOME HEALTH 2003-2004

	2003	2004
Total start-of-care (SOC) assessments included	960,711	980,328
Pressure ulcer prevalence at SOC (n, %)		
Pressure ulcer as only wound	48,615 (5.6%)	50,164 (5.1%)
Pressure and venous ulcer	1,757 (0.2%)	1,722 (0.2%)
Pressure ulcer and surgical wound	15,879 (1.7%)	16,782 (1.7%)
All instances of pressure ulcer	65,835 (6.9%)	68,312 (7.0%)
Stage of most problematic pressure ulcer (n, % of patients with pressure ulcers)		
Stage I	11,510 (17%)	12,535 (18%)
Stage II	35,130 (53%)	36,475 (53%)
Stage III	11,341 (17%)	11,003 (16%)
Stage IV	4,296 (7%)	4,457 (7%)
Most problematic pressure ulcer cannot be observed and therefore cannot be staged due to non-removable dressing	3,548 (5%)	3,838 (6%)
Status of most problematic pressure ulcer (n, % of patients with pressure ulcers)		
Fully granulating	9,257 (14%)	9,538 (14%)
Early/partial granulation	33,838 (51%)	33,722 (49%)
Not healing	19,574 (30%)	21,731 (32%)
Most problematic pressure ulcer cannot be observed and therefore cannot be staged due to non-removable dressing	3,153 (5%)	3,332 (5%)

TABLE 5
AVERAGE NUMBER OF VISIBLE PRESSURE ULCERS AT START OF CARE 2003-2004

		2003 (n = 65,835)	2004 (n = 68,312
Stage 1	Mean (range)	0.341 (0-4)	0.349 (0-4)
	SD	0.6786	0.6795
Stage 2	Mean (range)	0.889 (0-4)	0.872 (0-4)
	SD	0.9581	0.9419
Stage 3	Mean (range)	0.261 (0-4)	0.246 (0-4)
	SD	0.6320	0.6194
Stage 4	Mean (range)	0.094 (0-4)	0.094 (0-4)
	SD	0.4144	0.4116
Total	Mean (range)	1.585 (0-16)	1.561 (0-16)
	SD	1.1403	1.1140

IV pressure ulcers receiving NPWT had hospitalizations for wound-related problems (two, 7%) compared to patients in the comparison group with Stage IV pressure ulcers (116, 20%; P <.01). In terms of emergent care, patients with neither Stage III or Stage IV pressure ulcers receiving NPWT required emergent care for wound problems, compared to 126 (7%, P <.01) of patients with Stage III and 63 (11%, P <.01) of patients with Stage IV pressure ulcers in the comparison group.

Discussion

The prevalence of Stage III and Stage IV pressure ulcers at start of care and ulcers reported as "not healing" suggests that a considerable percentage of home health pressure ulcer patients are admitted to home health care with complex wounds.

Prevalence measures for pressure ulcers reported in this study fall within range of previously reported home health care data. Overall pressure ulcer prevalence reported in this study was 6.8%, compared to 9.12% by Ferrell et al[26] and 6.8% by Meehan et al.[5] Unlike previous studies that relied on data from well under 50 agencies or from fewer than 20 states,[15-17] prevalence reported in this study is based on data from almost 800 agencies and included nearly 2,000,000 start-of-care assessment records covering a full year of OASIS start-of-care assessments. Both the study sample size and study duration, which reduces the impact of seasonal variation, enhances the generalizability of these results, although it does not guarantee they are nationally representative from a statistical point of view.

This is the first published study comparing hospital admission and emergent care utilization between patients using NPWT and patients using other wound care technologies, quality measures that are especially important to home health agencies and that are aligned with the standards detailed in the OBQI process.[18] In the OBQI process, agencies are encouraged to evaluate a problematic outcome and identify care processes linked with that outcome that include at least 30 patients. In this study, the target outcomes are acute care hospitalizations and use of emergent care and the rate of problematic events was lower in patients receiving NPWT. The next logical step in the OBQI process is to develop a plan of action to implement and monitor care processes associated with excellence.

Using inclusion and exclusion criteria allowed researchers to match NWPT cases to non-NWPT comparisons to offer some adjustment for relevant risk factors that could potentially act as confounders in this study. Although this matching reduced the sample size, the number of NPWT patients included in emergent care and hospital admission comparisons was nearly three times larger than the number of NPWT patients included in studies conducted by Ford et al[28] and Wanner et al.[29] The number of NPWT patients also exceeded the number included in the retrospective analysis by Page et al,[30] which also found an association between the use of NPWT and reduced hospital admissions. Still, the validity of these results needs to be confirmed with a larger sample size as well as prospective clinical study designs.

Limitations

Although the agency client base of the OCS data warehouse is broad in terms of volume and characteristics, it does not definitively include a nationally representative sample; thereby, overall generalizability of the study results is limited. This limitation is mitigated to some extent by the large sample size used in calculating prevalence measures but the sample size of the comparison

TABLE 6
PATIENT CHARACTERISTICS BY TREATMENT GROUP

Patient Characteristic	NPWT therapy (n=60)	Comparison group (n=2,288)
Age (years)		
Mean (range)	65 (21-90)	71.4 (18-106)
SD	18.27	18.14
Gender – female (n, %)	32 (53%)	1,327 (58%)
Primary diagnosis – 707.0 decubitus ulcer (n, %)	60 (100%)	2,288 (100%)
Overall rehab prognosis – good (n, %)	37 (62%)	1,469 (64%)
Overall rehab prognosis – unknown (n, %)	1 (2%)	42 (2%)
High risk factor – obesity (n, %)	13 (22%)	290 (13%)
No secondary diagnoses (n, %)	6 (10%)	264 (12%)
First secondary diagnoses – 250.00 diabetes mellitus (n, %)	5 (8%)	138 (6%)
At least one secondary diagnosis (n)	54	2,024
Number of secondary diagnoses		
Mean (range)	2.76 (1-5)	2.68 (1-5)
SD	1.47	1.37

group is smaller, increasing concerns about generalizability of the results. Additionally, using a comparison group composed of all other wound care modalities is limiting — ie, comparisons between distinct types of wound care technologies, such as NPWT compared to calcium alginate dressings, would have been more informative. This was not possible given the limitations of the variables contained in the database.

The potential for information bias is also present as is the case in all retrospective comparisons that rely on data contained in a large database. Data utilized were collected through standardized assessment practices, mitigating 1) the possibility that substantial differences existed in the quality of the information obtained from NPWT and the comparison group and 2) the threat of bias due to non-response and loss to follow-up. However, errors could have occurred in data collection and data entry that might have affected how patients were selected or how study measures were calculated. Certainly, concerns have been raised about the assessment competencies of clinical staff using OASIS in general and for assessing wounds specifically.[29] In addition to concern about baseline assessment skills among clinicians, concern also exists regarding differing levels of baseline knowledge between clinicians. In a study comparing the accuracy of OASIS completion by home health nurses and therapists, Madigan, Tullai-McGuinness, and Fortinsky[30] observed that when a discrepancy exists between clinician responses, nurses' responses agreed more often with the "correct" answer than the therapists' responses. To improve the accuracy of wound assessment, the Wound Ostomy and Continence Nurse Society (WOCN), the CMS, researchers, and individual home health organizations have provided education in the form of guidance documents, self-learning modules, "hands-on" learning, and multimedia educational broadcasts.[27,30,31,32]

Conclusion

Pressure ulcers are a common concern in home health care. Given the multifaceted demands of achieving high quality outcomes for patients with pressure

TABLE 7
ACUTE CARE HOSPITALIZATION RATES BY TREATMENT GROUP

	NPWT therapy (n=60)	Comparison group (n=2,288)
Instances of hospitalization (n, %)		
Stage III pressure ulcers	7 (24%)[1]	756 (44%)[1]
Stage IV pressure ulcers	14 (45%)	337 (59%)
Total	21 (35%)	1,093 (48%)
Instances of unplanned hospitalization (n, %)	7 (24%)	659 (39%)
Stage III pressure ulcers	14 (45%)	278 (48%)
Stage IV pressure ulcers	21 (35%)	937 (41%)
Total		
Instances of hospitalization for wound problem (n, %)		
Stage III pressure ulcers	1 (3%)[1]	194 (11%)[1]
Stage IV pressure ulcers	2 (7%)[1]	116 (20%)
Total	3 (5%)[1]	310 (14%)[1]

Patients receiving NPWT were tracked during the time NPWT was applied plus 7 days following removal to take into account any wound infection or deterioration that may have related to NPWT. The comparison group was tracked from start of care through end of care.

[1] *P < .05 for differences between groups (t-test)*

[2] *P < .01 for differences between groups (t-test)*

TABLE 8
EMERGENT CARE RATES BY TREATMENT GROUP

	NPWT therapy (n=60)	Comparison group (n=2,288)
Instances of emergent care (n, %)	6 (21%)	551 (32%)
Stage III pressure ulcers	8 (26%)	220 (38%)
Stage IV pressure ulcers	14 (23%)	771 (34%)
Total		
Instances of emergent care for wound problem (n, %)		
Stage III pressure ulcers	0 (0%)[1]	126 (7%)[1]
Stage IV pressure ulcers	0 (0%)[1]	63 (11%)[1]
Total	0[1]	189 (8%)[1]

Patients receiving NPWT were tracked during the time NPWT was applied plus 7 days following removal to take into account any wound infection or deterioration that may have related to NPWT. The comparison group was tracked from start of care through end of care.

[1] *$P < .01$ for differences between groups (t-test).*

ulcers in a cost-conscious environment, home health agencies are compelled to implement wound care therapies associated with positive outcomes that also can reduce expenses. Negative pressure wound therapy appears to be a viable option. Because it requires fewer dressing changes than traditional gauze dressings and is associated with reduced use of emergent care and hospital admissions for patients with Stage III and Stage IV pressure ulcers, NPWT can potentially help home health agencies improve patient care, decrease unexpected health care costs, and decrease cost associated with number of visits. This study also provides QIOs with an example of how steps in the OBQI process can be used to identify "best practices" for achieving reduction in acute care hospitalization in home health, thus aiding in their new call to action with the upcoming 8th Statement of Work.[45]

While the results of this study suggest that NPWT is associated with reduced hospital admissions and emergent care utilization for home health patients with advanced stage pressure ulcers, more research is needed to compare other quality outcomes such as quality of life, pain, and time to healing as well as costs of care. The latter should include the direct and labor costs of implementing, maintaining, and using the system; cost associated with the duration of care for patients on the system; and potential savings achieved by preventing unplanned emergent care or hospitalizations. Pay-for-performance demonstration projects outside of home health in which emergent care and hospitalization rates may impact reimbursement are also underway.[33,46] Negative pressure wound therapy would be an interesting wound care technology to implement and evaluate in these settings. - (WM)

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