

News

Topical negative pressure therapy in wound management

– A consensus document (WHASA 2009)

Foreword

Wound management has many challenges and these challenges are becoming more and more complex. Topical negative pressure (TNP) therapy has become one of the most talked about resources in the current wound management environment. According to the European Wound Management Association (EWMA) Position Document on Topical Negative Pressure in Wound Management this important development in wound care is being shown in a growing number of randomised controlled trails, as well as case studies, to produce dramatic improvements in clinical outcomes. It should be noted that the majority of clinical trials of TNPT have used the vacuum assisted closure (VAC ® Therapy) system.¹

TNP dates back to the early 1950s where negative pressure was applied to wounds and successfully used to accelerate healing and manage exudate following radical surgery.²

As the clinical benefits of TNP therapy have become more established, different methods for delivering the therapy have been developed and, to avoid bias, the use of the generic terms is recommended by authors such as Banwell and Teot (2005).³

Recently there has been a proliferation of different negative pressure wound therapy systems internationally using either foam- or gauze-based dressing interface. Many questions have been raised regarding the efficacy of all these units and the Wound Healing Association of Southern Africa (WHASA), as the broadest multidisciplinary wound care specialist provider group, is faced with issuing advice regarding the efficacy of each of these modalities. In April 2009 WHASA facilitated a South African consensus meeting on topical negative pressure therapy at the 3rd national WHASA conference focusing on the theme “Potholes in Wound Care”. From this meeting it was agreed by quorum at the conference to publish the following with regards to the use of TNP therapy in South Africa. The compilation of this document would not have been possible without the work of the WHASA TNP Task group and the consensus reached by its members at the 3rd national WHASA conference. This document highlights the indications and also contra-indications for the use of TNP therapy.

Liezl Naude

President of the Wound Healing Association of Southern Africa

1. European Wound Management Association (EWMA). Position document: *Topical negative pressure in wound management*. London: MEP Ltd, 2007.
2. Raffi AB (1952). The use of negative pressure under skin flaps after radical mastectomy. *Annals of Surgery*; 136:1048.
3. Banwell PE, Teote L(2005). Topical Negative Pressure Therapy (TNP): the evolution of a novel wound therapy. *European Tissue Repair Society*; 12 (1&2):7–15.

TNP therapy techniques available and recognised in South Africa

The most well-known application of TNP therapy involves a foam interface, specialized tract pad and adhesive dressing; the technique is described as Vacuum Assisted Closure® (VAC). Another alternative technique is described as the Chariker-Jeter method where a single layer of non-adherent gauze is laid over a wound, a flat drain placed over, moistened gauze used to gently fill the cavity and then a transparent adhesive dressing placed on top to create an airtight seal.

The Wound Healing Association of Southern Africa (WHASA) supports the following two documents on Topical Negative Pressure in Wound Management:

1. World Union of Wound Healing Societies (WUWHS). Principles of Best Practice: Vacuum assisted closure, recommendations for use. A consensus document. London: MEP Ltd, 2008.
2. European Wound Management Association (EWMA). Position

document: Topical negative pressure in wound management. London: MEP Ltd, 2007.s

WHASA strongly advises all wound care practitioners to familiarise themselves with the supporting documents when using TNP therapy. Each patient should be seen as an individual and holistic patient and wound assessment is essential in determining the best treatment plan for your patient.

In the interests of patient care, and upholding the outcomes expected from TNP, WHASA may only recommend that practitioners make their judgement based on the principles of evidence-based medicine (EBM), which involves “the conscientious, explicit and judicious use of current best evidence in making decisions about the care of the individual patient. It means integrating individual clinical expertise with the best available external clinical evidence from systematic research.” (Sackett D, 1996.)

TNP therapy in wound management – A consensus document (WHASA 2009)

Postulated mechanisms of TNP therapy action:

- Removal of excess third space fluid from the area immediately adjacent to the wound, relieving the micro-circulation from pressure with increased oxygen and nutrition delivery to the wounded area.
- Reduction of bacterial load by simply removing it from the wound environment.
- Mechanical effect on the wound bed by forcing the wound edges closer together and by mechanical stress that increases angiogenesis and tissue growth.

EVIDENCE MECHANISMS OF ACTION:

Ubbink, Westerbos, Evans, Land, Vermeulen. 2008. *Topical Negative Pressure for treating chronic wounds*. Cochrane Collaboration.

Current indications as stipulated by the World Union of Wound Healing Societies:

- Diabetic foot ulcers
- Complex leg ulcers
- Pressure ulcers
- Dehisced sternal wounds
- Open abdominal wounds
- Traumatic wounds

EVIDENCE CURRENT INDICATIONS:

World Union of Wound Healing Societies (WUWHS). Principles of Best Practice: *Vacuum assisted closure, recommendations for use. A consensus document*. London: MEP Ltd, 2008.

Current contra-indications as stipulated by the World Union of Wound Healing Societies:

- Not stand alone treatment for infection
- Not for use in grossly infected wounds
- Not for use on visible ischaemic wounds
- Not for use with underlying osteomyelitis
- Not for use with TcPO₂ lower than 40 mmHg
- Not for use in malignancies UNLESS for palliative care

EVIDENCE CURRENT CONTRA-INDICATIONS:

World Union of Wound Healing Societies (WUWHS). Principles of Best Practice: *Vacuum assisted closure, recommendations for use. A consensus document*. London: MEP Ltd, 2008.

WHASA authorisation procedure for TNP therapy

All treatment to be motivated for authorisation purposes and should clearly include the following:

1. Patient details
2. Medical Aid details
3. ICD 10 CODE
4. Multi-disciplinary team (MDT) involved
5. Indication for treatment
6. Clear endpoint with a time frame
7. Goal of treatment is to be clearly stipulated i.e.:

- a. Wound bed preparation for surgical interventions
- b. Wound volume reduction
- c. Exudate management
- d. Wound closure

Abbreviations and terminology used

TNP	Topical negative pressure
WCP	Wound care practitioner
MDT	Multi-disciplinary team
ABPI	Ankle brachial pressure index
TCPO₂	Transcutaneous oxymetry measurement
RED FLAG	Caution or absolute contra-indication
GREEN FLAG	Indicated in special circumstances
MEDICAL MODALITY	Surgeon, general practitioner, specialist physician, etc

WHASA consensus indications

OPEN ABDOMEN

USE:	YES
APPLIED BY:	WCP with consultation or motivation from a medical modality
RED FLAG:	<ul style="list-style-type: none"> • Unexplored fistulas = ABSOLUTE CONTRA-INDICATION! • Interface dressing must be clearly stated • Stoma therapist to be consulted when in use on explored and identified fistulas

CURRENT EVIDENCE USED FOR DECISION:

1. Wild et al, 2006, Retrospective controlled study, N = 62. Less mortality: 14% VAC abdominal vs 21% classic VAC vs 59% conventional care $p < 0.0009$
2. Kaplan et al, 2005, Data compilation. Closure: 79% VAC vs 58% vacuum pack $p < 0.001$ Lower fistula formation 2.6% vs 7% $p = 0.034$
3. Kaplan et al, 2004, Retrospective controlled study, N = 22. Abdominal wall closure: 78% vs 12.5% Time 12 days vs 23 days Hospital stay 30 days vs 40.75 days. No values

STERNAL WOUNDS

USE:	YES
APPLIED BY:	WCP with consultation or motivation from a medical modality
RED FLAG:	<ul style="list-style-type: none"> • Patients critically ill should be managed in appropriate level of care in a multi-disciplinary team setting.

CURRENT EVIDENCE USED FOR DECISION:

1. Sjogren et al, 2005, Retrospective controlled study, N = 101. Survival: 100% vs 85% $p < 0.01$. Decrease surgical intervention 0% vs 57.5%. Reduced failure rate 0% vs 37% $p < 0.001$
2. Sjogren et al, 2005, Retrospective controlled study, N = 46 vs N = 4781. Similar early and late survival: no statistical significance
3. Kutscka et al, 2004, Retrospective controlled study, N = 10. Better lung function: no statistical significance
4. Fleck TM, 2002, Retrospective controlled study, N = 11. Complete healing in all: ICU stay shorter 1 day vs 9.5 days, no p-values

TRAUMA WOUNDS

USE:	YES
APPLIED BY:	WCP with consultation or motivation from a medical modality

RED FLAG:	<ul style="list-style-type: none"> • Critical organ involvement • Multiple foreign bodies • Does not replace good surgical principles • Dose not replace other modalities with good evidence base • ISCHAEMIA = ABSOLUTE CONTRA-INDICATION!
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CURRENT EVIDENCE USED FOR DECISION:

1. Stannard et al, 2006, RCT, N = 88. Reduced drainage duration in haematomas: 1.6 days vs 3.1 days $p = 0.03$. Reduced drainage in high risk fractures: 1.8 days vs 4.8 days $p = 0.02$
2. Yang CC et al, Retrospective controlled study, N = 68. Wound closure sutures or split skin graft: 6.7 days vs 16.1 days $p = 0.0001$
3. Labler et al, 2004, Retrospective controlled study, N = 23. Vac vs Epigard. Lower infection with VAC 15% vs 55%: not statistically significant

BURN WOUNDS

USE:	NO
APPLIED BY:	WCP with consultation or motivation from a medical modality
GREEN FLAG:	<ul style="list-style-type: none"> • Flaps or grafts (see trauma evidence and lower limb evidence)

CURRENT EVIDENCE USED FOR DECISION:

1. Yang CC et al, Retrospective controlled study, N = 68. Wound closure sutures or split skin graft: 6.7 days vs 16.1 days $p = 0.0001$
2. Vuerstaek et al, 2006, RCT, N = 60 hospitalised pts. Wound bed prep achieved: 7 days vs 17 days $p = 0.005$. Healing: 29 days vs 45 days $p = 0.0001$. Skin graft take: 83% vs 70% $p = 0.011$. Cost: \$3 881 vs \$5453 no p-value

PRESSURE ULCERS

USE:	YES
APPLIED BY:	WCP with consultation or motivation from a medical modality
RED FLAG:	<ul style="list-style-type: none"> • Clinical end point clearly defined • Does not replace basic wound care principles and the TIMES model evaluation • Untreated osteomyelitis = ABSOLUTE CONTRA-INDICATION!

CURRENT EVIDENCE USED FOR DECISION:

1. Schwien et al, 2005, Retrospective matched group, N = 60 vs N = 2288. Hospitalisation: 35% VAC vs 48% other $p < 0.05$. Fewer complications: 0% vs 8% $p < 0.01$
2. Joseph et al, 2000, RCT, N = 24. Mean volume reduction: 78% vs 30% $p = 0.38$. Fewer complications: 17% vs 44% $p = 0.0028$

LEG ULCERS

INITIAL ONSET OF ULCER	NO – First therapy of choice is COMPRESSION THERAPY if ABPI indicates sufficient lower limb arterial blood supply
THERAPY RESISTANT ULCER	YES – End point/treatment objectives to be clearly stated as well as a brief overview of failed treatment regimens
APPLIED BY:	WCP with consultation or motivation from a medical modality
RED FLAG:	<ul style="list-style-type: none"> • Clear ABPI in at least two of the three foot arteries of each leg involved • If ABPI is less than 0,8 a transcutaneous oximetry measurement (TCPO₂) to be included in motivation

CURRENT EVIDENCE USED FOR DECISION:

1. Vuerstaek et al, 2006, RCT, N = 60 hospitalised pts. Wound bed prep achieved: 7 days vs 17 days $p = 0.005$. Healing: 29 days vs 45 days $p = 0.0001$. Skin graft take: 83% vs 70% $p = 0.011$. Cost: \$3 881 vs \$5453 no p-value

DIABETIC FOOT ULCERS

USE:	YES
APPLIED BY:	WCP with consultation or motivation from a medical modality, such as a podiatrist
RED FLAG:	<ul style="list-style-type: none"> • TCPO₂ of above 40 mmHg OR • Toe pressure to be 0.6 or more • If none of the above = CONTRA INDICATED! • ARTERIAL INSUFFICIENCY IN THE DIABETIC FOOT IS AN ABSOLUTE CONTRA-INDICATION FOR TNP THERAPY!

CURRENT EVIDENCE USED FOR DECISION:

1. Armstrong et al, 2005, RCT, N = 162. 56% vs 39% healing with VAC. Significance $p = 0.04$
2. Eginton et al, 2003, RCT, N = 10. Reduced wound volume: 59% vs 0% ($p < 0.0005$) and depth 49% vs 8% ($p < 0.05$)
3. McCallon et al, 2000, RCT, N = 10. Decrease surface area: 28,4% vs 9,5% p-values absent

NON-HEALING OR TREATMENT RESISTANT WOUNDS

USE:	NO
APPLIED BY:	WCP with consultation or motivation from a medical modality, such as a podiatrist
RED FLAG:	<ul style="list-style-type: none"> • Could be requested for palliative care with good motivation and timeframe added in line with the postulated mechanisms of TNP therapy • Not to be extended past four weeks of treatment without extensive follow-up and motivation

CURRENT EVIDENCE USED FOR DECISION:

Not sufficient evidence in place see red flag

In conclusion

Further research is still needed to increase understanding of the therapeutic effects of TNP therapy in order to give WCP stronger arguments to support the issues when motivating for authorisation. It is clear that future trails should focus on level 1 evidence and further comparative data specifically between the different TNP wound interfaces, since most documented research is done on the foam interface – Vacuum Assisted Closure (VAC).

The use of TNP should not be seen as routine therapy, however in cases such as the Diabetic Foot timeous TNP therapy can be limb-saving and TNP should be applied post-op debridement of complicated diabetic foot ulcers as soon as possible in order for the postulated mechanisms of TNP action to work optimally.

Please note that this document should be seen as a guideline to the use of TNP therapy in wound management and should not replace good clinical judgement and wound management.