

# NEGATIVE PRESSURE WOUND THERAPY — DOES IT AFFECT QUALITY OF LIFE?

## KEY WORDS

- ▶ Negative pressure wound therapy
- ▶ Topical negative pressure
- ▶ Quality of life
- ▶ Systematic review

**Background:** To critically review, appraise and evaluate the available literature with regard to the impact that negative pressure wound therapy (NPWT) has on the quality of life reported by patients. **Methods:** A systematic review was undertaken using Cochrane Library, MEDLINE, EMBASE and CINAHL databases. Publications between 1950 and 2011 were included and all relevant papers were reviewed irrespective of the data collection method if they reported the use of NPWT and patient-reported quality of life data. Abstracts were read for relevance and to determine if the studies met the predetermined inclusion criteria. Once vetted, full copies of the papers were obtained and two reviewers independently completed a pre-set data collection form that was then sent to the third reviewer to enable central collation and establish the themes reported. Data queries were checked and consensus achieved by discussion. **Results:** Only five studies met the inclusion criteria, all had methodological flaws, and are of small sample sizes. While there is a growing body of evidence to suggest that NPWT has advantages in reducing healing times as opposed to the use of conventional therapy, there is very little evidence to support the use of NPWT in relation to its impact on patient reported quality of life from either a positive, neutral or negative perspective. **Conclusion:** It is clear from the review that more studies need to be undertaken in this area of practice before any clear consensus can be achieved. Until such time, practitioners working in the field will have to continue to assess patients on an individual basis by giving information about the therapy with the aim that the patient can make an informed choice about the impact that NPWT may have on their individual quality of life.

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The ability of topical negative pressure (also known as negative pressure wound therapy [NPWT]) to assist with wound closure in a range of surgical specialties has been well documented (DeFranzo et al, 1999; Sposato et al, 2001; Song et al, 2003). Although case reports and retrospective studies have demonstrated enhanced wound healing in numerous wound types, there are very few randomised controlled trials (RCTs) and those in existence report mixed results (Ousey and Milne, 2010).

Mendonca et al (2007) suggested that NPWT may reduce the quality of life of some patients, due to the treatment being prolonged with a risk of pain, malodour

and discomfort from the treatment, despite it promoting wound closure in complex wounds.

NPWT is not a new therapy — reports of the use of vacuum therapy for the treatment of open wounds can be traced back to 1908 with Bier's hyperaemic treatment (Meyer and Schmieden, 1908).

In the early 1990s, Fleischman et al (1993, 1995) and Dersch et al (1994) demonstrated that positive pressure leads to a decrease in skin perfusion and, therefore, hypoxia, while negative pressure increases skin perfusion (Mendonca et al, 2006). This theory was further developed by Argenta and Morykwas (1997) who asserted that the basic concept of applying

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Braakenburg A, Obdeijn MC, Feitz R, et al (2004) The clinical efficacy and cost effectiveness of the vacuum assisted closure technique in the management of acute and chronic wounds a randomised control trial. *Plast Reconstr Surg* 118(2): 390–97

mechanical forces influences the shape and growth of tissue. They achieved this through the use of topical negative pressure via a foam interface dressing and postulated that the transmission of mechanical forces to the surrounding tissues removed excess interstitial fluid, and caused resultant deformation of the extracellular matrix and cells thereby stimulating cell division, infill and contraction.

Studies by (Wackenfors et al, 2004; Malmjö, 2008) have further established that NPWT exerts a small negative pressure on tissue that creates a small zone of hyperaemia in the tissue in contact with the interface material and that this is surrounded in both cutaneous and muscle layers by a zone of hyperperfusion; the hyperperfusion is a direct result of the NPWT.

## RATIONALE

As previously described, NPWT is widely used as a technique to assist healing in acute, sub-acute and chronic wounds. Although the application of NPWT has been shown to help wounds heal quicker than traditional wound dressings, little work has been published in this area (Mendonca et al, 2007). Investigating the patient's level of satisfaction with the therapy delivered is pivotal to patient concordance, with Von Essen et al (2002) and Fitzpatrick (1993) identifying that satisfied patients are more likely to comply with treatment and take an active role in their own care.

## Objectives

This review systematically searches, critically appraises and then summarises RCTs and non-RCTs investigating quality of life issues for patients being treated with NPWT for wound management.

## METHOD

A systematic review was undertaken using Cochrane Library, MEDLINE, EMBASE and CINAHL databases. Any publications between 1950 and 2011 were included.

Criteria for considering studies for this review included:

## Types of studies

All relevant RCTs or quasi-methods of participant allocation, in addition to case studies and retrospective studies, were

sought. Studies which investigated and explored quality of life issues for patients who were prescribed NPWT in the management of wounds were eligible for this review.

## Type of participants

This review includes all types of patient in any healthcare setting who was prescribed NPWT as a part of their wound care treatment.

## Types of interventions

Trials in which participants received any form of NPWT therapy and the comparison group received alternative wound treatment. All types of NPWT application, fillers, devices and use of different modes of negative pressure (continuous or intermittent) were considered eligible. For the non-trial studies, once again, all types of NPWT therapy, application and delivery mode were considered.

## Types of outcome measures

Each study must have reported, at a minimum, one of the following outcome measures:

### Primary outcomes

The primary outcome of interest was any change to the patient's quality of life:

- ▶▶ Pain
- ▶▶ Any issues related to removal of NPWT due to quality of life issues.

### Secondary outcomes

- ▶▶ Any reports that NPWT was more effective than traditional dressings
- ▶▶ Adverse events (removal of NPWT due to reduction in quality of life).

## Search methods for identification of studies

The search was based on the search strategies recommended and updated by the Cochrane Back and Wounds Review Groups (Furlan, 2009).

### Electronic searches

The following databases were searched:

- ▶▶ The Cochrane Library (issue 2, 2011 which includes the Cochrane Wounds Review Groups)
- ▶▶ MEDLINE (1950 to June 2011)
- ▶▶ EMBASE (1974 to June 2011)
- ▶▶ CINAHL (1982 to June 2011).

Also searched were:

- ▶▶ The reference lists of all relevant papers

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Ford-Dunn S (2006) Use of vacuum assisted closure therapy in the palliation of a malignant wound. *Palliative Med* 20(4): 477–78

- to identify further studies
- ▶ Some of the main electronic sources of ongoing trials
- ▶ Journals and conference proceedings likely to have trials relevant to this review.

## Data Collection and analysis

### Selection of studies

Two of the reviewers (LC, JM) read all titles and abstracts resulting from the search process and eliminated any studies that were not relevant for this review. Full copies of all potentially relevant studies were obtained. Both reviewers acted independently to classify these as 'include' or 'exclude' studies.

Any discrepancy about the relevance and design of the studies between the reviewers was resolved through discussion and the decision to include the studies was based upon the inclusion criteria. Consensus was sought by the reviewers when differences in opinion occurred and was resolved by discussion.

## RESULTS

Searching the various databases for this review generated 517 potential papers for inclusion: MEDLINE (122), EMBASE (298), CINAHL (97). After reading all of the abstracts, a percentage of papers were excluded: MEDLINE (11 for being non-English and 87 for not being relevant), EMBASE (three for being non-English and 291 for not being relevant), CINAHL (59 for not being relevant), while 18 duplicates were removed. This left 48 papers considered relevant and thus included in the review.

A subsequent review of full papers excluded a further 20. Excluded papers included Augustin et al (2010), as this was a discussion surrounding the Friebury quality of life tool and did not relate directly to patient experiences, and six literature/systematic reviews, with the remaining excluded papers not focusing specifically on quality of life. None of the studies were RCTs involving the use of NPWT, nor did they seek to determine its impact on patient-reported quality of life.

### Results of review

Five studies focused specifically on investigating quality of life issues for patients undergoing NPWT (Augustin and Zschocke, 2006; Kanogunthornrat et al,

2006; Karatepe et al, 2011; Mendonca et al, 2007; Vuerstaek et al, 2006).

Augustin and Zschocke (2006) measured outcomes of 176 patients before and after NPWT and reported significant increase ( $P < 0.001$ ) in quality of life scores with a decrease in pain scores.

Kanogunthornrat et al (2006) reported on a mixed methods study of 30 patients enrolled in a wound care programme in Thailand. They focused on patient education for self-care in maintaining dressing vacuum, nutrition and avoidance of wound trauma. They identified that NPWT reduced dressing changes and was less painful than conventional dressings. However, they also reported disadvantages of NPWT as reported by the patients as being odour, itching, and not feeling free to go out. It is noteworthy that the NPWT device was homemade and not one of the mainstream devices currently available for practitioners to use.

Karatepe et al (2011) randomised 67 patients admitted to a diabetic foot clinic into two groups, NPWT ( $n=30$ ) and conventional wound dressings ( $n=37$ ). They used a Turkish version of the SF-36 health survey with all patients completing the questionnaire at the start of treatment and then once more following wound healing (mean was four months with a 2–8 months range). The authors identified that prior to commencement of treatment 28 patients in the NPWT group and 32 patients in the conventional wound dressings group experienced depressive moods.

Analysis of the quality of life scores following completion of treatment indicated that those patients in the NPWT group had a significant improvement in both mental ( $P=0.0287$ ) and physical health ( $p=0.004$ ) when compared with the conventional dressings group. Furthermore, those patients treated with NPWT were discharged earlier than the other group. The authors conclude that NPWT therapy is superior to conventional wound dressings for maintaining quality of life.

Mendonca et al (2007) undertook an exploratory prospective cohort study on 26 patients, using the Cardiff Wound Impact Schedule to investigate quality of



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Figure 1: An example of a negative pressure wound therapy (NPWT) device in situ.

life scores before therapy and four weeks after therapy or at wound closure. They identified that there was no significant change in quality of life in patients whose wounds healed during the study period ( $1 \pm 11.9$ ), while the physical-functioning domain improved in obese patients ( $20 \pm 21$ ,  $p < 0.05$ ) and worsened in ambulatory/mobile patients ( $-3 \pm 13$ ,  $p < 0.05$ ).

However, 11 patients (42%) experienced a deterioration in their physical-functioning symptoms that the authors suggest may have been related to the NPWT device limiting mobility. Meanwhile, 12 patients (46%) experienced an improvement in their social-functioning scores.

Vuerstaek et al (2006) undertook a prospective RCT involving 60 patients with venous and mixed ulceration. Patients were randomised to either a NPWT group or conventional treatment. Patients in the NPWT group maintained therapy until the ulcer was fully granulated and then progressed to skin grafts and post-operative compression. Quality of life and pain scores were measured at the commencement of treatment and weekly during hospitalisation using EQ-DSI (the EuroQOL-derived single index tool used to measure quality of life outcomes).

Vuerstaek et al (2006) completed the EuroQoL tool to explore quality of life issues for patients with NPWT weekly. Participants were divided into three groups: (Group one) venous insufficiency of the deep or superficial system without an arterial incompetence; (Group two) combined arterial and venous insufficiency of the deep or superficial system (ABI, 0.60 to 0.85), or (Group three) arteriosclerotic (Martorell's ulcer, biopsy proven) leg ulcers. Analysis of this study identified that quality of life scores improved during the study, but did not differ significantly to those reported at the outset of the study.

During dressing changes pain scores were measured using an SF-McGill pain questionnaire and present pain intensity scores. Data were analysed using Statistical Package for the Social Sciences (SPSS). Their analysis indicated that 56 ulcers healed with both groups seeing changes in quality of life and a reduction in pain scores. When both groups of results were compared, it revealed scores were initially similar during the first weeks of treatment, yet from week five onwards, scores were significantly lower in the NPWT group.

The authors noted a significant improvement in both groups at week eight and although in the first week of treatment

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there had been a decrease in quality of life scores for the NPWT group, the authors suggested the future improvement in scores for this group may have been due to an acceleration of wound healing for the NPWT group.

Immer et al (2005) conducted a retrospective review of 55 patients who had infected sternal wounds treated with NPWT therapy. They used the quality of life outcomes measurement tool, SF-36 to collect data. The authors concluded that the use of NPWT provided good clinical outcomes and that the quality of life scores were nearly normal for a matched aged population, suggesting that NPWT does not have an adverse effect on quality of life outcomes. It is, however, a retrospective study and as such the results are questionable as the reported quality of life is that which was perceived by the patient while reflecting on the experience as opposed to during the lived experience.

### Secondary Outcome measures

A total of five papers (Braakenburg et al, 2004; Ford-Dunn, 2006; Vuerstaek et al, 2006; Mandal, 2007; Stansby et al, 2010) reported improved healing times for patients using NPWT as opposed to conventional wound treatment. Stansby et al (2010), reported a 41% reduction in wound size from a sample size of 14 participants, with Braakenburg et al (2004) detailing that the NPWT group had a median healing time that was four days shorter compared with the conventional group, although the difference was not significant. Eginton et al (2003) established that NPWT was valuable in the early treatment period (the first two weeks) of diabetic foot wounds and associated with a decrease in all wound dimensions.

### Differences in quality of life outcomes

Fraccalvieri et al (2011) and Ford-Dunn (2006) reported decreased pain in patients with NPWT. Fraccalvieri et al (2011) compared levels of pain before and after dressing change with NPWT, identifying that gauze wound fillers were less painful than foam fillers. Ozturk (2009) compared levels of pain experienced during dressing change between NPWT, foam fillers and conventional dressings, concluding that as NPWT required fewer dressing changes, there was less need for analgesia and, therefore, a reduction in pain. Hurd et al (2010) reported the results of a

prospective non-comparative, multi-centred evaluation with the primary objective of wound closure, wound pain and wound odour. She concluded that patients treated with gauze-based NPWT reported a reduction in pain ( $P<0.001$ ) and a reduction in odour ( $P<0.001$ ).

Effective exudate management and minimal reports of pain were also reported by Stansby et al (2010) in patients using foam-based NPWT. Teot et al (2006) reported a reduction in pain when using Urgotul™ (Urigo Medical) as a liner for foam dressings used during NPWT therapy.

Nease (2009) details a reduction in pain during dressing changes when evaluating the use of NPWT therapy for three patient case studies, whereas Wallin et al (2011), in a retrospective study exploring the effect of NPWT therapy over a 24-month period, observed that NPWT therapy was discontinued on 20% of patients ( $n=4$ ) due to quality of life concerns, including decrease in general health status, particularly cognitive status, which made NPWT treatment problematic.

For one patient, medical staff discontinued the treatment due to suspicion of development of a bowel fistula. Equipment problems were reported as the reason for stopping treatment in two further patients. They concluded that further research was required to explore quality of life issues for patients undergoing NPWT.

### Issues related to removal of NPWT due to quality of life issues

Pain was the most frequently cited reason for removal of NPWT therapy (Schimp et al, 2004; Braakenburg et al, 2004; Bollero, 2007; Hurd et al, 2010; Fraccalvieri et al, 2011). Both Hurd et al and Fraccalvieri et al, reported that pain was greater in those patients who had foam fillers and less in the group with gauze fillers. They suggest this may be due to adhesion and tissue in-growth caused by the effect of the foam filler.

Franczyk et al (2009) undertook a controlled prospective randomised double blind study investigating the effect of topical lidocaine on pain level assessment during and after vacuum-assisted closure dressing. They administered either lidocaine or a placebo of 0.9% saline at the first dressing

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30 minutes prior to dressing removal. Pain was assessed using the Visual Analogue Scale pre-instillation, during removal and immediately after the procedure. Results showed pain scores to be less in the treatment group at dressing changes.

## Infection

Mendonca et al (2007) stated that NPWT assisted in the eradication of infection in 14/17 (82%) patients, while additionally 18/20 (90%) patients who had wound discharge pre-therapy were free of discharge post-therapy ( $p < 0.001$ ). Braakenburg et al (2004) reported no reduction in bacterial load post-NPWT, while 84% of wounds had bacterial growth as opposed to 58% in conventional treatment.

Schimp et al (2004) reported that one patient bled during NPWT therapy, but the bleeding stopped as soon as the therapy was discontinued. Fraccalvieri et al (2011) reported that three patients had the wound dressing filler changed from gauze to foam to improve granulation and one patient had their wound dressing filler changed from foam to gauze, due to evidence of the wound undermining. Vuerstaek et al (2006) illustrated that complications were higher in the NPWT group at 40% versus 23%, however, this was not statistically significant. There were no differences in wound recurrence rates — 52% at one year with the NPWT group and 42% with conventional care.

## DISCUSSION

NPWT can be expensive to fund and with ever-decreasing resources being available to healthcare practitioners, the importance of being able to justify its use has never been more essential. Crucially, the patient experience must be kept at the centre of any intervention and the fact that NPWT may impact on a patient's quality of life has to be a consideration when choosing an appropriate wound dressing technique. *Equity and Excellence: Liberating the NHS* (Department of Health [DH], 2010) identified that there must be shared decision making between practitioners and patients with the underpinning ethos being 'no decision about me without me.'

Patients must be informed of the possible impact that NPWT may have on their quality of life. Mobility may be decreased due to being attached to the pump, social

activities may be reduced and pain may increase along with wound exudate. However, the papers reviewed have highlighted that wounds do heal slightly faster with NPWT and that frequency of wound dressing changes are reduced, with few reports of a significant decrease in a patient's quality of life.

For some patients, NPWT will not be the ideal therapy, if, for example, mobility is restricted or if they are unable to manage the basic aspects of the device, and up to now, most studies have failed to uncover the true impact of having a negative pressure device *in situ*. For other patients, the benefits of therapy may outweigh the drawbacks.

## CONCLUSION

The papers reviewed have examined and explored some aspects of quality of life measures, however, none of the authors have offered any clear conclusions. The Wound Union of Wound Healing Societies [WUWHS] (2008) consensus document for NPWT does state, however, that this therapy can have a positive impact on a patient's quality of life.

The authors of this review conclude that NPWT therapy is an alternative to conventional wound dressings, but an in-depth, holistic patient assessment should be undertaken prior to prescribing the treatment. Patients must be able to manage their activities of daily living while using the therapy or must, at least, have family or carers who are able to assist them. Furthermore, cost must be taken into account — the therapy is more expensive than conventional wound dressings, although there can be cost savings when time to healing, amount of wound dressing changes and nursing time are reduced.

There is a need to undertake more qualitative and quantitative research of the effects of NPWT on quality of life for patients with a variety of wound types. The authors suggest that future studies should explore demographic differences, in addition to investigating if there are any differences in therapy type, pressure settings and use of wound filler.

## DECLARATION

*This article was produced with the aid of an unrestricted educational grant from Smith and Nephew.* 