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**A pilot study exploring quality of life experienced by patients undergoing negative pressure wound therapy as part of their wound care treatment compared to patients receiving standard wound care**

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# **A pilot study exploring quality of life experienced by patients undergoing negative pressure wound therapy as part of their wound care treatment compared to patients receiving standard wound care**

## **Abstract**

The use of Negative Pressure Wound Therapy (NPWT) has been widely documented as a technique to help heal complex wounds. This paper presents the findings of a preliminary study which aimed to explore quality of life experienced by patients undergoing negative pressure wound therapy (NPWT) as part of their wound care treatment in comparison to that of patients with a wound using traditional (standard) wound care therapies. A quasi-experimental study was undertaken, with patients treated in wound care/vascular clinics with chronic/acute wounds. Quality of life impact was measured using the Cardiff Wound Impact Schedule and administered post consent at timed intervals. Our results identified that there were no real differences in quality of life scores recorded by patients over the 12 week period. Although there was no overall interaction between the therapies used for wound healing, NPWT did have an effect on social life: during the first 2 weeks of the application of therapy, patients in the NPWT group reported an increase in the social life domain. The authors conclude that true QoL can only be elicited if an accurate baseline is established or if data is collected over a long enough period to allow comparison of scores over time.

## **Key Points**

1. Health care interventions aim to provide positive benefit to patients, however occasionally unintentionally cause harm. This is reported by way of physical deterioration, as this is easy to measure. However, some therapies clearly have an impact in other perceived health domains such as quality of life.
2. Reported quality of life scores one week after treatment indicated no significant effect of therapy on quality of life in either arm.
3. The therapy-social isolation interaction was not significant ( $F_{4,9}=0.269$ ;  $p=0.891$ ), indicating that the effect of therapy type was similar on those who lived alone and those who lived with friends or family.
4. Patients living alone and receiving standard therapy reported substantially lower quality of life scores than patients living with their families, and receiving standard therapy.

5. Patients living alone and receiving NPWT reported very similar quality of life scores to patients living with their families, and receiving standard therapy.

**Key Words**

Negative pressure wound therapy, quality of life, social isolation

**Conflict of Interest**

This study was funded by a non-restrictive educational grant from Smith and Nephew.

**Acknowledgments**

Cardiff Wound Healing Centre for permission to use CWIS. Thank you to all the practitioners for their help with recruitment and data collection and to the patients who completed the questionnaires.

## Background

Health care interventions aim to provide positive benefit to patients. However, occasionally they can also cause harm; if, for example, used inappropriately, or if the risk versus benefit or assessment fails to consider all known and potential variables. All interventions, no matter how safe or innocuous, have listed potential physical side effects. The complex combination of processes, technologies and human interactions that constitutes the modern health care delivery system can bring significant benefits (1). However, it also involves an inevitable risk of adverse events that can and often do happen (1). It is essential that any intervention undertaken is assessed for safety, and that patient satisfaction is evaluated to ensure interventions not only treat the medical symptoms effectively, but that quality of care is not compromised to ensure that the patient experience is consistently positive.

The ability to measure patient satisfaction has been discussed for many years, with reports of difficulties associated with the accurate measurement of patient satisfaction with care. Data collection tools have been criticised for not being sensitive enough to define exact levels of patient satisfaction, or indicate specific needs for improvement, and not showing areas perceived as important to patients (2). Studies have suggested that older patients are generally more satisfied than younger patients (3). Some studies have suggested that women are more satisfied with care than men are (4)); while conversely other studies have identified that men were more satisfied with care than women are (5,6).

The use of Negative Pressure Wound Therapy (NPWT) has been widely documented (7, 8, 9, 10, 11, 12, 13, 14,, 15 ) as a technique to help heal complex and chronic wounds. Managing patients with a complex wound is challenging, especially when in the case of NPWT, it necessitates the patient having to remain attached to the device for around 22 out of 24 hours a day. This leads to a requirement to explore quality of life issues for these patients (16). Investigating patient levels of satisfaction with the therapy delivered is pivotal to patient concordance. Von Essen et al. (17) identified that satisfied patients were more likely to comply with treatment, and take an active role in their own care.

There is a limited amount of literature that investigates and explores the effect NPWT has on patients' quality of life or satisfaction, and as such it is hoped that this study will enhance our knowledge of the patient experience associated with living with a wound and undergoing NPWT. Most clinicians acknowledge that NPWT has been shown to have the potential to promote wound healing, alleviate signs and symptoms of increasing exudate and odour, and to improve quality of life

(18). However the authors would argue that the success or failure of NPWT does not centre solely on the physical signs and symptoms of the wound. It is imperative that the patient involved is able to make an informed choice about the therapy, and also that the overall health and wellbeing of the patient is considered in the holistic assessment to ascertain if the patient would safely cope with the therapy. It is acknowledged that these considerations may be different, dependent on care setting, practitioner knowledge, both patient physical and mental infirmities, and actual and perceived support mechanisms. There are very few tools that aid practitioners' choices: as such these are often intuitive decisions made by clinicians based on their past experience of managing patients with a wound being managed with NPWT.

What is clear is that the clinician needs to carefully balance the benefits of using the therapy with the risks; this is not only limited to consideration of the potential physical side effects of the therapy. An honest account of knowledge of the therapy must be shared with the patient to enable the basis of a therapeutic relationship, as suggested initially by Peplau (19) between patient and practitioner. It could be argued that if care is taken over gaining informed consent at the outset of therapy, and a therapeutic relationship established, built on mutual respect and trust, the patient may perceive a positive health benefit even if the wound fails to progress, or if side effects are encountered with the chosen therapy; as the patient would be aware of any potential complications at the outset, and as such any disappointment may be alleviated.

### **Aim of Study**

To explore satisfaction and quality of life experienced by patients undergoing negative pressure wound therapy (NPWT) as part of their wound care treatment in comparison to that of patients with a wound using traditional (standard) wound care therapies.

### **Objectives**

- To explore the impact that living with a wound has on a patient's quality of life.
- To explore the impact of NPWT on a patient's quality of life.

### **Method**

A quasi-experimental study was undertaken, with patients treated in wound care/vascular clinics with chronic/acute wounds. Some of these patients were prescribed NPWT. Patients were screened using the inclusion and exclusion criteria below. If appropriate, and willing to participate, they were consented and assigned to either a control group (receiving standard therapy) or an intervention group (receiving negative pressure wound therapy). All participants were recruited by the tissue viability/vascular nurse services. Participants were referred to either of these services as part of their

normal patient pathway for their wound care management. Patients wounds were managed by either NPWT or standard dressing therapy, based on holistic assessment. If they were receiving NPWT they entered the intervention group; if standard dressing management they entered the control group.

The principal inclusion criteria for the study were:

- Patients who were over 18 years of age who had been receiving treatment for a wound
- Patients who were transferred onto NPWT
- Patients with wounds including leg ulcers, category 3 or 4 pressure ulcers; diabetic foot ulcers and other wound types healing by secondary intention
- Patients with the ability to understand the aims of the study and to give informed written consent
- Patients with wounds at least 4cm x 4cm x 2cm (L x W x D) in size

The principal exclusion criteria for the study were:

- Children
- Palliative patients
- Patients whose mental capacity prevented them giving informed consent and undertaking the interviews
- Those unwilling or unable to participate
- Patients with full thickness open abdomen, burn wound or Split Thickness Skin Graft

### **Data Collection**

All study participants received a comprehensive letter of invitation explaining the study objectives with respect to their quality of life. The letter of invitation and information relating to the study were given to potential participants during their first visit to clinic to see the vascular nurse or tissue viability specialist. The vascular nurse or tissue viability specialist explained the study to the potential participants, answering any questions or queries. Potential participants were given time to consider the information and to decide if they were willing to take part.

Appropriate wound management, as deemed by the tissue viability/vascular nurse specialist, was either continued or commenced immediately. This did not affect the patients' decision to enter the study. All standard dressing choices were logged to enable data analysis at the end of the study. Information was sent to the patient's General Practitioner and District Nurse, informing them of the patient's participation in the study and the chosen interventions, prescriptions and frequency of dressing changes and review. Quality of life impact was measured using the Cardiff Wound Impact

Schedule and administered post-consent. The Cardiff Wound Impact Schedule (CWIS) is a condition-specific quality of life tool, giving a profile of scores for Physical Symptoms and Daily Living, Social Life, Wellbeing, and overall quality of life.

Data was collected at nominal points during the wound treatment. The initial questionnaire also captured demographic and clinical information, plus information relating to wound characteristics. The remainder of the questionnaires captured quality of life information and were administered to patients at week 1, week 2, weeks 4, week 8 and week 12, irrespective of the wound treatment received. These were sent to patients by post with a prepaid return envelope in an effort to reduce researcher bias on the outcome. If the wound healed between administration times of the questionnaire no further questionnaires were completed. This allowed for any changes in quality of life indicators to be identified at specific points of the patients' treatment.

The sample included patients with acute and chronic wounds, as an aim of the pilot study was to examine the impact of NPWT on quality of life for a range of wound types. As the study was a quasi-experimental study, randomisation of patients to control and treatment groups was not possible. Furthermore, the small sample of patients analysed in this study precluded full consideration of all collected baseline data.

### **Data Analysis**

Multivariate analyses were undertaken, utilising the individual components of the CWIS tool as outcome measures, at 1 and 2 weeks after treatment, testing the null hypothesis of no difference between the quality of life score in the patients who used NPWT and those who did not use NPWT as part of their wound care treatment. Follow-up univariate analyses were also undertaken where appropriate; to identify any individual components of the tool in which significant differences between groups may exist.

It may be postulated that NPWT has more impact on quality of life in patients living alone than in those living with family or friends, due to the regular contact needed to maintain the wound using standard therapy, implying an interaction between the factors of therapy type and level of social isolation. Hence a further set of multivariate analyses was undertaken at various time points to test the null hypothesis of no difference between the quality of life score in patients assigned to NPWT and standard therapy who lived alone, and quality of life score in patients who lived with family or friends.

Further assessments of associations between quality of life scores and therapy type, and their associated interactions, were not performed, due to low numbers of patients remaining on NPWT



more than 2 weeks after study commencement. However, analyses of the effect of social isolation on quality of life scores were extended to the end of the 12-week follow-up period by means of a series of analyses of covariance (ANCOVA) models, in which the difference between mean change scores in each group over this period was assessed for statistical significance, using all components of the CWIS tool. In all cases, in the absence of true baseline quality of life scores, scores recorded after one week were included in the model as surrogate baseline scores; hence the follow-up period under investigation was 1-12 weeks after treatment.

## **Ethics**

The study protocol was subjected to University and NHS ethics panel review and was subsequently approved in accordance with Research Governance and Helsinki guidelines. All participants provided signed consent after being given patient information via written material, and the tissue viability nurse specialist.

## **Results**

### ***Summary of patient outcomes and therapies received***

Of the 21 patients included in the study, 10 started treatment on NPWT and 11 started standard treatment. Of the 10 patients who started treatment on NPWT, 6 were subsequently transferred to standard therapy and 4 remained on NPWT either until the end of the study or until loss to follow-up. All 4 patients who remained on NPWT for the duration of the study were lost to follow-up before wound healing was reported; with 3 of the patients followed for 56, 81 and 102 days; and the 4<sup>th</sup> patient failing to return any questionnaires after the baseline questionnaire. In the case of the NPWT patients lost to follow-up, this occurred at week 8 for one patient, and by the end of week 2 for the remaining three patients. Loss to follow-up of a particular patient implies the loss of the patient to the study due to failure to complete or return the questionnaires.

The 6 patients who started treatment on NPWT and were transferred to standard therapy did so between 2 and 57 days after commencement of NPWT treatment; and subsequently remained on standard therapy from between 8 and 77 days. One of the patients reported wound healing after a total of 103 days: all others did not report wound healing before either being lost to follow-up or reaching the end of the study.

The 11 patients who started standard therapy remained on this therapy for between 12 and 121 days before either being lost to follow-up or reaching the end of the study; or before reporting wound healing. Three patients reported wound healing in this group. Hence all instances of wound

healing occurred in patients experiencing standard wound therapy, and so it was not possible to compare standard and NPWT methods in terms of time to wound healing.

Mean and standard deviation scores of all sub-scales of the CWIS questionnaire are presented in Tables 1-3 below. Data from Week 1 to Week 12 is given for the entire cohort (Table 1) and additionally partitioned by social isolation (whether the patient lived alone or with their family) (Table 2). Table 3 also gives scores partitioned by therapy received for weeks 1 and 2 only: beyond the 2-week point, no more than 2 patients on NPWT returned each set of questionnaires: hence statistics applied to these groups would not be reliable.

*Table 1: Mean (SD) of CWIS Quality of Life Scores Weeks 1 – 12 (all patients)*

	Week 1	Week 2	Week 4	Week 6	Week 8	Week 12
<b>Physical symptoms / daily living</b>	81.4 (20.3)	80.7 (24.1)	83.5 (24.3)	82.9 (23.3)	87.7 (22.6)	87.3 (28.3)
<b>Social Life</b>	47.0 (12.4)	51.3 (13.1)	53.9 (12.8)	50.3 (15.5)	51.9 (15.4)	54.3 (16.6)
<b>Well-being</b>	21.2 (5.34)	20.4 (5.72)	21.5 (7.10)	22.1 (7.01)	22.7 (6.64)	23.3 (7.78)
<b>Overall quality of life</b>	11.0 (3.78)	11.4 (4.15)	11.6 (4.78)	10.7 (5.38)	11.4 (4.13)	12.5 (4.10)

Table 2: Mean (SD) of CWIS Quality of Life Scores Weeks 1 – 12 (by social isolation)

	Week 1	Week 2	Week 4	Week 6	Week 8	Week 12
<b>Physical symptoms / daily living</b>						
Live alone	55.5 (7.78)	66.5 (28.5)	71.0 (27.7)	70.0 (22.3)	73.3 (27.6)	75.0 (35.8)
Live with friends/family	77.8 (14.8)	84.9 (21.6)	88.1 (21.6)	85.7 (23.5)	92.6 (21.2)	93.4 (24.1)
<b>Social Life</b>						
Live alone	37.5 (0.71)	39.8 (9.98)	45.0 (13.6)	40.3 (11.4)	43.8 (15.5)	51.8 (17.4)
Live with friends/family	51.5 (12.4)	56.3 (12.7)	55.9 (12.5)	53.6 (17.7)	56.4 (16.4)	55.6 (17.2)
<b>Well-being</b>						
Live alone	16.5 (10.6)	16.3 (5.06)	17.3 (7.14)	19.0 (7.35)	20.3 (8.42)	19.0 (8.04)
Live with friends/family	21.7 (3.98)	23.4 (6.37)	22.6 (7.55)	23.0 (8.17)	24.9 (7.24)	25.4 (7.21)
<b>Overall quality of life</b>						
Live alone	4.00 (1.41)	4.50 (0.71)	8.00 (1.41)	2.50 (0.71)	5.00 (0.24)	6.00 (5.66)
Live with friends/family	12.2 (4.54)	12.2 (4.54)	12.3 (4.59)	12.0 (4.05)	12.0 (4.05)	13.2 (2.93)

Table 3: Mean (SD) of CWIS Quality of Life Scores Weeks 1 – 2 (by therapy type)

	Week 1	Week 2
<b>Physical symptoms / daily living</b>		
NPWT	86.9 (21.8)	98.2 (23.1)
Standard therapy	75.8 (18.1)	73.9 (21.6)
<b>Social Life</b>		
NPWT	44.5 (13.6)	59.4 (12.8)
Standard therapy	46.3 (12.6)	48.2 (12.2)
<b>Well-being</b>		
NPWT	22.6 (4.90)	23.2 (7.53)
Standard therapy	19.8 (5.63)	19.3 (4.79)
<b>Overall quality of life</b>		
NPWT	11.3 (1.10)	13.4 (2.97)
Standard therapy	10.7 (1.34)	10.7 (4.39)

Considering the group as a whole, the general pattern is of a static series with no underlying trend. Figures 1(a) to 1(d) illustrate the variation in the physical symptoms and daily living, social life, well-being and overall quality of life scores between 1 and 12 weeks after treatment. Mean scores with 95% confidence intervals are presented. It may be seen that there is substantial overlap of all confidence intervals; indicative of no significant differences in outcome measures between time periods.

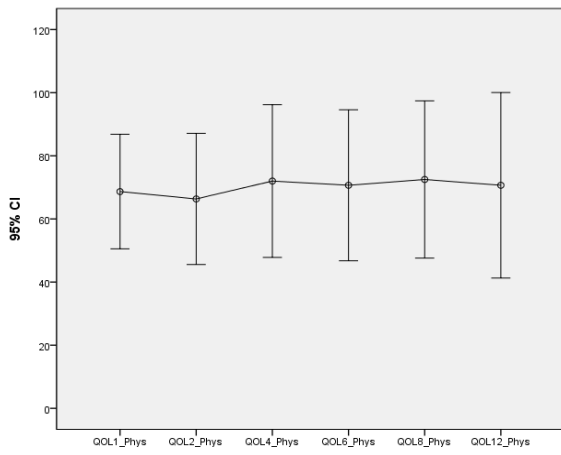


Figure 1(a) Trend in physical symptoms scores

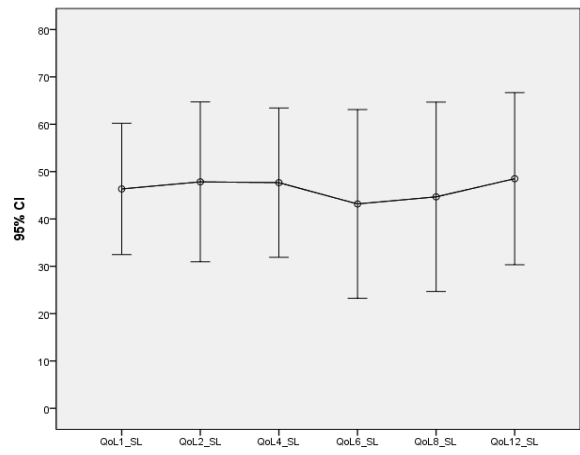


Figure 1(b): Trend in social life scores

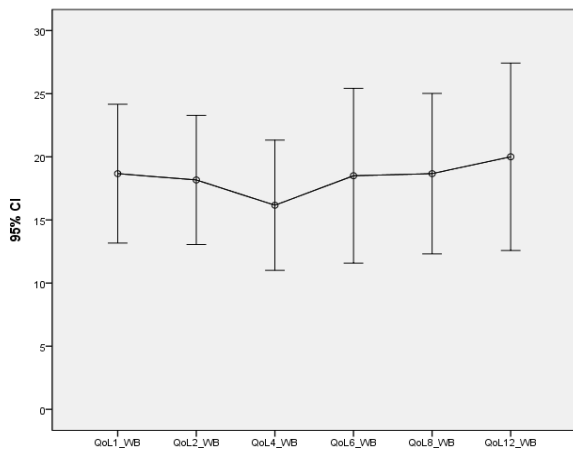


Figure 1(c): Trend in well-being scores

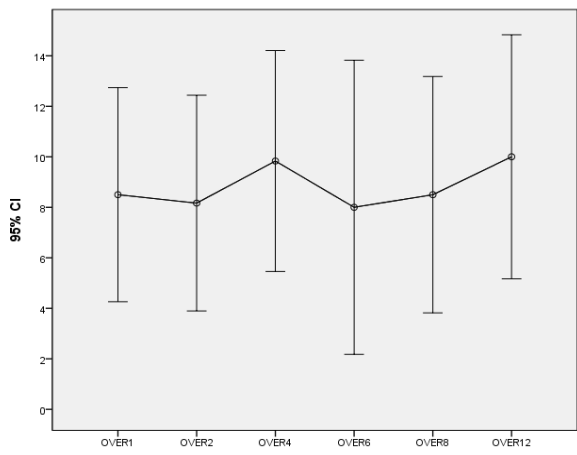


Figure 1(b): Trend in overall quality of life scores

### ***Association between therapy and quality of life scores: weeks 1-2***

Reported quality of life scores one week after treatment indicated no significant effect of therapy on quality of life ( $F_{4,11} = 1.34$ ;  $p=0.317$ ) in an uncontrolled multivariate general linear model considering the individual components of the CWIS quality of life tool as outcome measures. Follow-up ANOVAs also indicated no significant effect of therapy on any of the individual components of the tool.

Reported quality of life scores two weeks after treatment also indicated some substantive effect, but no statistically significant effect of therapy on quality of life ( $F_{4,9}=2.26$ ;  $p=0.143$ ) in an uncontrolled multivariate general linear model considering the individual components of the CWIS quality of life tool as outcome measures. Follow-up ANOVAs indicated that these effects were likely to be grounded primarily in the overall quality of life component of the CWIS tool in which a significant association was observed ( $F_{1,12}=5.77$ ;  $p=0.033$ ); and secondarily in the social life and well-being components of the CWIS tool, for which substantive associations were observed ( $F_{1,12}=3.16$ ;  $p=0.101$  for the social life component;  $F_{1,12}=2.67$ ;  $p=0.128$  for the well-being component).

### ***Association between therapy, social isolation and quality of life scores: weeks 1-2***

Reported quality of life scores one week after treatment indicated a substantive effect of therapy on quality of life ( $F_{4,9}=2.99$ ;  $p=0.079$ ); and a substantive and statistically significant effect of social isolation on quality of life ( $F_{4,9}=3.92$ ;  $p=0.041$ ) in a controlled multivariate general linear model. Follow-up ANOVAs indicated that despite the overall non-significance of therapy on the outcome measures jointly, the overall quality of life score was significantly associated with therapy ( $F_{1,2}=8.47$ ;  $p=0.013$ ); and that the substantive significance of social isolation also appeared to be grounded in differences in responses to the overall quality of life scores elicited in the CWIS tool ( $F_{1,12}=17.7$ ;  $p=0.001$ ). The therapy-social isolation interaction was not significant ( $F_{4,9}=0.269$ ;  $p=0.891$ ), indicating that the effect of therapy type was similar on those who lived alone and those who lived with friends or family. However, profile plots of marginal means indicated the presence of an interaction between social isolation and therapy on the social life component of the CWIS tool (Figure 2); in which it may be seen that amongst those patients who live alone, those receiving NPWT score more highly on the social life CWIS component than those receiving standard therapy, whereas amongst those patients who live with their families, those receiving standard therapy score more highly on the social life CWIS component than those receiving NPWT.

Some demographic and clinical baseline imbalances between the two groups were recorded. The ages of the patients were not recorded exactly, but were recorded within 10-year bands. The NPWT



group included a larger number of patients in the younger age ranges than the standard therapy group. The estimated ages in the sub-groups were; NPWT (original assignment) and living alone, 50.0 years; NPWT (original assignment) and not living alone, 45.0 years; standard therapy and living alone, 65.0 years; standard and not living alone, 52.5 years. Therefore the standard therapy group were slightly older than the NPWT group and those living alone were slightly older than those who lived with family. Assuming the age of an individual to be represented by the mid-point of the band to which they belonged, the average age of those in the standard therapy group was estimated to be 55.0 years; whereas in the NPWT group it was estimated to be 44.4 years.

The two groups were also imbalanced with respect to gender: the standard therapy group comprised 7 males and 4 females (64% male), while the NPWT group comprised 8 males and 2 females (80% male).

A large variety of wounds were included in the study, with some systematic differences in the sizes of the wounds in patients initially assigned to standard therapy, and those initially assigned to NPWT. The patients with the two largest wounds measured by length and depth (65cm x 50cm, 45cm x 40cm) and the patient with the two deepest wounds (22cm and 20cm) were all initially assigned to the NPWT group. All patients in this group had wounds of length 9cm or greater. Conversely, many patients with smaller wounds were assigned to the standard therapy group, although one patient in this group did have a wound comparable in length and depth to the largest wounds in the NPWT group.

Both groups included patients whose wound duration was in excess of 3 years. Wound duration in the standard group ranged from 1 week to 3.5 years (mean duration 41 weeks approximately), while in the NPWT group it ranged from under 1 week to 3.2 years (mean duration 31 weeks approximately).

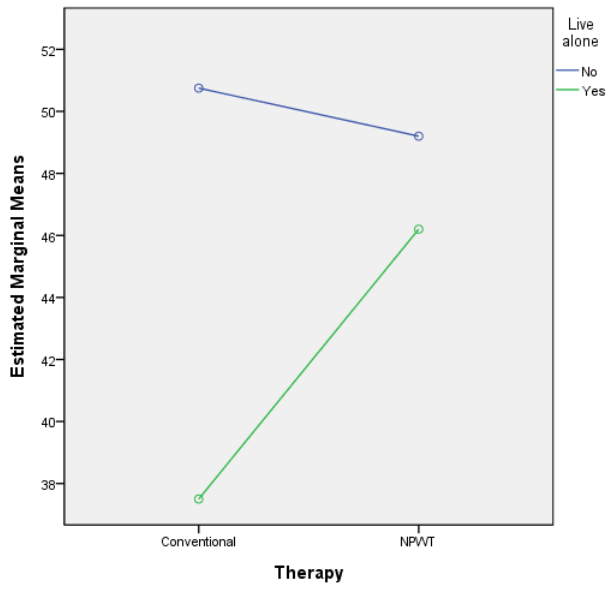


Figure 2: Interaction between social isolation and therapy type: CWIS social life scores at week 1

Reported quality of life scores two weeks after treatment indicated no significant effect of therapy on quality of life ( $F_{4,7}=2.84$ ;  $p=0.109$ ); or social isolation on quality of life ( $F_{4,9}=1.92$ ;  $p=0.212$ ) in a controlled multivariate general linear model. The therapy-social isolation interaction was also not significant ( $F_{4,9} = 0.665$ ;  $p=0.636$ ), indicating that the effect of therapy type was similar on those who lived alone and those who lived with friends or family. However, profile plots of marginal means indicated the presence of an interaction between social isolation and therapy on the social life component of the CWIS tool (Figure 3). By contrast to the interaction observed in the week 1 scores, all NPWT patients achieve better social life scores than patients receiving standard therapy. However, while patients living alone and receiving standard therapy report substantially lower quality of life scores than patients living with their families and receiving standard therapy, patients living alone and receiving NPWT report very similar quality of life scores to patients living with their families and receiving standard therapy.

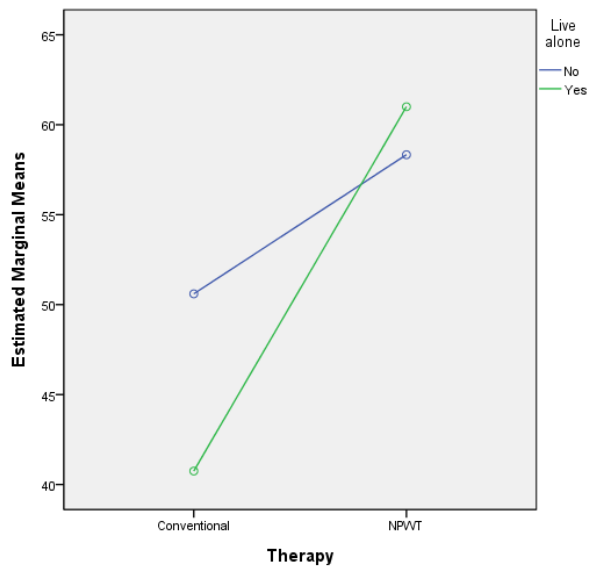


Figure 3: Interaction between social isolation and therapy type: CWIS social life scores at week 2

### ***Association between social isolation and quality of life scores: weeks 1-12***

An ANCOVA undertaken on the change scores of the individual components of the Cardiff CWIS tool found social isolation to be not significantly associated with physical symptoms and daily living ( $F_{1,3}=0.025$ ;  $p=0.885$ ); on social life scores ( $F_{1,3}=0.032$ ;  $p=0.870$ ); on wellbeing scores ( $F_{1,3}=0.989$ ;  $p=0.393$ ); or on overall quality of life scores ( $F_{1,3}=0.069$ ;  $p=0.810$ ). The surrogate baseline week 1 score was found to be a significant predictor of week 12 scores in the wellbeing component ( $F_{1,3}=13.9$ ;  $p=0.036$ ), but was not statistically significant for the other components of the CWIS tool.

### **Discussion**

During this pilot study we tested the null hypothesis of no difference between the quality of life score in patients assigned to NPWT and standard therapy who lived alone, and quality of life score in patients who lived with family or friends. Three studies (20, 21, 22) have identified improved quality of life indicators for patients with chronic wounds treated with NPWT, particularly in relation to decreased pain scores. Augustin and Zschocke (22), in their study of 176 patients, measured outcomes before and after NPWT, and reported significant ( $p<0.001$ ) increase in quality of life and higher satisfaction. Exploring quality of life using the CWIS was undertaken on 26 patients with acute ( $n=13$ ) and chronic wounds ( $n=13$ ) by Mendonca et al. (16). The authors reported no overall significant change in quality of life between the 2 groups, although NPWT produced favourable clinical results, with over 50% of patients achieving complete wound closure, 46% of patients reporting an improvement, and 42% reporting deterioration in their physical functioning. An improvement was noted in improved ability to physically function in obese patients ( $20\pm 21$ ,  $p<0.05$ ), in contrast to a decrease in the same domain for mobile patients ( $-3\pm 13$ ,  $p<0.05$ ). Mendonca et al. concluded that using NPWT could potentially reduce quality of life due to the decrease seen in the physical functioning domain; however, the study had a small sample size, leading to greater imprecision in parameter estimates.

Our results identified that there were no real differences in quality of life scores recorded by patients over the 12 week period. Although there was no overall interaction between the therapies used for wound healing, NPWT did have an effect on social life: during the first 2 weeks of the application of therapy, patients in the NPWT group reported an increase in the social life domain. Interestingly Hopkins et al. (23), during their phenomenological study of patients with living with pressure ulceration, identified that *nurses' visit restricted participants' lives and reduced their ability to remain involved in their social activities*. Furthermore, Franks et al. (24), in their study of quality of life in patients with leg ulceration, established that social isolation changed little in all groups over

the follow-up period. Franks et al. discuss that the term *social isolation* is often used as a proxy for loneliness and lack of social support and that it has a negative impact on patients.

Perceived levels of social support in patients with leg ulceration have been investigated by Moffatt et al. (25), who identified that patients with a larger social network had an increased chance of healing. This may be attributed to the nurse visiting regularly to care for the therapy and differences in quality of life: patients living alone and receiving standard therapy report substantially lower quality of life scores than patients living with their families and receiving standard therapy; patients living alone and receiving NPWT report very similar quality of life scores to patients living with their families and receiving standard therapy. It is difficult to ascertain why these results were obtained, as data collected in this largely quantitative study does not allow for the same level of rich analysis as qualitative research. As such the authors would suggest future studies use a blended approach to data collection, perhaps by combining a number of semi-structured patient interviews in order to gain a greater understanding of the background data that may have an effect or impact on patient responses: for example, levels of exudate, pain or odour.

The difficulty surrounding in-depth interpretation of the data may have been due to the small sample size or insufficient sensitivity of the CWIS tool. The tool was designed to collect quality of life data on patients living with a wound, not specifically those living with a wound and a device. It is also difficult to draw conclusions as we have no baseline data for patients - either pre-wound data or pre-NPWT with which to compare responses, and this is a recommendation for future studies.

There is no doubt that quality of life is dependent on functioning in many domains, and differs from patient to patient, as can be evidenced in the new consensus document on optimising wellbeing *in people living with a wound* (26). It suggests that those living with a wound face major changes in their everyday lives and need to integrate a number of treatment-related procedures that may be difficult to adopt long term and conflict with existing lifestyles, priorities and behaviours. Whilst clinicians measure and record data about the wound, such as the reduction in size and depth, and appearance of the wound bed, Wellbeing and Quality of Life are more difficult to define and capture. It recommends that clinicians develop a shared approach in order to meet the wide-ranging needs of people living with a wound and emphasises the need for a shared approach to optimise wellbeing. Additionally this approach will require clinicians, healthcare organisations and industry to:

- Work with individuals living with a wound to identify and address their concerns;
- Engender concordance through empowerment and choice;

- Implement an effective treatment plan through shared decision-making with individuals living with a wound (p.5).

It could be argued that such small differences were found in this study as a result that patients had developed a therapeutic relationship and that the patients were satisfied with the level of care. However it must be acknowledged that QoL is probably affected by wound healing much more than it is affected by type of therapy. Hence the true worth of NPWT should be evaluated by a comparison of wound healing times – which would require many more patients of both types of therapy who kept NPWT right up to wound healing. We would need cases of both healed and unhealed wounds treated by both NPWT and standard therapy to make meaningful comparisons. Also acknowledged is the mean duration of some of the patients wounds would indicate the chronic nature of the problem and this may have impacted on perceived quality of life in these patients. In general, QoL scores were negatively correlated with wound duration, with stronger correlations observed between wound duration and overall QoL scores than between wound duration and any of the individual components of the CWIS scale. However, most correlations were weak and not statistically significant.

QoL can and is affected by many factors: disease process, social factors, intelligence, expectations, anxiety and depression, patient involvement, perceived control. It would be difficult for any study to measure all of these factors and to accurately ascertain the relative impact of each. To do so would necessitate a healthy baseline pre disease questionnaire, a *living with chronic disease* questionnaire, pre-wound and post-wound questionnaires, coupled with an analysis of intelligence, coping, social interaction and other complex factors such as perceived relationships with healthcare professionals and the level of inclusion in decision making with regard to patient care. Interestingly all NPWT patients achieved better social life scores than patients receiving standard therapy during week 1. The researchers were surprised by this; however without any supporting evidence we can only surmise why this may be the case. It could be because the patient felt more confident to go out? It could be due to exudate containment? It is hypothesised that QoL scores may have been different some years ago with larger devices. We have also reported that the NPWT group consisted of younger patients, as such the socialisation element may be purely age-related and not device-related. What is interesting is the assumption that living alone could potentially preclude patients from NPWT in practitioners' minds from a risk management perspective. The introduction of smaller more patient-friendly devices to the market place may affect this in future years, allowing treatment to a greater patient population, and future studies should seek to explore these aspects of care.

As such the authors conclude that true QoL can only be elicited if an accurate baseline is established, or if data is collected over a long enough period to allow comparison of scores over time, In relation to patients with wounds they should be followed until the wound healing is achieved: as such the score with the wound could be then compared to that of the patients' life post-wounding. However if the incident that led to the wound has a larger impact on QoL than the wound itself, then the wound may be incidental to the effect on quality of life scores.

### **Limitations**

This was a small pilot study and as such does not allow for all potentially influencing factors to be considered: for example, size of the wound, how long the patient has had the wound, gender and age; a large scale study would be able to account for these. To account for all potentially influencing factors, a full-scale regression-based study would be likely to require at least 200 patients completing the 12-week follow-up period; a higher number would be required for a study which accounted for time to wound healing, with significant numbers of cases of both healed and unhealed wounds treated with both NPWT and standard therapy. It would have been beneficial if baseline quality of life scores had been recorded rather than relying on scores documented after week 1. It could be argued that the study engendered the Hawthorne effect (27) on participants and that the individuals involved may have changed their behaviour due to the attention they were receiving from researchers, rather than because of any manipulation of independent variables. However this could be argued for any study and as such can never be truly eliminated without randomisation and double blinding and added study complexity.



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