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Five-year outcomes for patients sustaining severe fractures of the lower limb from the Wound Healing in Surgery for Trauma (WHIST) trial

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Aims

The aims of this study were to report the outcomes of patients with a complex fracture of the lower limb in the five years after they took part in the Wound Healing in Surgery for Trauma (WHIST) trial.

Methods

The WHIST trial compared negative pressure wound therapy (NPWT) dressings with standard dressings applied at the end of the first operation for patients undergoing internal fixation of a complex fracture of the lower limb. Complex fractures included periarticular fractures and open fractures when the wound could be closed primarily at the end of the first debridement. A total of 1,548 patients aged ≥ 16 years completed the initial follow-up, six months after injury. In this study we report the pre-planned analysis of outcome data up to five years. Patients reported their Disability Rating Index (DRI) (0 to 100, in which 100 = total disability), and health-related quality of life, chronic pain scores and neuropathic pain scores annually, using a self-reported questionnaire. Complications, including further surgery related to the fracture, were also recorded.

Results

A total of 1,015 of the original patients (66%) provided at least one set of outcome data during the five years of follow-up. There was no evidence of a difference in patient-reported disability between the two groups at five years (NPWT group mean DRI 30.0 (SD 26.5), standard dressing group mean DRI 31.5 (SD 28.8), adjusted difference -0.86 (95% CI -4.14 to 2.40; p = 0.609). There was also no evidence of a difference in the complication rates at this time.

Conclusion

We found no evidence of a difference in disability ratings between NPWT compared with standard wound dressings in the five years following the surgical treatment of a complex fracture of the lower limb. Patients in both groups reported high levels of persistent disability and reduced quality of life, with little evidence of improvement during this time.

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Introduction

Complex fractures of the lower limb are associated with a high risk of complications,[1–3] and the cost of treating these injuries is extremely high for both patients and healthcare systems.[4–8]

The Wound Healing in Surgery for Trauma (WHIST) trial was a multicentre, randomized trial, embedded in the UK Major Trauma Network, which recruited patients aged ≥ 16 years with a complex fracture of the lower limb.[9] The trial compared two types of wound dressing, negative pressure wound therapy (NPWT) and standard dressings not involving negative pressure, which were applied at the end of the first surgical procedure after fixation of the fracture. The fractures included periarticular fractures and open fractures when the wound

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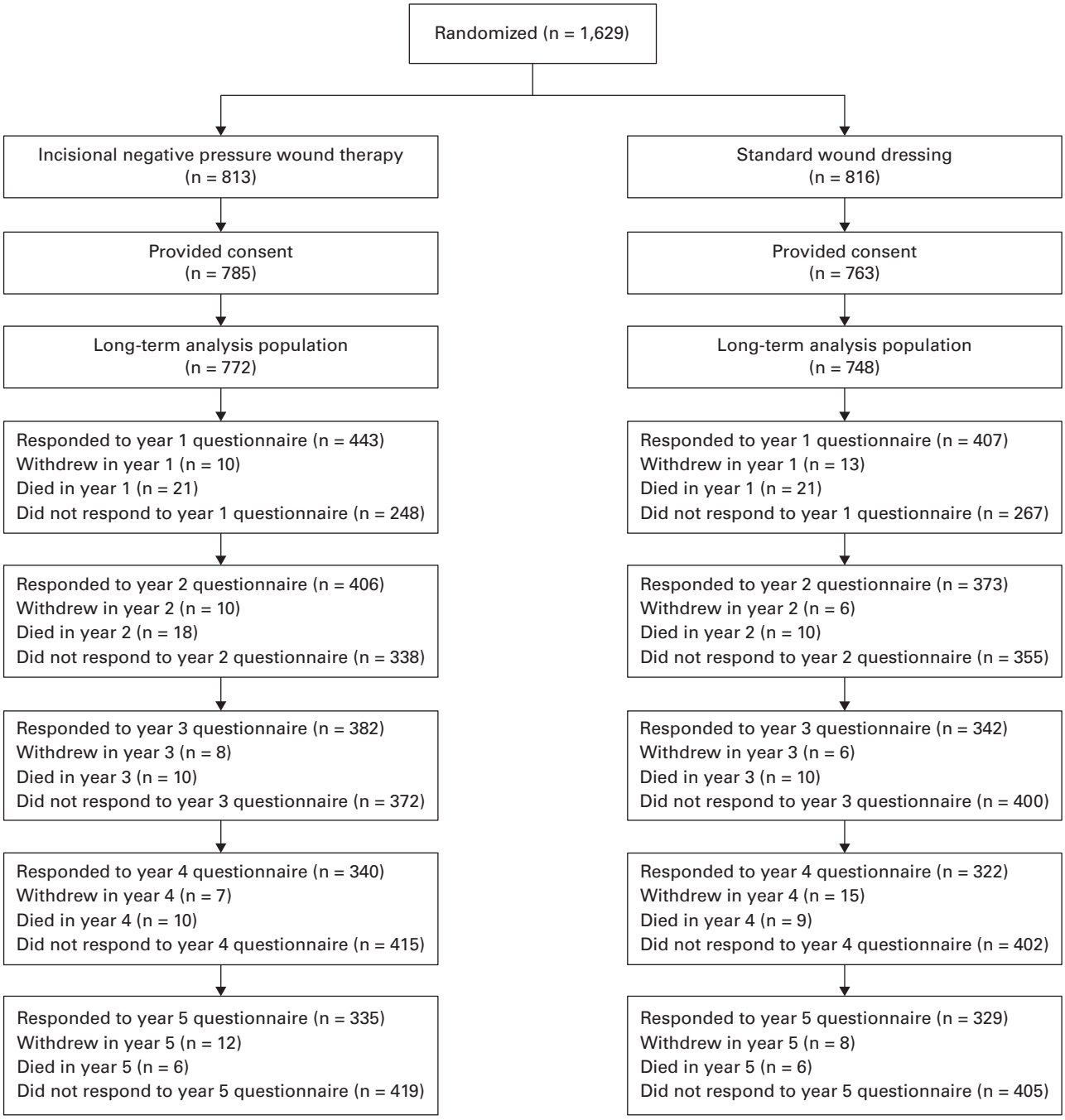

Fig. 1

Details of the patients who were analyzed at the different timepoints.

could be closed primarily at the end of the first debridement. The authors reported no statistically significant difference between the groups in the patients' Disability Rating Index (DRI)[10] or health-related quality of life six months after injury, at which time, however, they described high levels of disability and low quality of life compared with their pre-injury levels.[11] The aim of this study was to report the outcomes of the patients in this trial in a pre-planned analysis of the five-year follow-up.

Methods

The trial was approved by the National Research Ethics Service in England and registered with the International Standard Randomised Controlled Trials database (ISRCTN12702354). It was funded by the National Institute of Health and Care Research (ref. no. 14/199/14) and sponsored by the University of Oxford. A full description of the trial and its findings up to six months has been published.[11]

Table I. Baseline characteristics of the 1,015 patients reviewed at five years who returned at least one year follow-up questionnaire.

Characteristic	NPWT	Standard dressing
Patients, n	527	488
Sex, n (%)		
Male	306 (58.1)	301 (61.7)
Female	221 (41.9)	187 (38.3)
Mean age, yrs (SD)	50.5 (18.84)	50.1 (18.80)
Injury Severity Score ≤ 15, n (%)	414 (78.6)	391 (80.1)
Closed fracture, n (%)	429 (81.4)	396 (81.1)

NPWT, negative pressure wound therapy.

Table II. Analysis of Disability Rating Index, EuroQol five-dimension five-level health questionnaire utility score, EuroQol visual analogue scale from one to five years after injury.

Score	NPWT		Standard dressing		Adjusted difference (95% CI)	p-value*
	n	Mean (SD)	n	Mean (SD)		
DRI						
1 year	411	34.9 (27.6)	374	35.9 (28.5)	-1.84 (-4.94 to 1.27)	0.247
2 years	381	31.0 (26.7)	338	32.3 (28.1)	-1.07 (-4.25 to 2.11)	0.511
3 years	364	30.8 (26.7)	325	32.7 (28.4)	-1.93 (-5.15 to 1.29)	0.241
4 years	324	30.5 (26.8)	310	30.8 (27.7)	-0.42 (-3.71 to 2.87)	0.803
5 years	320	30.0 (26.5)	314	31.5 (28.8)	-0.86 (-4.14 to 2.43)	0.609
EQ-5D-5L utility						
1 year	442	0.59 (0.30)	401	0.59 (0.30)	0.01 (-0.03 to 0.04)	0.660
2 years	403	0.60 (0.30)	366	0.62 (0.28)	0.01 (-0.02 to 0.05)	0.485
3 years	379	0.67 (0.27)	340	0.64 (0.30)	0.03 (0.00 to 0.07)	0.069
4 years	335	0.67 (0.28)	314	0.67 (0.29)	0.01 (-0.03 to 0.04)	0.700
5 years	326	0.69 (0.26)	324	0.64 (0.33)	0.03 (0.00 to 0.07)	0.059
EQ- VAS						
1 year	441	70.3 (22.6)	406	70.7 (23.1)	0.08 (-2.61 to 2.77)	0.954
2 years	406	73.4 (21.2)	371	71.2 (22.9)	2.00 (-0.76 to 4.76)	0.156
3 years	381	73.1 (22.1)	342	71.8 (23.3)	1.14 (-1.69 to 3.96)	0.431
4 years	339	72.6 (22.6)	310	71.6 (23.7)	0.82 (-2.07 to 3.72)	0.578
5 years	335	74.3 (21.8)	328	71.7 (23.3)	1.28 (-1.61 to 4.17)	0.384

*Mann-Whitney U test.
DRI, Disability Rating Index; EQ-5D-5L, EuroQol five-dimension five-level health questionnaire; EQ-VAS, EuroQol visual analogue scale.

Table III. Pain scores from one to five years after injury.

Timepoint	NPWT			Standard dressing			p-value
	Mean (SD)	Median (IQR)	Total	Mean (SD)	Median (IQR)	Total	
1 year	2.8 (2.7)	2 (1 to 5)	439	2.9 (2.6)	2 (1 to 5)	404	0.381
2 years	2.6 (2.5)	2 (1 to 5)	405	2.6 (2.6)	2 (0 to 4)	370	0.983
3 years	2.5 (2.4)	2 (0 to 4)	379	2.5 (2.6)	2 (0 to 4)	342	0.987
4 years	2.2 (2.4)	1 (0 to 3)	336	2.5 (2.7)	1 (0 to 4)	321	0.675
5 years	2.1 (2.3)	1 (0 to 3)	334	2.4 (2.7)	1 (0 to 4)	328	0.483

*Mann-Whitney U test.
NPWT, negative pressure wound therapy.

A total of 1,548 patients were consented and randomized on a 1:1 basis to treatment either with NPWT or standard wound dressings, at the end of the first surgical procedure for their complex fracture of the lower limb. Patients were excluded if they presented > 72 hours after injury, their wound could not be primarily closed, or they were unable to adhere to the procedures involved in the trial. The five-year analysis included only those who consented to longer-term follow-up. Patients were excluded from this analysis if they were randomized in error, retrospectively declined consent, or withdrew and requested that their data should be removed, or consented to the reporting of routine data follow-up only.

Patients were followed up annually for five years after injury. Outcome data, including scores for disability, quality of life, pain, and complications, were collected by postal or electronic questionnaires with telephone follow-up for non-responders.

The primary outcome measure was the patient-reported DRI, which is a self-administered, 12-item visual analogue scale (VAS) questionnaire assessing the patients' rating of their disability.[10] For each item, they score their ability to carry out

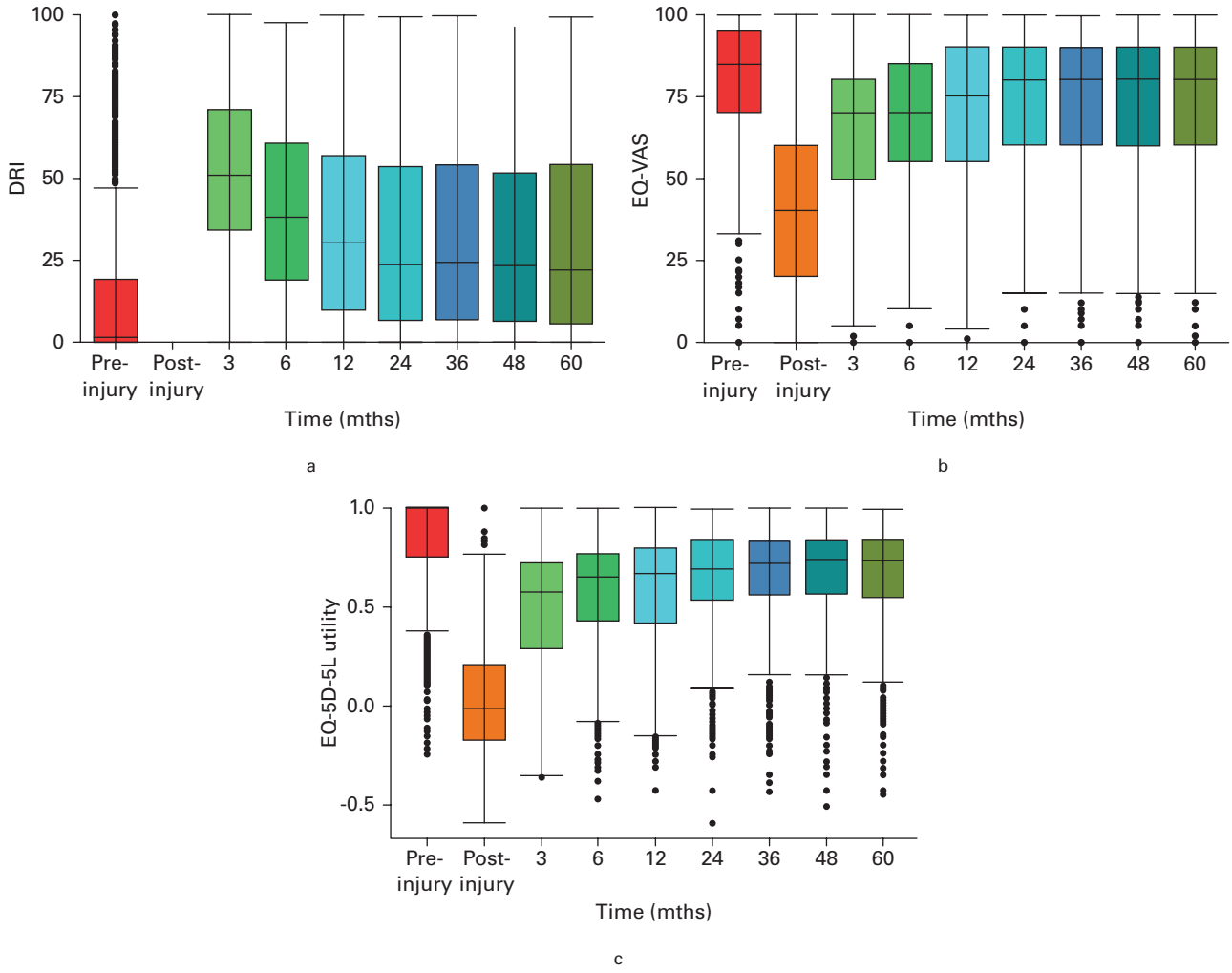

Fig. 2

Boxplots of pooled Disability Rating Index (DRI), EuroQol five-dimension five-level (EQ-5D-5L) utility and visual analogue scale (VAS) scores over the five years of follow-up. Pre-injury, post-injury, three and and six month data have also been added. The DRI was collected post-injury.

the activity from 0 (without difficulty) to 100 (not at all). Total DRI scores are calculated as a mean across all items, with higher scores indicating greater disability.

There were four secondary outcome measures. The first was the EuroQol five-dimension five-level questionnaire (EQ-5D-5L), a validated measure of health-related quality of life consisting of a five-dimension classification system with five levels of response (EQ-5D-5L utility) and a separate VAS (EQ-VAS).[12,13] These responses were converted to multi-attribute utility (MAU) scores using tariffs currently under development for England.[4] The scale is such that 1 is equivalent to perfect health, 0 is equivalent to death, and negative scores are possible. The EQ-VAS ranges from 0 (worst health) to 100 (best health).

The next secondary outcome was pain (VAS). Patients rated their pain "today" on an 11-point (0 to 10) scale where 0 represents "no pain" and 10 represents "pain as severe as you can imagine."

The third secondary outcome was the Doleur Neuropathique Questionnaire (DN4), a short validated neuropathic pain screening tool comprising seven questions.[14] This tool is recommended by the International Association for the Study of Pain (IASP).[15] Each question has a yes/no answer option, and total scores are the number of questions which are answered with "yes". Scores of > 3 are likely to be indicative of neuropathic pain.

The final outcome measure was complications. Patients were asked to report on wound-healing complications, antibiotic use, further surgery, and any other related complications using a short series of yes/no questions. The complications were verified by the recruiting hospital team where possible.

Statistical analysis. All the analyses were performed according to the intention-to-treat (ITT) principle using available patients only. Means and SDs of DRI scores, at each year of follow-up, were used to assess temporal trends during the study. A similar approach was also used for EQ-5D-5L utility and EQ-VAS

Table IV. Analysis of Douleur Neuropathique Questionnaire scores from one to five years after injury.

Timepoint	NPWT		Standard dressing		OR (95% CI)		p-value
	n (%)	Total	n (%)	Total	Raw	Adjusted	
1 year	133 (30.2)	441	119 (29.5)	403	1.03 (0.77 to 1.38)	1.19 (0.68 to 2.10)	0.532
2 years	122 (30.8)	396	110 (29.9)	368	1.04 (0.77 to 1.42)	0.98 (0.55 to 1.75)	0.949
3 years	117 (30.7)	381	109 (32.0)	341	0.94 (0.69 to 1.29)	0.76 (0.42 to 1.38)	0.370
4 years	90 (26.7)	337	102 (31.8)	321	0.78 (0.56 to 1.10)	0.62 (0.34 to 1.14)	0.126
5 years	96 (28.8)	333	93 (28.4)	328	1.02 (0.73 to 1.43)	1.10 (0.60 to 2.05)	0.755

NPWT, negative pressure wound therapy; OR, odds ratio.

Table V. Complications over time by treatment group.

Complication	NPWT	Standard dressing
Problem with wound healing, n (%)		
1 year	46 (6.0)	37 (4.9)
2 years	33 (4.3)	24 (3.2)
3 years	22 (2.8)	11 (1.5)
4 years	17 (2.2)	15 (2.0)
5 years	13 (1.7)	15 (2.0)
Antibiotics for problem with wound, n (%)		
1 year	27 (3.5)	20 (2.7)
2 years	16 (2.1)	16 (2.1)
3 years	13 (1.7)	8 (1.1)
4 years	10 (1.3)	7 (0.9)
5 years	8 (1.0)	7 (0.9)
Surgery under GA for problem with wound, n (%)		
1 year	15 (1.9)	21 (2.8)
2 years	10 (1.3)	17 (2.3)
3 years	14 (1.8)	8 (1.1)
4 years	9 (1.2)	4 (0.5)
5 years	5 (0.6)	6 (0.8)
Further surgery because of fracture, n (%)		
1 year	42 (5.4)	27 (3.6)
2 years	45 (5.8)	54 (7.2)
3 years	14 (1.8)	10 (1.3)
4 years	14 (1.8)	12 (1.6)
5 years	10 (1.3)	8 (1.1)
Other complications, n (%)		
1 year	105 (13.6)	109 (14.6)
2 years	106 (13.7)	87 (11.6)
3 years	70 (9.1)	60 (8.0)
4 years	53 (6.9)	47(6.3)
5 years	52 (6.7)	54 (7.2)

GA, general anaesthetic; NPWT, negative pressure wound therapy.

scores. DRI and EQ-5D scores from baseline (pre-injury) to five-year follow-up were analyzed with multilevel mixed-effects linear regression models using repeated measures over time (level 1) nested within patients (level 2). Data from all timepoints, including the short-term follow-ups at three and six months, were included in these models. The models included a random effect to account for any heterogeneity in response due to recruitment centre (level 3), and fixed effects to adjust for open versus closed fractures, Injury Severity Score (ISS) level (≤ 15 vs ≥ 16), the patient's age, sex, and pre-injury scores. Time was included as a categorical variable, and a treatment-by-time interaction was included in the model.

For each treatment group, means and SDs are reported at each annual follow-up, and adjusted differences between groups with associated 95% CIs and p-values are also reported. Pain scores were summarized for each group at each timepoint using means, SDs, medians and IQRs. The two groups were compared at each timepoint using a Mann-Whitney U test and p-values were calculated based on the normal approximation.

The number and proportion of patients in each group with neuropathic pain (i.e. DN4 ≥ 3) at each follow-up timepoint (one to five years) was calculated. A multilevel mixed effect logistic regression model with repeated measures (level 1) nested within patients (level 2) was used to compare rates of neuropathic pain in the two groups. The model was adjusted for recruitment centre as a random effect (level 3), and fixed effects were included to adjust for open versus closed fractures, ISS level (≤ 15 vs ≥ 16) and the patient's age and sex. Data from all timepoints, including the short-term follow-ups at three and six months, were included in this model.

Results are presented as odds ratios (ORs) with associated 95% CIs. The unadjusted OR and associated 95% CIs are also reported. Complications were summarized based on the total numbers of patients reporting each adverse event, with no formal test of association due to the low numbers in the groups. All tests were two-sided and significance was assessed at the 5% level. All analyses used complete-case data and were implemented in R Statistical Software v. 4.3.1 (R Foundation for Statistical Computing, Austria) and Stata Release 17 (StataCorp, USA).

Results

Of the original 1,548 patients in the WHIST trial, 1,520 (98.2%) were eligible to be reviewed five years after injury and 1,015 (66.8%) returned at least one follow-up questionnaire (Figure 1).

The baseline demographic data of the 1,015 patients whose results at five years were included in the analysis are shown in Table I.

Compared with the patients in the first phase of the WHIST trial (n = 1,548), those who completed this five-year follow-up (n = 1,015) were of a similar age (mean 49.8 years (SD 18.8) vs 50.3 years (SD 20.3)) and reported similar pre-injury DRI scores (13.22 (SD 22.63) vs 14.94 (SD 24.19)). The proportion of male and female patients who took part in the longer-term follow-up was similar to those in the first phase (males 60% vs 62%).

Of the 1,015 patients who were alive and willing to provide longer-term follow-up data, 850 (84%) were followed up at one

year and 664 (65%) completed questionnaires at five years: 335 from the NPWT group and 329 from the standard dressing group. There were 121 deaths: 65 in the NPWT group and 56 in the standard treatment group (Figure 1).

Means, SDs, and differences for the DRI, EQ-5D utility, and VAS scores for years 1 to 5 are shown in Table II. There was no evidence of a difference between the scores in the two groups at each year of follow-up.

Figure 2 shows the pooled data from both groups, including both short- and long-term outcomes. Pre-injury and, where available, post-injury (collected after consent was provided) values are included. Regarding the trajectory of recovery over the five years, there was little evidence of improvement in DRI or EQ-5D scores after the first year.

Pain scores, as measured with a VAS, are summarized in Tables III and IV. There was no evidence of a difference in pain scores or neuropathic pain scores between the groups at any timepoint during the five years.

The patients reported persistent pain, with high levels of neuropathic symptoms throughout follow-up and little evidence of improvement after the first year. The number and proportion of those reporting complications, or treatment for complications, in each group at each timepoint are summarized in Table V.

There was no evidence of a difference between the rates of complication in the two groups during the five years of follow-up. Complications requiring a medical intervention for wound-healing problems or related to the fracture were most common in the first two years after the injury and became less frequent with the passage of time. In the first year, 42 patients (5.4%) in the NPWT group and 27 (3.6%) in the standard dressing group had further surgery related to their fracture, mostly for removal of symptomatic metalwork. In the second year, this was 42 (5.4%) in the NPWT group and 54 (7.2%) in the standard dressing group. There was a similar pattern with regard to wound-healing complications.

Discussion

In keeping with the findings of the WHIST trial at six months, this five-year follow-up study showed no evidence of a difference in patient-reported disability between patients treated with NPWT and those treated with standard dressings following internal fixation of a complex fracture of the lower limb. There was also no evidence of a difference between the groups in health-related quality of life, pain, or complications related to their treatment.

Reviewing the overall outcomes of the patients in this trial provides an insight into the recovery of patients with these injuries more broadly. There was some improvement in disability between six and 12 months, but patients still reported a level of total disability of about 35%, one year after injury. There was also very little change thereafter up to five years. Health-related quality of life showed a similar pattern, with little change in EQ-5D utility or VAS scores after the first 12 months. The patients reported persistent pain and high levels of neuropathic pain, which remained five years after injury.[16] This is important information for patients and clinicians who may be expecting continued recovery during this period.

With regard to complications, about 10% of patients in both groups required further surgery related to their fracture in the first two years. This was mostly for the removal of symptomatic metalwork, but a few patients required other surgery for delayed fracture healing. A similar proportion also required further surgery related to their wound in the first two years. However, only about 5% were treated with antibiotics during this time, suggesting that only half of these procedures were likely to have been related to local infection.

The strengths of this study include the reporting of patient-reported outcomes and the further operations in a well-defined cohort of patients. The main limitation is the fact that only 66% of the 1,548 patients from the original study were willing to provide follow-up data during the five years of follow-up. This percentage is in keeping with other mid-term follow-up studies involving musculoskeletal trauma, in which patients are reluctant to commit to answering questionnaires beyond the early phases of their rehabilitation.[2,3,17] Since the number of patients who took part in this mid-term study was less than the number in the original report six months after injury, the CIs for the difference between the procedures are wider. Thus, this study did not have the same statistical power to detect subtle differences in outcome as the original report.

In conclusion, in this five-year follow-up study, we found no evidence of a difference in disability, quality of life, pain or the requirement for further surgery between patients treated with NPWT dressings compared with standard dressings following fixation of a complex fracture of the lower limb. There were also high levels of disability and reduced quality of life in the early stages of recovery after these serious injuries which persisted with little improvement between two and five years. Furthermore, there often remained chronic pain and neuropathic symptoms five years after injury. Patients and clinicians need to be aware of these long-term outcomes when discussing the rehabilitation and prognosis after the treament of these injuries.

Take home message

- This five-year follow-up study found no evidence of a difference in disability, quality of life, pain, or the requirement for further surgery between patients treated with negative pressure wound therapy versus standard dressings following fixation of a complex fracture of the lower limb.
- However, participants reported persistently high levels of chronic pain and neuropahtic symptoms at five years after their injury.

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References

1. **Trompeter AJ**, **Knight R**, **Parsons N**, **Costa ML**. The Orthopaedic Trauma Society classification of open fractures. *Bone Joint J*. 2020;102-B(11):1469–1474.
2. **Parsons N**, **Achten J**, **Costa ML**, **Collaborators F**. Five-year outcomes for patients with a displaced fracture of the distal tibia. *Bone Joint J*. 2023;105-B(7):795–800.
3. **Costa ML**, **Achten J**, **Parsons NR**, **Collaborators W**. Five-year outcomes for patients sustaining severe fractures of the lower limb: mid-term results from the Wound management for Open Lower Limb Fracture (WOLLF) trial. *Bone Joint J*. 2022;104-B(5):633–639.
4. **Parker B**, **Petrou S**, **Masters JPM**, **Achana F**, **Costa ML**. Economic outcomes associated with deep surgical site infection in patients with an open fracture of the lower limb. *Bone Joint J*. 2018;100-B(11):1506–1510.

5. **MacKenzie EJ**, **Castillo RC**, **Jones AS**, **et al**. Health-care costs associated with amputation or reconstruction of a limb-threatening injury. *J Bone Joint Surg Am*. 2007;89-A(8):1685–1692.
6. **Png ME**, **Madan JJ**, **Dritsaki M**, **et al**. Cost-utility analysis of standard dressing compared with incisional negative-pressure wound therapy among patients with closed surgical wounds following major trauma to the lower limb. *Bone Joint J*. 2020;102-B(8):1072–1081.
7. **Petrou S**, **Parker B**, **Masters J**, **et al**. Cost-effectiveness of negative-pressure wound therapy in adults with severe open fractures of the lower limb: evidence from the WOLLF randomized controlled trial. *Bone Joint J*. 2019;101-B(11):1392–1401.
8. **Png ME**, **Petrou S**, **Knight R**, **Masters J**, **Achten J**, **Costa ML**. Economic outcomes associated with deep surgical site infection from lower limb fractures following major trauma. *Bone Jt Open*. 2022;3(5):398–403.
9. **Costa ML**, **Achten J**, **Knight R**, **et al**. Effect of incisional negative pressure wound therapy vs standard wound dressing on deep surgical site infection after surgery for lower limb fractures associated with major trauma: the WHIST randomized clinical trial. *JAMA*. 2020;323(6):519–526.
10. **Salén BA**, **Spangfort EV**, **Nygren AL**, **Nordemar R**. The Disability Rating Index: an instrument for the assessment of disability in clinical settings. *J Clin Epidemiol*. 1994;47(12):1423–1435.
11. **Costa ML**, **Achten J**, **Knight R**, **et al**. Negative-pressure wound therapy compared with standard dressings following surgical treatment of major trauma to the lower limb: the WHiST RCT. *Health Technol Assess*. 2020;24(38):1–86.
12. **Brooks R**, **Charro F**. EuroQol: the current state of play. *Health Policy*. 1996;37(1):53–72.
13. **Dolan P**. Modeling valuations for EuroQol health states. *Med Care*. 1997;35(11):1095–1108.
14. **Bouhassira D**, **Lantéri-Minet M**, **Attal N**, **Laurent B**, **Touboul C**. Prevalence of chronic pain with neuropathic characteristics in the general population. *Pain*. 2008;136(3):380–387.
15. **Haanpää M**, **Attal N**, **Backonja M**, **et al**. NeuPSIG guidelines on neuropathic pain assessment. *Pain*. 2011;152(1):14–27.
16. **Keene DJ**, **Knight R**, **Bruce J**, **et al**. Chronic pain with neuropathic characteristics after surgery for major trauma to the lower limb: prevalence, predictors, and association with pain severity, disability, and quality of life in the UK WHiST trial. *Bone Joint J*. 2021;103-B(6):1047–1054.
17. **Costa ML**, **Achten J**, **Rangan A**, **Lamb SE**, **Parsons NR**. Percutaneous fixation with Kirschner wires versus volar locking-plate fixation in adults with dorsally displaced fracture of distal radius: five-year follow-up of a randomized controlled trial. *Bone Joint J*. 2019;101-B(8):978–983.

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Data sharing:
The data that support the findings for this study are available to other researchers from the corresponding author upon reasonable request.

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