International Journal of Orthopaedic and Trauma Nursing 33 (2019) 44–51

Contents lists available at ScienceDirect

International Journal of Orthopaedic and Trauma Nursing

journal homepage: www.elsevier.com/locate/ijotn

# Patient-reported symptoms of 'calm', 'irritated' and 'infected' skeletal external fixator pin site wound states; a cross-sectional study

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ARTICLE INFO

*Keywords:*
Pin sites
Percutaneous wounds
Wound infection
External fixation
Symptoms
Dermatitis

ABSTRACT

*Objective:* To explore the frequency, severity and variances in patient-reported symptoms of calm, irritated and infected skeletal pin sites.
*Methods:* A cross-sectional within-subjects repeated-measures study was conducted, employing a self-report questionnaire. Patients (n = 165) treated with lower limb external fixators at 7 English hospitals completed a designed questionnaire. Three sets of retrospective repeated-measures data were collected relating to calm, irritated and infected pin sites.
*Results:* Significant differences were revealed between each of the three pin site states (calm, irritated & infected) in the degree of: redness, swelling, itchiness, pain, wound discharge, heat/burning, shiny skin and odour. In relation to difficulty or pain using the affected arm or leg, difficulty weight bearing on the leg, nausea and/or vomiting, feeling unwell or feverish, shivering, tiredness/lethargy and disturbed sleep, significant differences were demonstrated between infected and irritated states and infected and calm states, but not between irritated and calm.
*Conclusions:* The findings provide greater depth of understanding of the symptoms of pin site infection and irritation. Patients may be able to differentiate between different pin site states by comparing the magnitude of the inflammatory symptoms and the presence of other specific symptoms that relate solely to infection and no other clinical state. The irritated state is probably caused by a different pathological processother than infection and may be an indication of contact dermatitis.

## Introduction

This paper reports on a study aiming to explore the patient-reported symptoms of *calm, irritated and infected* skeletal external fixator pin site wound states. External fixation is an approach to the management of skeletal injury and deformity involving the insertion of pins or wires that penetrate soft tissue and bone and are held in place with an external metal framework, often over several months (Timms et al., 2011). Percutaneous wounds, formed at the interface between the pin or wire and the skin, present significant opportunity for infection. Early diagnosis of pin site infection facilitates rapid treatment and avoidance of the spread of infection and development of osteomyelitis (Kazmers et al., 2016). Diagnostic criteria are needed for infection and other wound problems, but there is currently limited information about the nature, frequency and severity of symptoms (Santy, 2010; Lethaby et al., 2013) and uncertainty about the difference between the symptoms of infection and of foreign body reaction to the skeletal implanted wires or pins (Anderson et al., 2008).

## Background

Pin site infection is a common complication of external fixation, with worldwide incidence varying from 10% to 100% (Britten et al., 2013; Wu et al., 2017). Factors contributing to the development of infection include; exposure of subcutaneous tissue, the implanted material and the interface between the implant and tissue (Fleckman & Olerud 2008). Superficial infection can track down to the bone, leading to osteomyelitis - a complication that can become chronic, prevent bone healing and lead to long term pain and disability (Fenton et al., 2007).

Diagnosis is central to early management of infection and aims to discriminate between infection and other wound states. This usually involves one of two approaches; 1) assessment of the clinical symptoms,

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https://doi.org/10.1016/j.ijotn.2019.01.002
Received 4 October 2018; Accepted 12 January 2019
1878-1241/ 

and, 2) microbiological analysis of wound samples. Microbiology confirms the presence of organisms in or around the wound, but does not provide information about any detrimental effect on host tissue (Sibbald et al., 2003, Bessa et al., 2013), making it an unreliable approach to distinguishing between colonisation and infection. The symptoms of infection include pain, redness, swelling and purulent discharge (Stevens et al., 2014). Apart from purulent discharge, these can also signify the inflammatory response to the presence of the pin or wire which cannot easily be differentiated from infection. This has not been empirically explored in pin site wounds, although there is some discussion about the difference between wound infection and pin 'reaction' (Patterson, 2005; Britten et al., 2013). Ongoing tissue irritation can trigger inflammatory responses (Gardner et al., 2001), so the presence of inflammatory symptoms can be due to other sources besides infection.

There is no 'gold' standard test for wound infection. Wound tissue biopsy has been used as a reference standard in chronic wounds, but biopsy is too invasive for use in percutaneous wounds. Research comparing tissue biopsy and wound swabbing has shown test specificity and sensitivity to be inadequate and the methodological quality of many studies considering the diagnosis of infection in all types of wounds is poor due to the use of inappropriate reference standard tests, lack of clarity in defining positive results and problems with concurrent use of antimicrobials (Nelson et al., 2006). Study findings are rarely based on data relating to patient experience of symptoms. One grounded theory study (Santy-Tomlinson et al., 2011) explored patients' experiences of the symptoms of suspected wound infection in external fixator pin sites. Participants described three categories of the clinical state of pin sites; 1) calm 2) irritated 3) infected. Each clinical state was described with reference to the presence and magnitude of pain, redness, discharge, swelling and general symptoms (see Table 1).

Diagnostic criteria are needed to discriminate between a wound that is infected and one that is not. Five published assessment schemes claim to identify and categorise pin site infections (Saleh and Scott, 1992; Checketts et al., 1993; Dahl et al., 1994; Patterson, 2005; Clint et al., 2010). These are usually focused on inflammatory symptoms, but none have been empirically developed, with no attempt to examine their internal and external validity or reliability (Ktistakis et al., 2015). The tools employ rudimentary definitions of infection that do not consider detail about the nature of the symptoms. All recognise phenomena such as pain and redness, but do not differentiate between infection and foreign body reaction. Items in the existing tools are based on clinician, rather than patient, experience. Streiner & Norman (2008) point out that patients are often overlooked in the development of items in assessment tools, highlighting the value of illuminating their experiences through exploratory work to enable a better understanding of each symptom and facilitate more accurate diagnosis of infection.

## Methods

### Aim

To explore the frequency severity and variances in patient-reported symptoms of *calm, irritated and infected* pin sites.

### Design

A cross-sectional within-subjects, repeated-measures study was conducted, employing a self-report postal questionnaire. Data were collected relating to patients' experiences of the symptoms of calm, irritated and infected pin site wounds.

### Setting and participants

A purposive sample of adult volunteers reaching the end of their treatment with an external fixator was recruited from seven English hospital trauma outpatient departments. Inclusion criteria were: 1) adults over 18 years of age with an external fixator; 2) at least one external fixation device had been in situ for at least 6 weeks and, 3) considered to be reaching the end of their treatment with the external fixator.

The most important symptom of infection, indicated by participants in an earlier study (Santy-Tomlinson et al., 2011), was moderate or severe pain, and clinicians involved in the pilot of the questionnaire considered that this would occur in 80% of respondents. A minimum sample size of 150 was proposed, which would allow the estimation of this percentage with a 95% confidence interval of ± 6.4%.

### Data collection

Data were collected using questionnaire that was designed using the findings of an earlier grounded theory study (Santy-Tomlinson et al., 2011) conducted by two of the present authors as part of a mixed methods study from which three clinical pin site states; *calm* (absence of infection with no, or minimal, symptoms), *irritated* (moderate signs of inflammation, but not infected) and *infected* (severe symptoms suggesting an inflammatory response to infection) were identified (see Table 1). In addition to questions relating to patient characteristics, their treatment and their experience of infection, the questionnaire contained three sections asking participants to retrospectively record the presence and severity of the symptoms they experienced when their pin sites had been; a) infected, b) irritated or c) calm. The same set of questions was asked in each of the three sections using five-point ordinal scales (0 = no symptoms to 4 = extreme symptoms), enabling reporting of the magnitude of; redness, swelling, itchiness, pain, wound discharge, hot or burning, shiny skin, dry flaky skin and odour. Dichotomous (yes/no) responses were also sought for the presence of; difficulty or pain using the affected leg, difficulty in bearing weight on the leg, nausea/vomiting, feeling unwell, feeling feverish, shivering, tiredness/lethargy and disturbed sleep. To enhance its validity, the wording used in the questionnaire was derived from terminology commonly used by participants in the earlier study (Santy-Tomlinson et al., 2011). The questionnaire was reviewed for face and content validity by twenty clinical experts, piloted with 10 patients and revised accordingly.

### Ethical considerations

Both national NHS (UK National Health Service) research ethics and institutional approval were obtained for all study hospitals. Participants were informed of their right to decline to participate at any time and consent was implied by returning the questionnaire.

**Table 1**
Patient descriptions of three clinical pin site states

| | |
|---|---|
| Calm | Absence of infection: absence of, or minimal, pain, redness, discharge, swelling without other symptoms |
| Irritated | Moderate signs of inflammation, but not infected: mild to moderate pain redness, discharge, swelling along with dry flaky skin and itchiness which did not respond to antimicrobials. |
| Infected | Severe symptoms suggesting inflammatory response to infection: severe pain, 'angry' redness, increased (which may be purulent), diffuse swelling and feeling generally unwell. |

**Table 2**
Distribution of respondents across study sites

| Hospital | n | % |
|---|---|---|
| A | 20 | 12.1 |
| B | 17 | 10.3 |
| C | 5 | 3.0 |
| D | 24 | 14.5 |
| E | 7 | 4.2 |
| F | 13 | 7.9 |
| G | 78 | 47.3 |
| Missing | 1 | 0.6 |
| Total | 165 | 100.0% |

*Data analysis*

Analysis was conducted using IBM SPSS Statistics version 22.0. Descriptive statistics enabled summary of the sample and the nature, frequency and severity of symptoms in each of the three pin site states. For ordinal data, Friedman's tests were used to compare the variances between scores for each of the pin site states (independent variables) for redness, swelling, itchiness, pain, wound discharge, heat/burning, shiny skin, dry/flaky skin and odour (dependent variables). Pairwise Wilcoxon signed rank tests with Bonferroni corrections were used to make post-hoc comparisons between the wound states. To explore the variances between the three sets of responses, dichotomous data were subjected to Cochran's Q tests with post hoc pairwise McNemar's tests.

## Results

Of 428 patients who were offered a questionnaire, 165 responded (response rate 38.5%). The number of respondents from each study hospital is shown in Table 2. Differences in numbers reflect the nature of the unit at each hospital and the timing of joining the study. Table 3 provides a summary of the characteristics of the sample.

The frequency and magnitude of redness, swelling, itchiness, pain, wound discharge, heat/burning, shiny skin, dry/flaky skin and odour (ordinal variables) are shown in Table 4.

Difficulty or pain using the affected leg, difficulty in bearing weight on the leg, nausea/vomiting, feeling unwell, feeling feverish, shivering, tiredness/lethargy and disturbed sleep (dichotomous variables) in Table 5.

**Table 3**
Participant and treatment profile

| Participant age | Mean 45.8 yrs (range 18–74 yrs) |
|---|---|
| Type of fixator | Lower limb 100%<br>Comprising:<br>Entirely lower leg: 84.8%<br>Lower leg including foot: 11.5%<br>Lower leg including ankle: 29.7%<br>Lower leg including knee: 12.1%<br>Upper leg: 9.1%<br>Upper limb: none |
| Weeks since application of external fixator | Mean 20 weeks (range 7–30 weeks) |
| Pin site state experience: | |
| Infection | n = 106 (64.2%) |
| Irritation | n = 129 (78.2%) |
| Calm | n-163 (98.8%) |
| Time between infection and responding to questionnaire | Within 35 days of the start of an infection: n = 65 (60.8%) |
| Antibiotic therapy | Had taken antibiotics n = 103 (96.3%)<br>Antibiotics: had worked: n = 72 (67.3%)<br>partly worked: n = 21 (19.6%)<br>had not worked: n = 8 (7.5%)<br>did not answer: n = 9 (5.8%) |

*Variance in experience of reported symptoms*

The results of Friedman's tests for all ordinal variables (skin-tissue related symptoms) are shown in Table 6. Redness, swelling, pain, wound discharge, heat and burning, shiny skin and odour (odour) were a feature of all three pin site states. The magnitude of these symptoms was most severe in infected pin sites, less severe in irritated pin sites and not present at all, or minor, in calm pin sites. Itchiness was a feature of all three states but was of greater magnitude in irritated pin sites than infected pin sites and least severe, although still present, in calm pin sites. Difficulty or pain in using the affected leg was a feature of all three states, but greatest when there was an infection, less so when there was irritation and even less when sites were calm. Nausea and vomiting, feeling unwell, feeling feverish and shivering were largely features of infection. Tiredness and lethargy were significant features of pin site infection and less so, but still considerable, for irritation and calmness. Disturbed sleep was worst with infection, but remained a problem for those with irritated and calm pin sites.

Redness, swelling and pain showed the greatest variability between the three states and the magnitude was highest for infection, less for irritation and none or much lower for the calm state. Significant variance was identified in the magnitude of symptoms between all three pin site states for redness, swelling, itchiness, pain, wound discharge, heat and burning, shiny skin and odour. For dry, flaky skin there was significant variance between infected and calm and irritated and calm, but not between irritated and infected. Wound discharge and shiny skin showed a similar pattern of variability, but their severity during infection was less than for redness, swelling and pain. Itchiness was also much less during infection. Dry flaky skin showed considerably less variability than other symptoms and appeared to be a feature of all three states. Odour was mainly a feature of infection and not of irritated or calm pin sites.

Table 7 presents the results of Cochran's Q tests for difficulty or pain using the affected leg, difficulty in bearing weight on the leg, nausea/vomiting, feeling unwell, feeling feverish, shivering, tiredness/lethargy and disturbed sleep (dichotomous variables). There was a significant difference between infected and irritated and infected and calm for all symptoms, but not between irritated and calm for any symptom.

Absence, or minimal experience, of most symptoms denoted calm pin sites, whilst more severe or increased symptoms indicated irritated or infected states. Exceptions were itchiness - demonstrating a slightly higher magnitude in irritation than in infection - and disturbed sleep; the latter was most common in infection, but was almost equal when pin sites were irritated or calm.

## Discussion

Pin site wound states are often simply described as either infected or not, with some limited recognition of the potential for another state sometimes referred to as 'reaction' (Britten et al., 2013). Clint et al. (2010) assessed the inter-rater reliability, but not validity, of a pin site assessment tool that identified three pin site states as "good, bad and ugly" in the only study that has previously examined three distinct states. They described "ugly" sites as those which were extremely painful, erythematous, discharging pus and requiring antibiotic treatment. They were less able to define the "bad" pin site, characterised as inflamed and "slightly" angry, stating that the source of this problem is less easily understood and requires a better understanding of the pathological processes.

'Calm' is the pin site state desired by patients and care providers (Timms et al., 2011), indicating the absence of either infection or irritation and indicating a wound without problems. Clint et al. (2010) stated that "good" pin sites exhibit no, or minimal, erythema, pain or wound discharge. There is less clinical focus on the calm wound state in comparison to states with more noticeable pain and discomfort but patients use their experience of calm pin sites for comparison in helping

**Table 4**
Frequency and severity/magnitude of pin site skin/tissue related symptoms

| Symptom | State | Not at all | Slightly | Moderately | Quite a lot | Extremely |
|---|---|---|---|---|---|---|
| Redness | Infected | 0% | 8.4% | 15.9% | 44.9% | 30.8% |
| | Irritated | 11.0% | 34.6% | 26.0% | 20.5% | 7.9% |
| | Calm | 58.7% | 34.8% | 5.2% | 1.3% | 0% |
| Itching | Infected | 22.4% | 24.3% | 17.8% | 18.7% | 16.8% |
| | Irritated | 12.2% | 19.8% | 28.2% | 29.8% | 9.9% |
| | Calm | 45.8% | 34.2% | 12.9% | 5.2% | 1.9% |
| Swelling | Infected | 6.5% | 17.8% | 18.7% | 33.6% | 23.4% |
| | Irritated | 26.4% | 26.4% | 30.2% | 9.3% | 7.8% |
| | Calm | 76.6% | 14.3% | 6.5% | 1.9% | 0.6% |
| Pain | Infected | 3.7% | 7.4% | 13.0% | 34.3% | 41.7% |
| | Irritated | 10.7% | 23.7% | 32.8% | 26.0% | 6.9% |
| | Calm | 62.4% | 20.4% | 9.6% | 6.4% | 1.3% |
| Discharge | Infected | 6.5% | 17.6% | 25.9% | 29.6% | 20.4% |
| | Irritated | 29.5% | 31.8% | 17.8% | 17.8% | 3.1% |
| | Calm | 64.7% | 29.5% | 4.5% | 1.3% | 0% |
| Hot/burning | Infected | 8.4% | 17.8% | 20.6% | 33.6% | 19.6% |
| | Irritated | 44.1% | 26.8% | 18.9% | 8.7% | 1.6% |
| | Calm | 85.2% | 10.3% | 1.3% | 1.9% | 1.3% |
| Shiny skin | Infected | 18.9% | 20.8% | 29.2% | 18.9% | 12.3% |
| | Irritated | 27.3% | 43.8% | 19.5% | 6.3% | 3.1% |
| | Calm | 60.0% | 31.0% | 5.8% | 2.6% | 0.6% |
| Dry, flaky skin | Infected | 21.3% | 35.2% | 25.0% | 9.1% | 4.6% |
| | Irritated | 24.2% | 32.8% | 18.8% | 17.2% | 7.0% |
| | Calm | 26.8% | 45.2% | 18.5% | 7.0% | 2.5% |
| Odour (odour) | Infected | 55.2% | 19.0% | 13.3% | 6.7% | 5.7% |
| | Irritated | 83.6% | 10.2% | 4.7% | 0.8% | 0.8% |
| | Calm | 93.6% | 5.1% | 1.3% | 0% | 0% |

**Table 5**
Frequency and severity/magnitude of pin site non-skin-tissue related symptoms

| | State | Yes | No |
|---|---|---|---|
| Difficulty/painful to use affected leg or arm | Infected | 80.7% | 19.3% |
| | Irritated | 53.9% | 46.1% |
| | Calm | 53.8% | 46.2% |
| Difficulty weight bearing | Infected | 76.0% | 24.0% |
| | Irritated | 50.8% | 49.2% |
| | Calm | 45.5% | 54.5% |
| Nausea and/or vomiting | Infected | 22.4% | 77.6% |
| | Irritated | 5.6% | 94.4% |
| | Calm | 2.6% | 97.4% |
| Feeling unwell | Infected | 46.3% | 53.7% |
| | Irritated | 13.3% | 86.7% |
| | Calm | 8.4% | 91.6% |
| Feverish | Infected | 50.5% | 49.5% |
| | Irritated | 5.3% | 94.7% |
| | Calm | 5.3% | 94.7% |
| Shivering | Infected | 31.2% | 68.8% |
| | Irritated | 8.7% | 91.3% |
| | Calm | 5.9% | 94.1% |
| Tired and/or lethargic | Infected | 58.3% | 41.7% |
| | Irritated | 31.0% | 69.0% |
| | Calm | 28.1% | 71.9% |
| Sleep disturbed | Infected | 75.9% | 24.1% |
| | Irritated | 52.8% | 47.2% |
| | Calm | 51.6% | 48.4% |

them to recognise irritation or infection (Santy-Tomlinson et al., 2011).

The “bad” pin site appears to be related to the irritated pin site described by participants in the present study; moderately red, painful on palpation or percussion of the pin and having sufficient wound discharge to require more frequent wound dressing changes (Clint et al., 2010). The mild to moderate signs of inflammation with irritation appear to indicate an inflammatory response that is unlikely to be related to the presence of infection but may be due to other inflammatory pathology. Itchiness, dry flaky skin and odour are not symptoms of infection reported in the specialist literature so may also indicate the presence of different pathological processes. Itchiness and dry flaky skin are, for example, consistent with symptoms of dermatitis, a common skin condition with an estimated point prevalence of around 20% (Gawkrodger and Ardern-Jones, 2012). Contact dermatitis is an inflammatory skin reaction caused by a response to an external agent that acts as either an irritant or an allergen (Bourke et al., 2009). Allergic contact dermatitis is the result of a hypersensitivity reaction following sensitisation and subsequent re-exposure to an allergen and irritant contact dermatitis is an inflammatory response that occurs after damage to the skin from an external irritant (Warshaw and Hook, 2013). These two conditions often co-exist, as may be the case during external fixation. Acute symptoms of both forms of dermatitis are similar and often include; vesiculation (blistering), erythema, itching (pruritus), oedema, (swelling), papules (small solid elevations of the skin) and exudation (Bourke et al., 2009).

There are many potential irritants and allergens involved in the care of the patient with external fixation, ranging from the presence of metal in tissue to antiseptic and other solutions used for wound cleansing. Patients with fixators have difficulty carrying out skin care resulting in an inability to shed dead cells and maintain skin health (Timms and Pugh, 2012). Chlorhexidine and alcohol are recommended for cleansing external fixator pin site wounds (Timms et al., 2011) but are implicated in the aetiology of dermatitis (Frigerio et al., 2011). Metals such as nickel, cobalt, chromium and zinc are ever-present in the human environment and sensitivity to one or more of these is a common cause of allergic contact dermatitis. The most common sensitising metals used in orthopaedic implants are nickel cobalt and chromium (Yoshihisa and Tadamichi, 2012). Nickel is a constituent of stainless steel from which most external fixator wires and pins are manufactured and is a common allergen implicated in contact dermatitis (Martin, 2015).

Patients who report mild to moderate pain, redness, swelling and discharge but severe itching and dry flaky skin may be experiencing contact or allergic dermatitis. However, moderate pain, redness and swelling, may also be indicators of an inflammatory reaction to the presence of percutaneous metal pins and wires, especially in the early stages of treatment with an external fixator. Some seminal literature also highlights confusion between symptoms of inflammation in both irritation and infection and the importance of recognising both clinical states as potential causes of inflammatory symptoms. For example, Anderson et al. (2008) summarised the inflammatory response to

**Table 6**
Differences between scores for redness, swelling, itchiness, pain, wound discharge, hot/burning, shiny skin, dry flaky skin and odour

| | State | Mean Rank | Friedman | | Wilcoxon Signed Ranks Tests – Pairwise comparisons (Bonferroni-corrected) | |
|---|---|---|---|---|---|---|
| | | | $\chi^2$ (df = 2) | P-value | Z value | P-value |
| Redness | Infected | 2.79 | 117.502 | < 0.001 | −8.017 | Irritated v Calm < 0.001 |
| | Irritated | 2.04 | | | −8.657 | Infected v Calm < 0.001 |
| | Calm | 1.17 | | | −6.417 | Infected v Irritated < 0.001 |
| Swelling | Infected | 2.75 | 116.134 | < 0.001 | −7.713 | Irritated v Calm < 0.001 |
| | Irritated | 2.08 | | | −8.455 | Infected v Calm < 0.001 |
| | Calm | 1.18 | | | −5.994 | Infected v Irritated < 0.001 |
| Itchiness | Infected | 2.10 | 58.632 | < 0.001 | −7.809 | Irritated v Calm < 0.001 |
| | Irritated | 2.48 | | | −6.066 | Infected v Calm < 0.001 |
| | Calm | 1.42 | | | −2.262 | Infected v Irritated 0.024 |
| Pain | Infected | 2.82 | 129.326 | < 0.001 | −8.519 | Irritated v Calm < 0.001 |
| | Irritated | 2.05 | | | −8.717 | Infected v Calm < 0.001 |
| | Calm | 1.13 | | | −6.704 | Infected v Irritated < 0.001 |
| Wound Discharge | Infected | 2.73 | 101.048 | < 0.001 | −7.051 | Irritated v Calm < 0.001 |
| | Irritated | 1.99 | | | −8.420 | Infected v Calm p < 0.001 |
| | Calm | 1.28 | | | −6.031 | Infected v Irritated p < 0.001 |
| Hot/burning | Infected | 2.83 | 121.299 | < 0.001 | −7.114 | Irritated v Calm < 0.001 |
| | Irritated | 1.89 | | | −8.320 | Infected v Calm < 0.001 |
| | Calm | 1.28 | | | −6.748 | Infected v Irritated < 0.001 |
| Shiny skin | Infected | 2.55 | 77.775 | < 0.001 | −6.852 | Irritated v Calm < 0.001 |
| | Irritated | 2.09 | | | −7.100 | Infected v Calm < 0.001 |
| | Calm | 1.36 | | | −4.338 | Infected v Irritated < 0.001 |
| Dry flaky skin | Infected | 2.10 | 10.351 | 0.006 | −2.959 | Irritated **v** Calm 0.003 |
| | Irritated | 2.12 | | | −2.393 | Infected **v** Calm 0.017 |
| | Calm | 1.78 | | | −0.274 | Infected v Irritated 0.784 |
| Odour (smell) | Infected | 2.42 | 59.807 | < 0.001 | −2.668 | Irritated v Calm < 0.001 |
| | Irritated | 1.83 | | | −5.869 | Infected v Calm < 0.001 |
| | Calm | 1.75 | | | −5.031 | Infected v Irritated < 0.001 |

implantation of wires and pins as; “a temporary variation in the events of the inflammatory response leading to wound healing (p101)” and a manifestation of the acute inflammatory response, chronic inflammatory response and foreign body reaction. Burny (1984) identified foreign body pathological processes following the implantation of biomaterials as; protein absorption, monocyte/macrophage adhesion, macrophage fusion to form foreign body giant cells, consequences of the foreign body response on biomaterials and cross-talk between macrophages/foreign body giant cells and inflammatory/wound healing cells. Andrianne et al. (1989) suggested that pin movement is also likely to be partly responsible for a continued inflammatory reaction and that pin insertion techniques and aftercare should be scrutinised to ascertain causes and solutions.

The symptoms of infection described in the present study closely

**Table 7**
Differences between pin site symptoms scores

| Symptom | State | Percentages | | Cochran's Q | | McNemar's test – Pairwise comparisons (Bonferroni-corrected) | | |
|---|---|---|---|---|---|---|---|---|
| | | | | n | P-value | Infected-irritated | Infected-Calm | Irritated-Calm |
| | | Yes | No | Total n = | | P-value | P-value | P-value |
| Difficulty or pain in using the affected arm or leg | Infected | 80.7% | 19.3% | 82 | < 0.001 | < 0.001 | < 0.001 | 0.560 |
| | Irritated | 53.9% | 46.1% | | | | | |
| | Calm | 53.8% | 46.2% | | | | | |
| Difficulty weight bearing on the leg | Infected | 76.0% | 24.0% | 76 | < 0.001 | 0.001 | < 0.001 | > 0.999 |
| | Irritated | 50.8% | 49.2% | | | | | |
| | Calm | 45.5% | 54.5% | | | | | |
| Nausea/vomiting | Infected | 22.4% | 77.6% | 79 | < 0.001 | < 0.001 | < 0.001 | 0.625 |
| | Irritated | 5.6% | 94.4 | | | | | |
| | Calm | 2.6% | 97.4% | | | | | |
| Feeling unwell | Infected | 46.3% | 53.7% | 81 | < 0.001 | < 0.001 | < 0.001 | 0.607 |
| | Irritated | 13.3% | 86.7% | | | | | |
| | Calm | 8.4% | 91.6% | | | | | |
| Feverish | Infected | 50.5% | 49.5% | 80 | < 0.001 | < 0.001 | < 0.001 | 0.18 |
| | Irritated | 5.3% | 94.7% | | | | | |
| | Calm | 5.3% | 94.7% | | | | | |
| Shivering | Infected | 31.2% | 68.8% | 81 | < 0.001 | < 0.001 | 0.000 | 0.453 |
| | Irritated | 8.7% | 91.3% | | | | | |
| | Calm | 5.9% | 94.1% | | | | | |
| Tiredness/lethargy | Infected | 58.3% | 41.7% | 80 | < 0.001 | < 0.001 | < 0.001 | > 0.999 |
| | Irritated | 31.0% | 69.0% | | | | | |
| | Calm | 28.1% | 71.9% | | | | | |
| Disturbed sleep | Infected | 75.9% | 24.1% | 79 | < 0.001 | < 0.001 | 0.000 | 1.000 |
| | Irritated | 52.8% | 47.2% | | | | | |
| | Calm | 51.6% | 48.4% | | | | | |

resemble the features of the classic inflammatory response, reflecting some of the criteria used in previously published pin site infection assessment tools (Checketts et al., 1993; Clint et al., 2010). However, such tools are not based on systematically patient derived data (Santy, 2010) and, hence, cannot be considered to have enough content validity.

It is important to consider each symptom in detail, including its specific features such as magnitude. Considering the underlying pathological response to infection and inflammation may, for example, assist in illuminating the nature of different pin site states.

The source of pain in wound infection is the inflammatory response to bacterial invasion which stimulates peripheral pain receptors in the skin, and an understanding of its origins is central when developing valid criteria for the identification of pin site infection and irritation. One source of pain in infection is the increase in plasma and tissue content leading to tissue tension and pressure (Majno and Joris, 2004). The severity of pain is significant when assessing the inflammatory response and may help to indicate the most likely cause of inflammation. Pain of inflammatory origin may also result in loss of function (Clay et al., 2010), an important feature of the patient's experience of infection that can lead to reducing mobility at the onset of the infection. Pain is a subjective and individual experience, making its measurement complex. It is also a universal experience for patients who have sustained injury, have wounds, are undergoing limb reconstruction procedures and/or are receiving treatment with external fixation (Beltsios et al., 2009). The difference between 'injury' and 'procedure' related pain may explain why some patients experienced significant pain in pin sites, even when their wounds were calm. For most patients with external fixation, weight bearing is actively encouraged during mobilisation and is an important stimulus for bone healing. The infection-related pain described by participants in the present study was so severe that it affected their previously improving ability to bear weight on the affected limb, making them suspect they had an infection. There was significant variance for difficulty in weight bearing between infected and irritated and infected and calm, but not between irritated and calm; indicating that this experience is a specific feature of infection.

Erythema was frequently reported; initiated by vasoactive mediators such as histamine which instigate and maintain dilation of the small blood vessels and lead to increased blood flow and increased capillary filling, changing the colour and temperature of surrounding tissue (Fierheller and Sibbald, 2010). The loss of fluid from blood eventually leads to a reduction in flow and decreased effectiveness of the local immune response. Localised oedema around an infected pin, also frequently reported, is caused by increased contents of the tissue due to accumulation of excess interstitial fluid. Increased tissue fluid can cause leakage from intravascular spaces (Taussig, 1984), providing an explanation for the shiny, tightness of skin described by some participants.

Wound discharge was a significant feature of both irritation and infection. In infection it was more prolific and consistency and colour were different. A change in the degree and nature of exudate is a feature of the tissue response to infection (Inglis, 2007). Purulence (or 'suppuration') is an unequivocal sign of infection. Pus contains spent phagocytes, inflammatory exudate and tissue debris that produce creamy, viscous fluid often with colouring that reflects the nature of the infecting organism (Gardner et al., 2007). Suppuration occurs only when the infecting organism is pyogenic (Taussig, 1984), making it an unreliable assessment factor for wound infection. Foul odour is also sometimes associated with wound infection (Woo and Sibbald, 2009), specifically with anaerobic, and some gram negative, bacteria. Odour demonstrated significant variance between irritated and calm, but was nearing a non-significant result in infected and irritated states, suggesting that odour is only a feature of infection, but that it occurs infrequently. Odour may also depend on the level of attention given to wound care and personal hygiene.

The more general symptoms of infection experienced by many participants reflect a broader systemic response to the presence of infection. Such symptoms could be useful in the identification of pin site infection, but seem not to be universal. Fever, often described by participants in the present study, is a manifestation of infection that includes: loss of appetite, sleep disturbance, lethargy, aches and pains and reaction to pyrexia, although it can occur without infection in the first few days following surgery (Johnson, 2008).

Skin itch is a common feature of contact dermatitis and tended to be more severe in irritation than infection. More than half (54.2%) of patients said they experienced some degree of itchiness, although less severe, when their pin sites were calm, indicating that some other process, such as contact dermatitis, may be responsible for this, even when the pin sites are not judged to be irritated or infected. When the skin barrier is affected by physico-chemical disruption such as in contact dermatitis, the stratum corneum is more likely to shed, increasing the flaking of skin cells, also leading to transepidermal water loss, disruption to microcirculation and nutrient flow to the skin periphery, along with acceleration of the loss of cells from the outer layer of the skin (Penzer and Ersser, 2010). Dry flaky skin did not reach significant variance between the three pin site states in the present study, suggesting that it is a feature of all pin site states and is unlikely to be useful in distinguishing between infection and irritation.

Patients with external fixation suffer sleep problems whether they have infection, irritation or not (Humphries, 2008) because of the invasive and cumbersome nature of devices and the discomfort they cause. Sleep is a common problem for patients who have undergone surgery, are hospitalised (Chouchou et al., 2014) and experience post-operative and trauma pain. Sleep has not been studied in patients with external fixation or as a potential symptom of infection. The data from the present study does not offer full insight into how much sleep is affected in the three different pin site states.

### *Limitations of the study*

Problems and delays in achieving institutional approval, along with work pressures for the clinicians responsible for recruitment, led to a low response rate (38.5%) even though the intended completion date was extended. The researchers did not know to whom questionnaires had been sent, so it was not possible to increase the response rate with individual postal or telephone reminders.

Patients' own perceptions of whether there was an infection or not have been relied on. The fact that participants had taken antibiotics specifically to manage a suspected infection and the majority who claimed to have experienced infection said that the treatment had either worked or partly worked, suggests that they were experiencing infection rather than some other condition such as irritation. However, this captures only their 'lay' understanding of the presence of infection and might not be deemed a reliable clinical diagnosis. Considering, however, the need to focus on patient experience, it could be argued that this approach is a valid basis for developing an assessment tool for pin site infection as it is only the patient who can describe such subjective experiences. This reinforces the importance of developing a more objective definition of the infected pin site state. One difficulty with this remains the lack of a validated diagnostic tool for comparison identified by studies of discriminant validity. It is important to acknowledge, however, that no reliability analyses have been attempted in the present study and that an assessment of aspects of reliability is an important next step.

The study relied on patients' ability to remember the symptoms of infection up to four weeks after the infection started. Different pin site states also occurred at different times and retrospective recall may have been longer for some wound states than others. Collecting data at the time patients are experiencing symptoms would help to confirm the accuracy of this.

The nature of the data has restricted the potential use of some of the more sophisticated multivariate/parametric statistical techniques, such as discriminant analysis and logistic regression, to examine the criterion

or discriminant validity of the items. Such approaches to data analysis, for which interval data is required, may have been able to identify those symptom experiences which are 'best' for identifying each of the pin site states. It has not, therefore, been possible to identify those symptoms which are of most use in identifying infection; restricting the ability to propose an assessment tool with a minimum number of items.

The study employed a retrospective quasi-longitudinal cross-sectional design by asking the same set of questions relating to the three different states or points in time. This works as a proxy for data which might have been better collected prospectively at the time of the experience. Because such an undertaking would have been difficult given the relatively small population of patients with external fixation, the retrospective design was difficult to avoid. The data has, therefore, been treated as within-subjects, repeated measures and quasi-longitudinal. The longitudinal approach was largely chosen because an earlier study (Santy-Tomlinson et al., 2011) identified that change in the participants' experience of symptoms was an important element in them recognising the different clinical states. The retrospective approach was also used to resolve potential problems with attrition, difficulties with follow-up and the need to collect a large amount of data from a small population. The within-subjects nature of the data is not independent and has restricted the scope for using more powerful multivariate statistical techniques.

The language employed in the questionnaire was based on common terminology used by participants in a previous qualitative (grounded theory) study (Santy-Tomlinson et al., 2011). The terminology used was, therefore, based on English spoken in the United Kingdom. Terminology to describe symptoms such as pain may differ in other cultures, dialects and languages and further work is needed to verify their transferability into English spoken elsewhere or in other languages.

## Conclusion

Pin site infection remains a significant problem, with little consensus about how to manage the wounds or how to define and assess infection. In one of the most recent studies attempting to assess the value of methods for the prevention of external fixator pin site infection, Camathias et al. (2012) classified a successful outcome in the prevention of pin site infection as a pin/soft tissue interface that is dry/without secretions. However, they further stated that inflammatory changes, including secretions or granulation tissue, were evident in 35% of pin sites and that this did not necessarily denote an infection. These views reflect confusion about the diagnosis and assessment of wound infection. It also reflects the lack of consideration of the patient's experience of the symptoms of infection. One attempt to proffer an assessment tool for pin site infection (Clint et al., 2010) also does not focus on the experiences of the patient and those authors admit that there is a lack of knowledge about the pathology of inflamed pin sites. The standardisation of the diagnosis and documentation of pin site infections is difficult (Britten et al., 2013), but the findings of the study reported here have been able to offer a practical, patient-focussed insight into this problem and the related problem of contact dermatitis.

This study has demonstrated that patients may be able to differentiate between different pin site states by comparing the magnitude of the inflammatory symptoms and the presence of other specific symptoms that relate solely to infection and no other state. The irritated state may have different pathological manifestations which correspond with the symptoms of contact dermatitis. Clinicians should be able to use the findings from this study to help them recognise the possible causes of irritation, as opposed to infection, in their assessment of pin site wounds.

These findings help in gaining a greater depth of understanding of the symptoms explored in this study and their value in identifying the pin site states, and will assist future development of a valid and reliable assessment tool for clinical use. Combined with the findings of Clint et al. (2010), the data suggests that three symptoms; redness, pain and wound discharge, are central aspects of the experience of pin site infection. The nature of irritation and its underlying pathological processes, how these affect the development of pin site infection and the patient's experience of its symptoms, are central to further work. Further study of the nature of the irritated state of pin sites is also needed.

A key finding of the present study is that there are distinct characteristics that manifest with infection, but do not occur with irritation or calmness. These characteristics — especially redness, pain and wound discharge — are central to the experience of pin site infection and could be used to help clinicians to understand the patient experiences of those symptoms, as well as develop assessment methods for the identification of pin site infection.

The recognition of contact dermatitis is an important and understudied feature of the patient's experience of external fixation. Having recognised its potential to be responsible for some pin site wound state symptoms, clinicians are more likely to apply it to an understanding of its causes and potential solutions. This is, however, a significant area for future study so that such causes and solutions can be explored.

## Declaration of interest

There are no interests to declare for any author

## Ethical statement

The study design and procedures were approved by Nottingham Research Ethics Committee 1 (Approval number: 11H04036)"

## Funding

The study was funded by a Smith and Nephew Foundation Nursing Research Scholarship.

## Acknowledgements

Statistical advice was provided by Victoria Allgar, Senior Statistician, Hull York Medical School/University of York Health Sciences. Further advice was provided by Malcolm Campbell, Lecturer in Statistics, Division of Nursing, Midwifery & Social Work, University of Manchester. The study was funded by a Smith and Nephew Foundation Nursing Research Scholarship.

## Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.ijotn.2019.01.002.

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