

# Clinical evaluation of postsurgical scar hyperaesthesia: a longitudinal observational pilot study

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# Abstract

**Introduction:** The mechanisms underlying persistent scar pain are not fully elucidated and evidence for the clinical evaluation of scar pain is limited. This pilot observational study investigated participation data and sought to identify objective clinical scar evaluation measures for future trials.

**Methods:** With ethical approval and consent, adults undergoing planned hand surgery were enrolled from one NHS hospital. At 1- and 4-months post-surgery scar thermal and mechanical pain thresholds were evaluated with quantitative sensory testing; peri-scar inflammation with infrared thermometry and pliability with durometry. Participation data were analysed with descriptive statistics; the association of clinical measures with patient reported scar pain was analysed.

**Results:** Twenty-one participants (22% eligible patients) enrolled before study closure due to the COVID-19 pandemic; 13 completed follow up. No adverse events or dropouts resulted from clinical scar evaluation. Seventy percent of participants reported undertaking topical, nonprescription scar treatment independently. Neuropathic Pain Symptom Inventory (NPSI) scores were dispersed across the score range, capturing variability in participant-reported scar symptoms. Scar morphology, pliability and inflammation were not associated with scar pain. Differences between scar and contralateral skin in thermal and mechanical pain sensitivity were identified.

**Conclusion:** People with acute hand scars participate in clinical research and independently initiate scar treatment. Clinical testing of acute post-surgical hand scars is well tolerated. The NPSI demonstrates utility for exploring scar pain symptoms and may support the elucidation of mechanisms of persistent scar pain. Clinical tests of thermal and mechanical and sensitivity are promising candidate clinical measures of scar pain for future trials.

# Keywords

Scar, quantitative sensory testing, hyperaesthesia, pain, pliability, outcome

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# Lay Summary

**Background:** it is unknown why some scars remain painful long-term. We do not know if scar flexibility, inflammation or sensitivity to temperature or pressure relate to scar pain. We investigated if patients would enrol in scar research, if scar testing was tolerated and if clinical tests are useful for future scar studies. **Study conduct:** with ethical approval and consent, adult hand surgery patients were enrolled from one NHS hospital. Scar pain, inflammation and response to thermal, sharp and pressure tests were assessed at 1- and 4-months after surgery. Statistically, we analysed study participation, tolerance for clinical scar tests and if the scar tests related to scar pain.

**Findings:** 21 participants (22% eligible patients) enrolled before study closure due to the COVID-19 pandemic; 13 completed follow up. No participants were injured due to scar testing. 70% of participants reported treating their scar independently. Neuropathic Pain Symptom Inventory (NPSI) allows participants to give a broad range of answers about their scar symptoms. Scores for clinical tests of scar flexibility and inflammation did not relate to participant-reported scar pain. Scars were more sensitive to tests of pin prick and cold than unaffected skin.

What we learned: people with new hand scars participate in research and independently initiate scar treatment. Clinical testing of post-surgical hand scars is well tolerated. The NPSI is useful for exploring scar pain symptoms and may help us to learn about persistent scar pain. Pinprick and cold clinical tests may be useful objective pain tests for future scar research.

# Introduction

When skin is wounded by injury or surgery, a scar results. It is estimated that over 100 million people develop scars yearly, primarily as a result of surgical procedures.<sup>1</sup> Scarring may be burdensome and deleterious, causing unpleasant or painful symptoms which interfere with activities of daily living and social participation.<sup>2</sup> The imperative to improve scar outcomes has resulted in the development of a vast array of scar treatments with variable efficacy;<sup>3–5</sup> at present there is an estimated \$12 billion market annually in the United States for scar treatment.<sup>6</sup>

Scars are often persistently painful or hypersensitive, however, the evaluation of scar pain is not standardised<sup>7–10</sup> and currently there is no gold-standard outcome measure for evaluating scars.<sup>11</sup> In practice, scar pain evaluation predominantly focuses on quantifying pain intensity with patient reported scales. Beyond intensity, evaluation generally fails to consider important pain parameters including symptoms, quality, and functional interference. The objective physical evaluation of scar pain has received little attention.<sup>12–14</sup> Secondarily, the nature of scar pain and associated impairment is poorly understood.

Although the physical characteristics of scar are thought to be related to scar pain, there is no evidence for how the morphology of a hyperaesthetic scar differs from a quiescent scar.<sup>15,16</sup> Mechanisms underlying scar pain are not fully elucidated and are likely multifactorial. Scar pain may be related to the severity of tissue trauma and to psychological factors including anxiety.<sup>9</sup> It is further theorised that scar pain is driven by an increase in small nerve fibre density; increased density of pro-inflammatory sensory neuropeptides promoting sensitisation; and mechanical compression of A $\delta$  & C-fibres by dense scar tissue.<sup>9</sup>

As an outcome, scar pain lacks a working definition, vital to consistency in assessment. The International Association for the Study of Pain defines hyperaesthesia as increased sensitivity to stimulation, including touch and thermal stimuli, that may or may not be painful.<sup>17</sup> Utilising 'scar hyperaesthesia' and its working definition in outcome evaluation may promote standardisation.

There is scant evidence for the objective, clinical evaluation of scar hyperaesthesia and this reduces the rigour of clinical research and impedes the development of best evidence for scar treatment. The first step in building evidence to support objective scar clinical evaluation in future studies is justifiably a pilot study, defined as an "investigation designed to test the feasibility of methods and procedures for later use on a large scale or to search for possible effects and associations that may be worth following up in a subsequent larger study".<sup>18</sup> Therefore, this pilot study aimed to test the feasibility and safety of performing quantitative sensory testing on acute postsurgical scars; to evaluate recruiting and compliance parameters; to explore possible associations between objective physical measures of scar and participant reported scar symptoms and to investigate the clinical utility of patient completed pain questionnaires for identifying heterogeneity in patient-reported symptoms. Post-surgical (elective, or planned surgery) hand scars were chosen as a suitable model for investigation, as they are prevalent, relatively homogeneous, and physically accessible for examination. However, it is anticipated that study findings will be generalisable to surgical scars throughout the body.

#### Pilot study aims:

- Identify number of participants enrolled/ participants recruited.
- Identify breaches to the testing protocol; adverse events associated with clinical scar testing.
- Monitor participant independent uptake of scar treatment during the trial.
- Investigate association, if any, of objective clinical measures of thermal and mechanical pain threshold, scar inflammation and scar pliability with patient-reported scar pain.
- Investigate if the Neuropathic Pain Symptom Inventory (NPSI) and Brief Pain Inventory (BPI) patient-completed questionnaires identify variability or heterogeneity in patient-reported scar pain symptoms.

#### Methods

A longitudinal, observational, pilot study was conducted in accordance with the 18th World Medical Assembly, Helsinki 1964 and later revisions. Ethical approval was received from the Health Research Authority (HRA) and Health and Care Research Wales (HCRW) on 20 December 2018 (18/LO/2161). Two patientcollaborators reviewed study measures, procedures and documentation and provided feedback to improve rigour, transparency and clarity. National Health Service Trust pathways for patient care continued throughout. Sequential adult patients listed for elective hand surgery were recruited with posters, at clinic appointments and by post. Participants attended two appointments for study purposes additional to any ongoing clinical care. Where extra travel was incurred, this was reimbursed. Reporting is in keeping with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines.<sup>19</sup>

#### Participation criteria

Adults over 18 years undergoing unilateral elective hand surgery were recruited. Exclusion criteria were inadequate English language to comprehend and consent to study measures, diagnosed serious medical or psychological comorbidity, surgery for a traumatic hand injury, post-surgical wound complication (i.e., infection), history of pathological scarring, previous hand or wrist trauma or surgery, neurological conditions, blood thinning medication and pregnancy – by patient report.

# Procedure

With informed, written consent, participants completed baseline assessment 4-weeks ( $\pm$  14 days) post-surgery and follow-up 4-months ( $\pm$  30 days) post-surgery at Charing Cross Hospital, London, United Kingdom. Four months post-surgery was identified as a relevant period, as tissue healing would be adequate for return to functional activity.

At baseline, demographic data and medical history were recorded. Outcome measures were repeated at baseline and follow-up, except pressure and thermal pain thresholds were assessed only at follow-up to avoid risk of injury in healing scar. At follow up, wound healing complications were recorded as well as information regarding clinician provided or participant-initiated scar care.

#### Participant-completed questionnaires

Participant-completed questionnaires were used to evaluate scar outcome and pain parameters. Scar appearance, consciousness and satisfaction with symptoms were evaluated with the Patient Scar Assessment Questionnaire (PSAQ).<sup>20</sup> The PSAQ is a valid, reliable patient-completed outcome measure.<sup>10,21,22</sup> Subscale items have 4-point categorical responses with 1 point for the most favourable category and 4 for the least favourable. The PSAQ appearance subscale has nine questions (score range 8–32), scar consciousness six questions (range 6–24) and satisfaction with symptoms five questions (score range 5–20).

Scar pain parameters including pain dimensions, severity and interference were assessed. Pain dimensions were evaluated with the Neuropathic Pain Symptom Inventory (NPSI),<sup>23</sup> a validated inventory for evaluating the nature of pain, including spontaneous, paroxysmal and evoked pain and paraesthesia/dysaesthesia. Pain dimension scores range from 0 to 10 with

greater scores implying worse severity. Scar pain severity was assessed with the validated<sup>24</sup> Brief Pain Inventory severity scale (BPS)<sup>25</sup> and the Palmar Pain Severity Scale (PPS).<sup>26</sup> The BPS is calculated as the mean of present pain and the least, worst, and average pain over the last week, rated on an 11-point scale from 0 (no pain) to 10 (pain as bad as you can imagine). The PPS is a patient-completed pain severity rating that was developed and validated in patients following carpal tunnel decompression surgery.<sup>26</sup> The PPS was the primary outcome measure for identifying scar pain and correlation with objective scar measures. Scar pain interference was assessed with the Palmar Pain Interference Scale (PPI),<sup>26</sup> rated from none (zero) to extremely (100).

#### Investigator-completed measures

Scar morphology (vascularity, pliability, pigmentation, height, relief and surface area) was evaluated with the Observer Scar Assessment Scale (OSAS).<sup>27</sup> Morphology dimensions are rated on a 10-point Likert scale, with 1 the same as normal skin and 10 the worst imaginable. The OSAS is validated for use in linear scars and has acceptable reliability (ICC for single parameters: 0.89–0.96).<sup>11</sup>

Infrared skin thermometry was used to evaluate peri-scar inflammation. Using an EXTECH Instruments dual laser InfraRed thermometer (model 42512), skin temperature was recorded three times. Mean temperature was reported for scar and a comparable site on the contralateral hand. Infrared skin thermometry is a reliable clinical assessment tool; an increase in skin temperature of  $1.67^{\circ}$ Celsius is significant and suggests inflammation or infection.<sup>28</sup>

Scar pliability was evaluated using a Checkline electromatic RX-1600-OO Type Durometer. Durometry is a reliable measure of the elastic and mechanical properties of scar and normal skin.<sup>29,30</sup> Indentional load is quantified with a retractable probe, determining tissue hardness. Indentional load is dependent on viscoelastic properties and test duration. The durometer was applied manually, perpendicular to skin. Tissue firmness was expressed in arbitrary units from 0 to 100; with 100 equating to maximal firmness. Three trials were completed, with a timer started on application of the durometer to the scar. Pliability values were recorded after one second (initial hardness) and 15 s (plasticity/ creep).<sup>31</sup> Mean pliability values were calculated and relative difference between the scar and contralateral hand was determined.



**Figure 1. A-D.** Quantitative Sensory Tests. A) Mechanical pain threshold, mechanical pain sensitivity; B) dynamic mechanical allodynia; C) cold and heat pain detection threshold; D) pressure pain threshold.

#### Quantitative sensory testing

Mechanical and thermal pain detection thresholds were evaluated with the German Research Network on Neuropathic Pain (DFNS) quantitative sensory testing (QST) protocol<sup>32</sup> by a trained examiner (D.L.K.). This protocol is validated and widely used to assess somatosensory function.<sup>33</sup> Participants were seated with the test hand supported on a table and introduced to procedures before testing. Assessment was first conducted on the contralateral limb in a comparable area. For all detection threshold measures, three trials were performed, and mean reported. Where participants found a test too uncomfortable and were unable to complete the test parameter, this was recorded as a protocol breach.

Mechanical pain threshold (mechanical hyperalgesia) (Figure 1A) was evaluated using blunt, spring-loaded probes with forces ranging from 8 to 512 mN (pinprick stimulator, MRC, Heidelberg, Germany) and using a method of limits protocol; threshold was calculated as the geometric mean of five series of ascending and descending stimuli. Mechanical pain sensitivity was evaluated using the same weighted probes. Participants rated pain from the range of stimulators on a scale of 0 for no pain and 100 for the worst pain imaginable. Dynamic mechanical allodynia was assessed by participant pain ratings (0-100) to contact with a cotton wisp, a cotton bud (Q-Tip) and a standardised brush designed to produce minimum friction (Somedic, Sweden)

(Figure 1B). Thermal pain thresholds were evaluated with a Somedic MSA thermal stimulator (Sweden) with an 18 mm<sup>2</sup> metal Somedic thermode. This device has a baseline-temperature of 32°C, which increases or decreases in a predefined order (Figure 1C). Pressure pain threshold was tested with a Wagner FDN 200 pressure algometer. The algometer was placed perpendicular to the skin, with a rubber tip against the participants' scar. Pressure was gradually increased until the participant noted the change in sensation from pressure to discomfort, this value was recorded in  $Kg/cm^2$  (Figure 1D).

Statistical analysis was completed using IBM SPSS version 28 (IBM Corp; Armonk, NY). Participant characteristics, demographics and distribution of measures were summaried using descriptive statistics. Normality of data was assessed visually with histograms and statistically with the Kolmogorov-Smirnov test. Continuous measures were reported as means (standard deviations) or medians (interquartile range); categorical data as counts (percentages). Box plots were generated to aid data analysis for the Brief Pain Inventory (BPI) and Neuropathic Pain Symptom Inventory (NPSI) questionnaire results. Box plots provide statistical summaries (median and interquartile range) while showing the dispersion of scores across the full range of the sample data and are robust in capturing outliers.<sup>34</sup> Pearson or Spearman correlations were calculated to identify associations between the Palmar Pain Scale (primary outcome measure) and cliniciancompleted clinical outcomes. Statistical significance was set at p < .05.

# Results

The study opened 25 February 2019 and was scheduled to close on 31 December 2020. However, in keeping with national guidance, recruitment closed on 1 April 2020 due to the COVID-19 pandemic. Prior to suspension, 21 participants (22% of eligible patients) provided



Figure 2. Study recruitment and enrolment.

Table 1. Key demographic and health parameters.

	Baseline N = 21	Follow-up N = 13
Age mean years (SD)	60 (15.6)	66 (10.6)
Female sex n (%)	16 (76)	9 (69)
Surgical procedure n (%)		
Carpal tunnel decompression (open)	12 (57)	7 (54)
Trigger finger release (A1 pulley)	3 (14)	3 (23)
Trapeziectomy	2 (10)	2 (15)
Dorsal wrist ganglion excision	1 (5)	0
Dupuytren's fasciectomy (regional)	1 (5)	0
Interphalangeal joint cyst excision	1 (5)	1 (7)
Trigger thumb release	1 (5)	0
Wound closure n (%)		
Absorbable suture	3 (14)	1 (7)
Prolene	18 (86)	12 (93)
Surgical hand n (%)		
Dominant	14 (67)	
Health parameters n (%)		
Diabetes	5 (24)	
Thyroid disease	2 (10)	
Smoking		
never smoked	13 (62)	
current smoker	0 (0)	
Employment status n (%)		
Employed	6 (28)	
Self-employed	2 (10)	
Unemployed	3 (14)	
Retired	10 (48)	
Profession		
Elementary occupations	1 (5)	
Sales; customer service	1 (5)	
L	1	(Continued

 Table 1. (Continued)

	Baseline N = 21	Follow-up N = 13
Administrative & secretarial	3 (14)	
Associate professional & technical	2 (10)	
Professional occupations	12 (57)	
Managers, directors	2 (10)	

SD, standard deviation.

Table 2.	Patient-reported	scar pain	parameters	at baseline
and follo	w up.			

	Baseline N = 21	Follow-up N = 13
Palmar Pain Severity (PPS) [0–100] mean	33.33 (24.8)	9.23 (19.34)
Palmar Pain Interference (PPI) [0– 100] mean	38.09 (24.5)	9.62 (28.0)
BPI Pain Severity Mean (BPS) [0–10] mean	2.18 (2.2)	0.48 (1.5)
NPSI spontaneous pain [0–10] median		
ongoing burning	0 (4)	0 (0)
ongoing squeezing	0 (1)	0 (0)
ongoing pressure	0 (5)	0 (0)
paroxysmal shocks	0 (2)	0 (0)
paroxysmal stabbing	2 (5)	0 (0)
NPSI evoked pain [0– 10] median		
Pain with brushing	0 (3)	0 (0)
Pain with pressure	5 (7)	0 (2)
Pain with cold exposure	0 (3)	0 (0)
NPSI dysesthesia [0– 10] median		
Pins & needles	0 (0)	0 (0)
Tingling	0 (2)	0 (2)

Data reported as mean (standard deviation) or median (interquartile range).

informed consent and enrolled. Two participants (9%) dropped out after baseline assessment (one moved away; one became unwell). There were no study dropouts secondary to the study testing protocol. At study closure, 13 participants completed baseline and follow up assessments (Figure 2).

Demographic and health parameters are reported in Table 1. Choice of suture material was by surgeon preference and included absorbable (Vicryl Rapide; Ethicon, Somerville, NJ USA) and prolene sutures (polypropylene; Ethicon, Somerville, NJ USA). Prolene sutures were removed at mean (standard deviation) 13.4 (2.2) days. Baseline assessments were performed at mean (standard deviation) 32.6



**Figure 3.** BPI Pain Severity Scale scores. Box represents mean (top line) and standard deviation, individual scores are represented by each dot. The mean of four scales (worst, least, average and present pain) is reported. 1 M = assessment at 1 month; 4 M = assessment at 4 months.



**Figure 4.** NPSI baseline scores. Box represents interquartile range, black horizontal line the median, individual participant scores are represented by each dot.

(14.4) days; follow-up at 132 (18.5) days. At follow-up, there were no scar healing complications and no participants reported receiving clinical care for their scar. However, nine participants (70% of participants followed up) reported performing scar care based on the advice of others or secondary to internet information (scar massage n = 6; silicone gel n = 2; Bio-Oil n = 1).

#### Participant-reported scar pain parameters

Scar pain parameters are reported in Table 2. Scores for the Palmar Pain Severity (PPS) indicate participants experienced, on average, mild scar pain at baseline. In contrast, scar interference as evaluated with the Palmar Pain Interference (PPI) was moderate at baseline. The dispersion of scores for the Brief Pain Inventory (BPI) scales and mean score are illustrated in Figure 3. There was a large, significant association between the Palmar Pain Severity score and Brief Pain Inventory severity mean score (BPS) (r=.72, P<001).

Dispersion of scores, or variability in pain symptoms was explored using the Neuropathic Pain Symptom Inventory (NPSI) (Figure 4). At baseline, median (interquartile range) total NPSI score was 3 (8) and at follow-up diminished to 0 (3). At baseline, five (24%) participants reported pins and needles in the painful scar area; nine (43%) reported tingling. Participant rated scar appearance, consciousness and satisfaction with symptoms was evaluated with Patient Scar Assessment Questionnaire (PSAQ) subscales (Figure 5).

#### Investigator completed scar evaluation

Scar morphology was evaluated with the Observer Scar Assessment Scale (OSAS). Baseline OSAS score mean (standard deviation) was 13.86 (4.18) and follow-up score 12.92 (2.1). Scar morphology was not associated with patient-reported scar pain at baseline (p=.74) or follow-up (p=.8).

Scar inflammation was assessed with infrared thermometry. At baseline, median (IQR) scar temperature was  $34.6^{\circ}$ C (3.2), contralateral hand was  $34.5^{\circ}$ C (2.8), the difference was not significant (p=0.39). At follow-up, scar temperature was  $33.2^{\circ}$ C (2.0) and the contralateral hand was  $33.03^{\circ}$ C (1.8) (p=0.60).

Scar pliability was evaluated with durometry. Differences in pliability of the scar and skin in a comparable area in the contralateral hand are reported (Table 3). Neither baseline scar pliability measures (scar 1; scar 15) were associated with patient-reported scar pain (r=-0.138, p=0.55; r=-.138, p=0.47); respectively.

Quantitative sensory testing (QST) measures of mechanical and thermal pain were completed at baseline and follow-up (Table 4). There were no adverse events associated with QST testing and no protocol breaches (all participants



**Figure 5.** PSAQ subscales. Top line of the box represents the mean, the box the standard deviation and each dot a participant. 1 M = assessment at 1 month; 4 M = assessment at 4 months.

Table 3. Durometry assessment of scar pliability.

		mean (sd)
Baseline (N $=$ 21)	Skin 1ª	31.83 (6.85)
	Scar 1	44.65 (10.12)
	Skin 15 <sup>b</sup>	31.49 (6.70)
	Scar 15	42.98 (9.62)
Follow-up ( $N = 13$ )	Skin 1	33.85 (7.86)
	Scar 1	47.82 (9.21)
	Skin 15	33.05 (7.86)
	Scar 15	46.10 (7.85)

'Skin' pertains to unaffected skin in a comparable region on the contralateral limb. <sup>a</sup>Measurement '1' is completed at one second. bMeasurement '15' is completed at 15 s.

Table 4. Pinprick and thermal evoked pain measures.

	Test site	Baseline	Follow-up
Mechanical pain	Skin	157.6 (142.2)	84.5 (223.34)
threshold	Scar	128.0 (133.4)	78.8 (85.69)
Mechanical pain sensitivity	Skin	0.24 (0.17)	0.32 (0.43)
	Scar	0.33 (0.39)	0.29 (0.46)
Cold pain	Skin	NT	7.17 (17.4)
threshold (°C)	Scar	NT	24.07 (16.4)
Heat pain threshold (°C)	Skin	NT	44.30 (8.6)
	Scar	NT	41.57 (3.7)

'Skin' pertains to unaffected skin in the anatomically comparable region on the contralateral limb. *NT*, not tested. Data reported with median (interquartile range).

completed all measures). For all mechanical and thermal pain parameters, scars were more sensitive than unaffected, contralateral skin. However, statistical analysis of differences was not appropriate because the study was not powered to detect between-groups differences. Results for mechanical pain threshold were not associated with participant reported pain on the PPS (r=-0.207; p=0.40). Results for the association of mechanical pain sensitivity and participant reported scar pain approached significance

(r=0.41; p=0.06). Dynamic mechanical allodynia, assessed at baseline and follow up, indicated no participant presented with dynamic mechanical allodynia, i.e., no participant scored any of fifteen stimuli exposure as >0. Thermal pain detection and pressure pain threshold were assessed at follow up. Cold pain threshold was associated with patient-reported scar pain evoked by cold exposure on the NPSI questionnaire (r=.56; p=.05). Heat pain threshold was not associated with patient reported scar pain. Pressure pain threshold was tested in seven of 13 (54%) participants at follow up. Per protocol (32), pressure pain threshold is tested over soft tissue. Therefore, where scars were over a bony excluded. prominence. participants were Pressure pain threshold was median (IQR) 412 (75) kg/cm<sup>2</sup> at the unaffected skin,  $3\widetilde{53}$  (294)  $kg/cm^2$  at the scar, demonstrating decreased pressure pain threshold, or increased pressure pain sensitivity at the scar.

# Discussion

This longitudinal pilot study took a novel approach to investigating scar hyperaesthesia in adult patients following elective hand surgery for acquired conditions. This exploratory work aimed to evaluate study enrolment and compliance parameters and to identify objective clinical outcome measures associated with patient-reported scar pain as potential candidate outcome measures for future scar clinical research.

Twenty-two percent of eligible patients participated in the study, providing important data for sample size estimation and recruitment in future studies. Despite attempting to recruit study participants using multiple methods, selection bias may have resulted in a study sample that was not fully representative of the population of interest. Exploring sample demographics, the mean age was 60 years and participants were predominately retired or working in professional or managerial roles. There was little representation of those working in skilled trades, service workers or machine operators. In addition, protected characteristics were not included in the demographics, so it is unknown if there is representation of the whole community in the sample. Importantly, it was identified at follow-up that 70% of participants were performing scar care based on the advice of others or secondary to internet information. This highlights the need for monitoring of compliance to allocated treatment group in future randomised studies of scar treatment.

Importantly, there were no study protocol breaches, adverse events or study dropouts secondary to quantitative sensory testing (QST) of post-surgical scars. While the DFNS QST protocol is widely used for the evaluation of pain and somatosensory dysfunction, there is scant evidence to support the use of these clinical measures in patients with acute scars. The work reported here suggests that QST is safe and well tolerated by patients with acute, healing scars.

Candidate psychophysical clinical tests for quantifying scar thermal and mechanical sensitivity in future studies were identified. Differences in mechanical pain sensitivity, cold pain threshold and pressure pain threshold between scars and unaffected skin were identified and results were associated with patient reported scar pain, and patient reported cold evoked pain, respectively. In future studies, quantification of thermal and mechanical pain sensitivity may support a personalised approach to scar pain treatment; changing scores will support the evaluation of treatment effects in future studies.

Pain intensity was explored with the Palmar Pain Severity score (PPS) and Brief Pain Inventory severity score (BPS). Both scores were highly associated suggesting the PPS may be a valid measure of scar pain intensity in other than carpal tunnel surgery populations. This requires confirmation in a larger cohort of patients presenting with both palmar and dorsal hand scars. In the present study, 81% of participants underwent surgery to the palmar surface of the hand, therefore it was inappropriate to further explore measure responsiveness.

While the PPS uses one overall pain rating, in contrast the BPS includes four pain scales: the worst, least, average and present pain severity, and a mean pain rating. In this study, the baseline mean (standard deviation) BPS was 2.2 (2.2); in contrast the mean (standard deviation) for the worst pain scale was 3.6 (3.3). The distribution of baseline scores demonstrated that roughly 30% of participants rated their worst pain as  $\geq 7$ out of 10, highlighting severe pain that is undetected by mean or single rating pain intensity scales. Future scar trials may improve from using multiple scar pain severity ratings (worst, least, average and present pain) to capture heterogeneity in scar pain, and a composite score, as composite scores demonstrate greater reliability in pain research.<sup>35</sup>

We Investigated if the Neuropathic Pain Symptom Inventory (NPSI) patient-completed questionnaire identified variability or heterogeneity in patient reported scar pain symptoms. Exploring scar pain symptoms within the NPSI domains enabled the identification of variability in pain features in this sample. While there is scant evidence for the use of the NPSI for scar pain assessment, Huang et al.<sup>36</sup> employed the NPSI in a study of the effectiveness of autologous fat grafting to alleviate neuropathic scar pain. The authors reported a statistically significant improvement in total NPSI scores, and similarly used the NPSI symptom scales to extrapolate dominant scar pain features. Use of the NPSI for the evaluation of scar pain symptoms in future studies may aid the interrogation of the drivers of persistent post-surgical scar pain and better inform treatment decisions for persistent scar pain.

In this sample, participant-rated scar appearance, consciousness and satisfaction with symptoms were evaluated with the relevant PSAQ subscales. A large proportion of participants rated the appearance of their scar as poor and had a high degree of scar consciousness at baseline and follow up. This highlights the importance of patient-rated scar appearance; it is important that a patient-centred scar evaluation identify this psychological burden to ensure patients are adequately supported.

Scar morphology, as assessed with the OSAS, was not associated with participant reported scar pain. Scar inflammation, as assessed with infrared thermometry, identified no difference between scar and unaffected matched skin. Scar pliability was different to unaffected matched skin; however, pliability measures were not associated with participant reported scar pain. However, this pilot may have been underpowered to detect a significant association between these physical measures and participant reported pain; data gleaned here will inform a relevant sample size calculation in future studies.

A number of study limitations require consideration. Due to premature study closure, follow up data in this sample of participants is limited. All clinical scar measures were completed by one trainer investigator (D.L.K.). Because the study procedures precluded the possibility of investigator blinding, this may have introduced bias. Study participants were adults with scars in the hand and wrist after planned hand surgery and the findings reported herein may require validation in other clinical patient cohorts.

## Conclusion

Findings from this longitudinal pilot study suggest that of the population studied, >20% of eligible

patients will enrol in scar research studies; that patients independently seek out and initiate scar care treatment and that quantitative sensory testing of acute post-surgical hand scars is safe and well tolerated. The dispersion of pain severity scores and NPSI scores suggest these tools have clinical utility for identifying heterogeneity or variability in patient reported scar pain severity and symptoms. Psychophysical quantitative sensory testing measures of mechanical pain sensitivity, cold pain threshold and pressure pain threshold were well tolerated and identified mechanical and thermal pain sensitivity. These QST measures merit exploration in future scar evaluation studies. While investigator evaluated scar morphology, pliability and inflammation were not associated with patient reported scar pain, the study sample size may not have been adequate to detect this difference.

#### **Author contributors**

D.L.K. and S.H. researched literature and conceived the study. D.L.K. and C.M.A. developed the study protocol, gained ethical approval and performed data analysis. D.L.K. was responsible for patient recruitment and data acquisition. All authors reviewed and edited the manuscript and approved the final version of the manuscript.

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