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PILOT STUDY
Peripheral Nerve

SCOPING: A Pilot Study Exploring the Role of A Series of Clinical Observational Parameters as Indicators of Nerve Regeneration

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Background: Following the repair of a mixed peripheral nerve, functional recovery requires successful nerve regeneration across the repair site and, eventually, reinnervation of distal targets. Reliably determining a failing nerve repair so that revision may be performed before irreversible muscle atrophy remains a challenge in peripheral nerve surgery. This study aimed to ascertain whether any commonly used clinical examination tests during surveillance after nerve repair can detect a failing repair and prompt earlier salvage intervention.

Methods: A prospective observational cohort study was performed to evaluate commonly used clinical determinants of neuron regeneration that may provide early surrogate recovery measures. Sequential cutaneous thermography was used to identify temperature differences between denervated and normal skin in the hand operated on, with the contralateral hand as a control.

Results: Six out of nine patients completed between 6 and 18 months of follow-up. Tinel sign progression was observed in all subjects. Tinel progression rate was associated with motor and sensory Medical Research Council grade. The delta temperature was calculated to document the size and direction of any temperature differentials in the hand detected by thermography, but we did not have sufficient data to calculate any correlations with motor and sensory Medical Research Council grade.

Conclusions: Specifically, the progression of Tinel sign is associated with recovery measured by progression of the British Medical Research Council motor and sensory grades. The use of thermographic imaging demonstrates that there is a difference in temperature between an injured and noninjured nerve. Future studies could investigate to what extent thermographic imaging predicts final nerve repair outcomes.
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INTRODUCTION

The surgical gold standard for complete acute peripheral nerve transection is microscopic neurorrhaphy.[1,2] Following the repair of any peripheral nerve, functional recovery requires successful nerve regeneration across the repair site and, eventually, reinnervation of sensory, motor, and autonomic distal targets. A review of the literature indicated factors associated with outcomes after nerve repair include the nerve injured, level of injury, surgical technique, length of defect, repair time, associated injuries, age of the patient, and duration of follow-up.[3,4] Other studies looking at the long-term clinical outcome after epineural coaptation of digital nerves found that there was no correlation observed between the sensory outcome and age, smoking, mechanism of injury, lesion to or anastomosis of a digital artery, or time of immobilization; the only predictor was the surgeon's level of experience.[5] The inevitable delay before determining an outcome as successful or otherwise may render late salvage interventions with revision reconstruction with nerve grafts obsolete.[6]

Limitations regarding long-term follow-up inherently exist in this article type.

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Standard nerve regeneration assessment includes monitoring sensory and motor recovery, autonomic changes, and provocation tests to identify repair site neuroma formation. Electrophysiology testing may demonstrate sensory and motor improvement but does not provide a clinically useful measure to quantify functional recovery.[6]

Thermography is a safe and noninvasive tool that detects infrared radiation emitted by the skin surface to create an image that depicts temperature distribution.[7] Medical applications of thermography range from breast cancer screening to assessment of depth of burn injuries,[8] peripheral vascular disease,[7] carpal tunnel syndrome,[9] and rheumatoid arthritis.[10] Currently there is a gap in the literature regarding the application of thermography in traumatic upper limb nerve injury. This technology may prove helpful in detecting autonomic vasomotor and sudomotor changes seen after complete transection of a peripheral nerve.[11] Reliably determining a failing nerve repair so that revision may be promptly performed before irreversible muscle atrophy remains a challenge in peripheral nerve surgery. The aim of this study is to ascertain the utility of thermography alongside commonly used clinical tests to identify failing repair after traumatic nerve injury. This aims to address the gap in the literature regarding thermography in traumatic nerve injury.

We hypothesize that commonly used clinical tests, specifically Tinel sign,[12] differential Tinel and Semmes Weinstein monofilament[13] (SWM pressure threshold detection), and thermography, could be used to be predict early outcome.

Takeaways

Question: Can commonly used clinical assessments detect a failing nerve repair prompting earlier salvage intervention?

Findings: Thermographic imaging demonstrates a difference in temperature between injured and noninjured nerves. However, it did not predict sensory recovery using quantitative sensibility thresholds. Further studies are required to ascertain the value of using thermography in testing peripheral nerve regeneration. Tinel sign progression and Semmes Weinstein monofilaments were correlated with motor and sensory nerve function.

Meaning: Monitoring nerve recovery following an injury is essential in ascertaining final outcome.

METHODS

The Series of Clinical Observational Parameters in Nerve Regeneration study (SCOPING) was designed as a prospective observational cohort study to evaluate commonly used clinical determinants of axonal regeneration that may provide surrogate measures of recovery. Ethical approval (17/WSO125)/IRAS 212529 (RRK5981) for SCOPING was received on October 17, 2017. Patients were recruited between February 8, 2018 and December 16, 2019. A recruitment target of 12 participants was set with an anticipated loss to follow-up of around 50%. The inclusion criteria were adults at a single regional hand trauma center with a complete isolated median nerve transection injury at zone VI, (within 0–10 cm proximal to the volar wrist crease) at their first postoperative therapy appointment. The exclusion criteria were infections and previous injury to the median nerve or peripheral neuropathy conditions, pregnancy, and imprisonment. Participants provided written informed consent before study enrollment. A hand therapist completed all clinical assessments. Clinical follow-up was planned at 2 weeks, 6 weeks, 3 months, 6 months, 12 months, and 18 months. We were aware during the implementation of this study that the limitations were going to be the small sample size owing to the impact of corona virus disease 2019 (COVID-19) on both recruitment and follow-up.

The motor outcome was recorded using the British Medical Research Council (MRC) grading system, and for sensory recovery, the modified Sensory Medical Research Council scale (SMRC). Threshold for successful innervation was M3 for motor and S3 for sensation. The clinical measures evaluated included Tinel progression rate, the differential Tinel sign, SWM pressure threshold detection, and thenar muscle motor power (abductor pollicis brevis). Tinel progression rate was assessed by lightly tapping along the proximal course of the nerve being tested. A measurement of the distance from the proximal to distal Tinel was then recorded to provide the estimated rate of neural regeneration in millimeters.[14,15] A clinically nonprogressing Tinel at 3–6 months is considered to represent failed axonal regeneration and further assessment is usually recommended by our authors. The Tinel differential sign is a test that was designed and used within our practice. This test assesses the subjective relative strength of the Tinel at the repair site and at the distal Tinel point. The participant is asked to score out of 100 the relative strength of both points. Differential Tinel may be helpful in identifying a nerve that is not progressing as expected.[14,15]

Secondarily we evaluated the numeric rating scale (NRS) for pain, cold intolerance, hyperesthesia, tender muscle squeeze test [using abductor pollicis brevis (APB)], and static and moving two-point discrimination using the grading scale used by Taras et al[16] (modified from Weber et al[17]). The NRS score comprises a score of zero (representing no pain) to a score of 5 (representing excruciating pain). Cold intolerance and hyperesthesia were rated in how the patient experienced the cold: scoring from 0 to 4 as 0 = hinders function, 1 = disturbing, 2 = moderate, 3 = minor, 4 = none. This rating scale is used within the author's hand department. The tender muscle test[18] was used to ascertain whether the patient could feel pain when the APB muscle was squeezed on a scale of 0–10 with zero being no pain and 10 being excruciating pain. Other secondary outcomes used were patient-reported outcome measures (PROMs) including the Disabilities of the Arm, Shoulder and Hand (DASH, range 0–100),[19] EuroQual 5 Dimension (EQ5D, range 0–100) and the Patient Evaluation Measure (range 0–98).[20–22]

Thermographic imaging was conducted in a temperature controlled medical photography studio after patient acclimatization for 10 minutes and was performed by a medical photographer using a standardized protocol. This involved the patient being previously informed not to

Table 1. Patient Demographics

Patient	Age	Hand Dominance	Male/ Female	Occupation	Mechanism of Injury	Injury to Repair (d)	Vascular Repair	Further Surgery	Antibiotics
1	39	Right	Male	Manual worker	Glass	2	Not repaired	No	Yes
2	20	Right	Male	Manual worker	Blade	2	Repaired	No	Yes
3	22	Right	Male	Student	Glass	2	No injury	No	Yes
4	30	Left	Female	Nonmanual	Glass	2	No injury	No	Yes
5	33	Right	Female	Nonmanual	Glass	4	No injury	Yes	Yes
6	65	Right	Female	Retired	Ceramic	4	Repaired	Yes	Yes

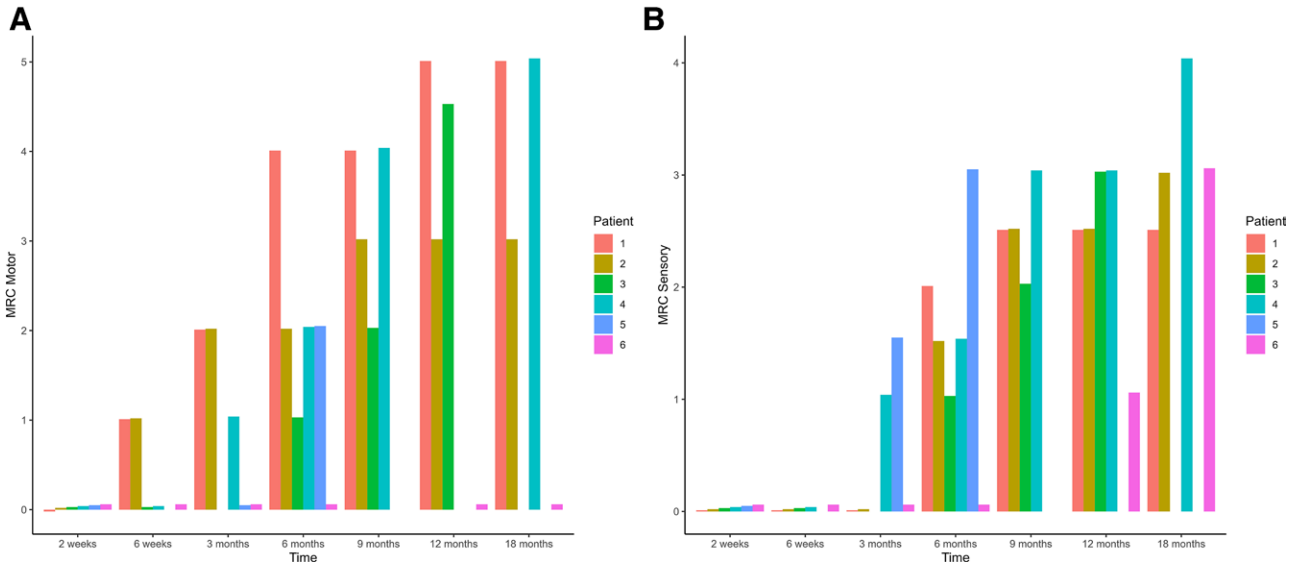

Fig. 1. Sensory and motor MRC gradings during study follow-up. MRC motor (A) and sensory (B) scales over time for individual patients.

wash their hands or to use cream before the appointment and the core temperature and images being recorded. Thermographic images were taken at 2 weeks, 6 weeks, 3 months, and 6 months. Calibration of the thermographic imaging was standardized, and cutaneous temperature of the injured hand was recorded at each set interval. The non-injured hand was recorded at the baseline 2-week time point only. The delta temperature (delta-T) was defined as the difference in cutaneous temperature between median and ulnar territories in the same hand. It was calculated at each time point: delta-T = little – (average thumb, index, middle finger). A positive score meant that the ulnar nerve cutaneous territory was warmer, and a negative score meant that the ulnar nerve was cooler than the median nerve territory.

STATISTICAL ANALYSIS

All primary and secondary outcomes were handled as continuous data. Statistical analyses were performed for the association between MRC scales and Tinel, differential Tinel, and SWM pressure thresholds. Multilevel mixed models were used to adjust for variation within patients due to measurements being taken at multiple timepoints. Normal linear regression models were used if the patient level did not explain any variance. All other outcomes were assessed via descriptive statistics. All analyses were performed using R, 4.0.3; *P* values lower than 0.05 were considered significant.

RESULTS

Study Population

Target recruitment was reduced from 12 to nine patients due to early termination of the study owing to local COVID-19 pandemic restrictions on research delivery. A final total of six of nine patients were included in the results. One patient was withdrawn due to not having a complete median nerve repair and was thus excluded. One patient died after completing only one follow-up. One patient was lost to follow-up due to suspension of the study during the response to the COVID-19 pandemic. For patient demographics of the six included patients (see Table 1). Patients 1–4 had surgery 2 days postinjury; patients 5 and 6 had surgery 4 days postinjury. Mechanism of injury included four glass injuries, one ceramic injury, and one blade injury. All patients were treated with antibiotics post injury/surgery.

Primary Outcome

Patients 1–5 all improved in both MRC motor grade and SMRC scale. (Fig. 1). Patient 6 did not improve in

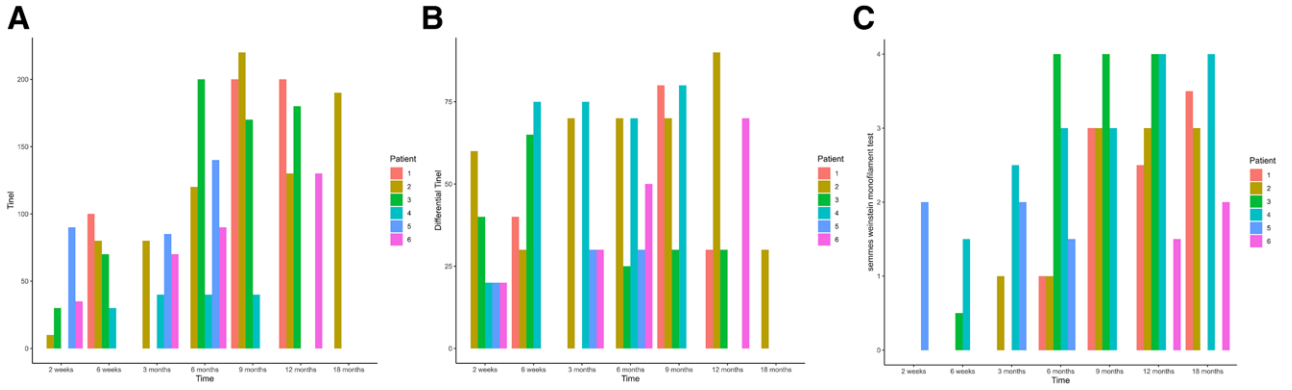

Fig. 2. Sensory assessments including Tinel sign during study follow-up. Tinel (A), differential Tinel (B), and Semmes Weinstein monofilament (C) over time.

Table 2. Delta-T: Little (Average Thumb, Index, and Middle)

Patient	Noninjured	2 Weeks	6 Weeks	3 Months	6 Months
1	0.5	1.1	9.6	5.5	2.4
2	–0.3	5.4	0.0	1.9	1.3
3	0.3	2.2	3.1	—	0.6
4	1.2	1.7	1.0	0.5	1.2
5	0.0	–1.4	—	–0.6	2.2
6	–0.8	1.9	–0.5	0.4	-1.5

The delta-T is the difference between the mean temperature of the thumb, index, and middle finger pulp versus the small finger pulp temperature. The positive means that the ulnar nerve is warmer, and the negative means that the ulnar nerve is cooler than the median nerve.

MRC motor grade but did improve on the SMRC scale. For both scales, 83% of patients improved equal to or greater than the predetermined success threshold. SMRC grades continued to improve up to the cessation of the planned follow-up.

Primary Clinical Assessments

Tinel progression rate and SMW threshold detection improved over time. (Fig. 2). For the differential Tinel sign, this pattern was not observed. Furthermore, conventional Tinel sign and the SWM were correlated with the MRC motor grade and SMRC scale. It was shown that with every increase of 10mm in the Tinel from the site of repair there was an increase of 0.06 (95% CI 0.01–0.12, $P < 0.05$) in the SMRC scale and 0.09 (95% CI 0.01–0.17, $P < 0.05$) in MRC motor scale. Similarly, increase in SWM threshold was associated with an increase of 0.7 (95% CI 0.69–0.71, $P < 0.05$) in the SMRC scale and 0.83 (95% CI 0.82–0.84, $P < 0.05$) in the MRC motor grade.

Temperature Measurements

Two patients missed a single thermographic imaging assessment. Thermographic imaging was completed in full for four patients (Table 2). Figure 3 shows an example of one patient's thermography imaging at 2 weeks, 6 weeks, 3 months, and 6 months. In all patients, maximum trend in temperature was at 6 weeks with the range of temperature wider in the injured hand compared with the noninjured hand. Interestingly, two patients (5 and 6) with a warmer median nerve cutaneous territory at the time of injury had further surgical interventions (patient 5 had neurolysis at 6 months and patient 6 had neurolysis and opponensplasty at 3 months). There was no recorded documentation in the medical notes of either patient having an infection. One (patient 6) of the two patients underwent vascular repair, and thus, no correlation can be drawn between warmer temperatures and vascular repair in this cohort. Temperature was measured up to the 6-month time point and due to this, the hand temperature for patient 5 following revision surgery is unknown.

Secondary Clinical Assessments

The tender muscle squeeze test was positive in two of six patients. Cold intolerance affected all patients and was still present at 18 months. At 18 months, four of six patients had no more symptoms of hyperesthesia. There was a mean reduction of the DASH score between baseline and the final follow-up of 49.5 (SD 30.6). The mean reduction in the NRS pain score was 0.67 (SD 1.03). The Patient Evaluation Measure score showed a mean decrease of 26.5 points (SD 29.2) between recruitment and final follow-up. At the final follow-up, the mean EQ5D general health score was 81.2 (SD 20.9), showing a decline in improvement in health. According to the two-point discrimination using the modified Weber et al[17] grading scale described by Taras et al,[16] two patients were unable to identify between one or two points; two patients scored poor, one fair, and one good.

DISCUSSION

This study aimed to find clinical signs correlated with early nerve regeneration. The results indicate that the progression of a Tinel sign is correlated with both the MRC motor grade and SMRC scale. This supports the

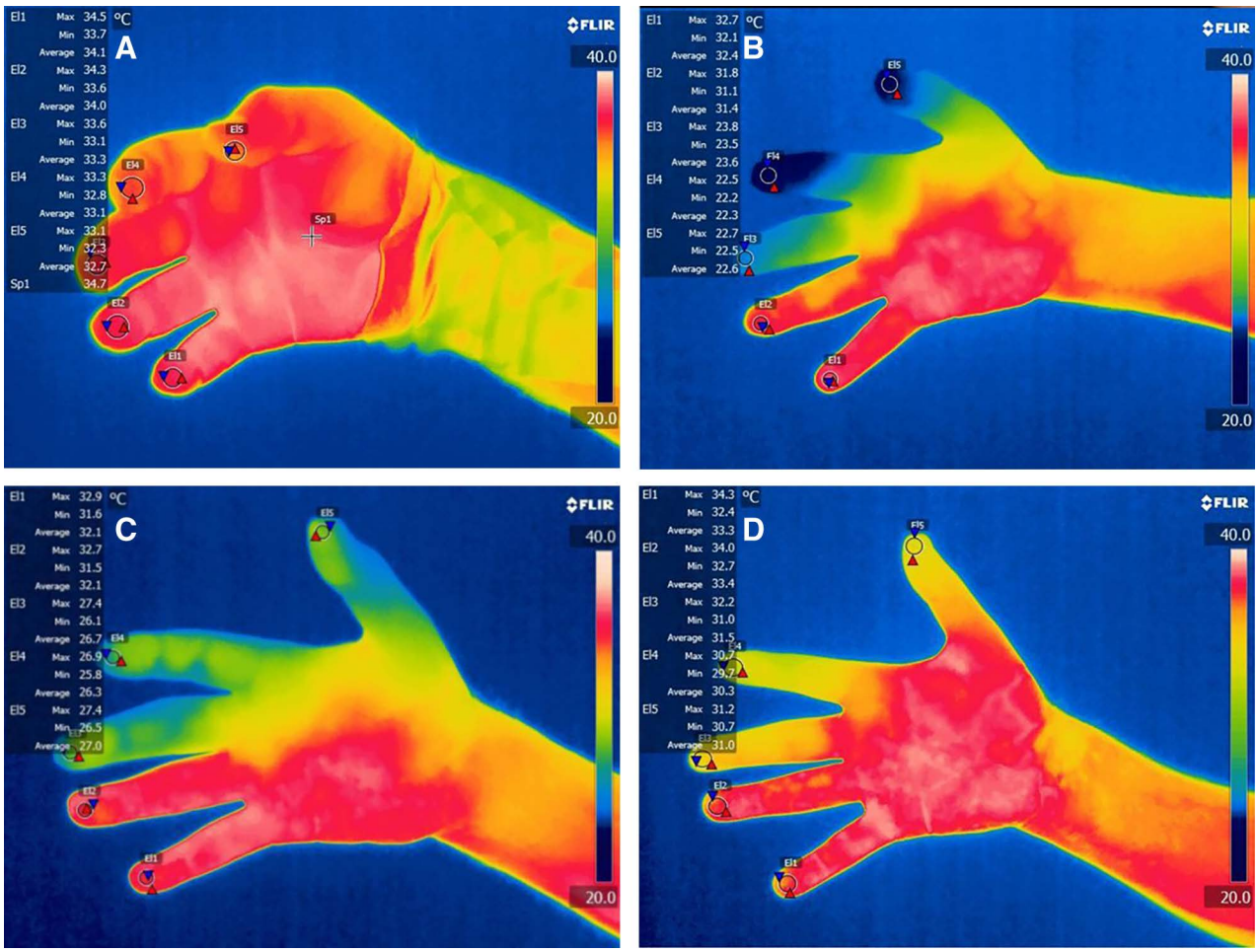

Fig. 3. Thermographic imaging postinjury in one participant over four intervals. A, 2 weeks: median nerve average temperature 33° and ulnar nerve average temp 34°. B, Six weeks: median nerve average temperature 25° and ulnar nerve average temperature 28.6°. C, Three months: median nerve average temperature 26° and ulnar nerve average temperature 32°. D, Six months: median nerve average temperature 30° and ulnar nerve average temperature 33°.

already established hypothesis that Tinel sign is an early indicator of nerve regeneration.[23] The positive response fades proximally with time and distal regeneration, presumably because of distal axon regrowth, pruning of misguided axonal projections and progressive myelinization in the more proximal regenerated segment.[24] Recognition of markers of early nerve regeneration is important when clinically assessing a patient's progress and whether a nerve is progressing as anticipated following intervention. This in turn informs the further management of the patient's treatment and outcome, with current practice in our center being consideration of further surgical intervention should there be two episodes of nonprogressive Tinel sign between 3 and 6 months following initial surgery. Severity of injury would then inform which surgical modality could be used: decompression, neurolysis, debridement and grafting, or tendon transfer.

In this study patients showed improvement in all domains measured. Most patients had progressive improvement in motor and sensory assessments in the 18 month follow-up period following repair of the initial injury. Improvement was also noted in the other assessed clinical signs, with exception of differential Tinel sign and cold intolerance. Of note, it also seemed that the improvement in motor and sensory function was perceived by patients as improving their daily function as indicated trough demonstrable improvement in PROMs. The use of thermographic imaging is well documented in other areas of medicine.[25–27] This study establishes that it may be practicable in nerve injury and observed that there was a generally lower temperature in the median nerve territory after an acute repair compared with an un-injured ulnar nerve territory. This contrasts with the expected dry, warm, and erythematous skin usually thought to signify autonomic nerve disruption due to loss of vasoconstriction.

In this study, two patients required further surgery (patient 5 and patient 6) with each case having a higher temperature in the injured territory. Of note is that patient 6, who required a tenolysis and opponesplasty, was older than the other participants, and although in this case SMRC improved, which may be due to ulnar nerve sprouting, the motor MRC did not improve. Both patients 5 and 6 had surgery 4 days postinjury, with patient 6 also having associated injuries with flexor tendon repairs that would have

required a period of splinting. This may have been a factor in a poorer outcome with increased scar formation around the nerve and less neural glide of the nerve. Other factors may also influence the thermography results such as age, body mass index, and type of injury. To prove the value of thermography, an additional study needs to be conducted in a larger population to determine if it can be used as an objective measure of recovery following nerve injury.

One of the limitations of this study is the small sample size. This prevented us from performing any prediction model and seeing whether any baseline value was predictive of the final outcome. A further limitation is that the follow-up time was for 18 months; other studies have demonstrated improvements over 5 years.[28] A shorter follow-up window was selected to observe only early signs of nerve progression or failure. We could find correlations between the clinical signs and outcomes over time with the available data. Furthermore, because multiple clinical signs and PROMs were measured, we had to select a few of these for our main analysis; correlating all other signs and PROMs would have resulted in multiple testing problems. This only allowed us descriptive depiction of outcomes, instead of calculating correlations. However, the descriptive data showed remarkable improvement in most domains, which might provide promising opportunities for future research. We propose to also correlate the clinical signs and motor and sensory nerve function to PROMs, as these might indicate functional improvement instead of just clinical improvement. A final limitation was the reduction of the sample size due to the COVID-19 pandemic. This caused us to terminate active enrollment, resulting in a final recruitment of nine participants. Due to the early termination and resultant small sample size, it was not possible to identify further factors that may have influenced nerve recovery such as age, time to repair, and medical comorbidity. However, with this limited data set, we were able to find a correlation between Tinel sign and motor and sensory function, which indicates that the effect size is even more significant than we speculated in our initial power calculation.

Future studies could explore how patients' baseline characteristics are associated with their final outcomes, which could facilitate medical decision-making. In these predictive models, clinical signs and PROMs could also be considered. These studies would provide a definitive answer to the main question of this study in which we were ultimately interested, which signs could predict good or bad nerve regeneration outcomes.

CONCLUSIONS

A wide range of clinical assessments can be used to assess nerve progression and recovery. The use of thermographic imaging demonstrates that there is a difference in temperature between an injured and noninjured nerve. However, it did not predict sensory recovery measured using quantitative sensibility thresholds. Further studies are required to ascertain the value of using thermography in testing peripheral nerve regeneration. Clinical signs such as Tinel sign progression and SWM pressure thresholds were correlated with both motor and sensory nerve function.

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DISCLOSURES

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ETHICAL APPROVAL

Ethical approval was obtained, and NHS REC approval was given for the study. Ethics board: West of Scotland Research Ethics Service 17/WSO125. All patients were provided with written informed consent approved by NHS REC.

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