Surgical Treatment of Symptomatic End-Neuroma With a New Bioresorbable Copolyester Nerve Capping Device

A Multicenter Prospective Cohort Study

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Background: Neuroma-induced neuropathic pain is associated with loss of function and reduced quality of life. No consistently effective standard-of-care treatment has been defined. Neurocap, a bioresorbable nerve capping device, has been designed to isolate the nerve stump from surrounding tissues to reduce development of symptomatic end-neuromas.

Methods: Patients with peripheral symptomatic end-neuromas were included in a prospective, multicenter, single-arm design. Data were collected presurgery up till 24 months postsurgery. Eligible patients with neuromas were identified based on blocks using anesthetic. Intervention included surgical excision and capping of the transected proximal nerve end with the Neurocap. Main outcome measures were pain, function, recurrence of symptomatic neuroma, use of analgesics, and adverse events.

Results: In total, 73 patients with 50 upper-extremity and 23 lower-extremity end-neuromas were enrolled. End-neuromas were predominately located in the digits and lower leg. Statistical power of the study outcomes was preserved by 46 of 73 patients completing 24-month follow-up. The mean VAS-Pain score at baseline was 70.2 ± 17.8 (scale 0–100) and decreased significantly to 31 ± 32.5 ($P < 0.001$). Function significantly improved over time. The recurrence rate of confirmed symptomatic neuroma was low (2 of 98 capped nerves). Adverse event rate was low and included pain and infection; there were no unexpected device-related adverse events. Most patients reported lower use of nonsteroidal anti-inflammatory drugs, opioids, and antineuropathic medications at last follow-up compared with baseline.

Conclusions: End-neuroma treatment with excision and capping resulted in long-term significant reduction in reported pain, disability, and analgesic medication use. Adverse event rate was low.

Key Words: nerve capping, Neurocap, symptomatic neuroma

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A neuroma is a benign neoplasm mainly composed of disorganized nerve fibers arising from injured nerves.[1] Typically related to trauma, neuromas can develop in intact nerves (neuroma-in-continuity) or transected nerve ends (end-neuroma). After traumatic injury or iatrogenic nerve transection or rupture, unguided regenerating axons proliferate in a disorganized fashion becoming intertwined with fibroblast-induced collagen forming small bulbous masses known as (end-)neuromas.[2,3] The cutaneous location of sensory nerves renders them particularly vulnerable to injury, and should a neuroma form, there is an increased likelihood for them to be symptomatic. Symptomatic neuromas can elicit profound painful impulses when mechanically stimulated by direct pressure or traction, causing a variety of symptoms including shooting, burning, tingling, and parasesthesias.[3,4] The enlarged nerve and disordered axons are vulnerable to pressure or contusion resulting in evoked pain from mechanical stimulation. Aberrant neuron firing at reduced thresholds can result in spontaneous pain. Symptomatic neuroma occurs in up to 30% of peripheral nerve injuries and can result in severe pain and disability depending on the nerve, location, and patient related comorbidities.[1–3,5,6] The triggers for development of a symptomatic neuroma after peripheral nerve injury remain unclear. Contributory factors include injury mechanism, nerve type, and location. Patient factors undoubtedly play a role in symptom severity and response to treatment. Smoking is associated with higher rates of symptom persistence and recurrence after neuroma surgery.[2] Neuroma-induced neuropathic pain not only causes patient suffering but has a substantial socioeconomic impact.[2]

Numerous techniques have been described to treat symptomatic end-neuromas. Passive ablative techniques, including neuroma resection with or without proximal nerve relocation,[4] are commonly reported strategies but have higher rates of symptom recurrence[7,8] than active techniques that provide a regeneration target. Active techniques include reconstruction with grafts (if a distal nerve end is available) and targeted muscle reinnervation (TMR). They enable axon regeneration, and favorable outcomes have been reported,[8] but the local anatomy however may not lend itself to proximal relocation, gap reconstruction, or TMR. Therefore, there is a need for a technique that enhances local resection alone. At this time, however, no technique has demonstrated sufficient efficacy to become the de facto solution for neuroma-associated neuropathic pain. Limitations of existing methods include a need for substantial surgical time and specific surgical techniques, and inconsistent efficacy.[9] Epineurial sleeves[10] and silicone caps[11] have been attempted. Epineurial sleeve application is technically tedious, and silicone cap usage was hampered by dislodgement, inconsistent results, and local irritation.[11,12]

Neurocap, a bioresorbable nerve capping device, was developed to reduce symptomatic neuroma formation by isolating and protecting the peripheral nerve end from the surrounding environment. The design specifically limits sprouting and the disorganized axonal swirling observed in a rodent sciatic neuroma model.[13]

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Registration number: The study was prospectively registered at Clinicaltrials.gov; registration number NCT02993276.

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TABLE 1. Inclusion and Exclusion Criteria

Inclusion Criteria	Subjects who are able to provide a written informed consent before participating in the clinical investigation
	Subjects who are able to comply with the follow-up or other requirements
	Subjects who are ≥18 years old
	Subjects with a diagnosis of peripheral symptomatic (end-) neuroma in the upper- or lower-limb
	Subjects with a positive Tinel sign
	Symptomatic neuroma confirmed by pain relief following a 10 min ± 2 min nerve block with xylocaine (lidocaine)—pain relief defined as minimally 50% reduction in VAS questionnaire score
	Subjects that are indicated for surgery to treat symptomatic neuroma
Exclusion criteria	Subjects who do not complete the informed consent
	Subjects who are not willing to follow postsurgery protocols (eg, avoiding pressure on the implant zone or immobilization).
	Subjects who are unable to comply with the follow-up or other requirements and/or have a life expectancy of less than 24 mo
	Subjects with congenital neuropathy
	Insufficient amount of soft tissue to cover the investigational device, as assessed by the surgeon. Use of the device over a joint is advised against.
	Subjects who have had historical radiotherapy in the area of the (end-)neuroma
	Subjects who have a known allergy to anesthetic agent or bioresorbable copolyester Poly(68/32[15/85 D/L] Lactide-ε-Caprolactone) (PLCL)
	Proximal nerve end <8 mm diameter

The current study aimed to prospectively establish short- and long-term efficacy and safety for Neurocap in the treatment of symptomatic end-neuromas in peripheral nerves in patients during a 24-month follow-up period.

MATERIALS AND METHODS

Study Design

This was a prospective, multicenter, single-arm trial. Data were collected at a presurgical screening visit, at surgery, and at 3, 6, 12, and 24 months follow-up time points. The study was prospectively registered at Clinicaltrials.gov on December 8, 2016 (registration number NCT02993276). Written Ethical Committee or Institutional Review Board approval was obtained for all participating centers. The study was performed according to the Declaration of Helsinki and in agreement with the guidelines for conducting a clinical investigation.

Patient Population

Patient enrollment was from April 17, 2017 through July 12, 2018 across 19 European, British, and American hospitals. Male and female patients, 18 years and older, scheduled for treatment of 1 or more symptomatic peripheral end-neuromas were recruited. Alternative treatment options were discussed with all patients. Subjective pain relief of 50% on the visual analog scale (VAS) following a xylo/lidocaine challenge was necessary for enrollment. Inclusion and exclusion criteria are specified in Table 1. The block was performed as a local block around the suspected neuroma as per surgeon preference, and neither the quantity of anesthetic nor the use of advanced imaging such as ultrasound was compulsory specified or recorded in the study database. The diagnostic pathway used in the study aligns with the pathway suggested in a subsequent publication by Arnold et al.[14] Written informed consent was obtained for all patients before enrolment. Patients could be compensated for travel expenses for additional study visits outside standard-of-care at the hospital.

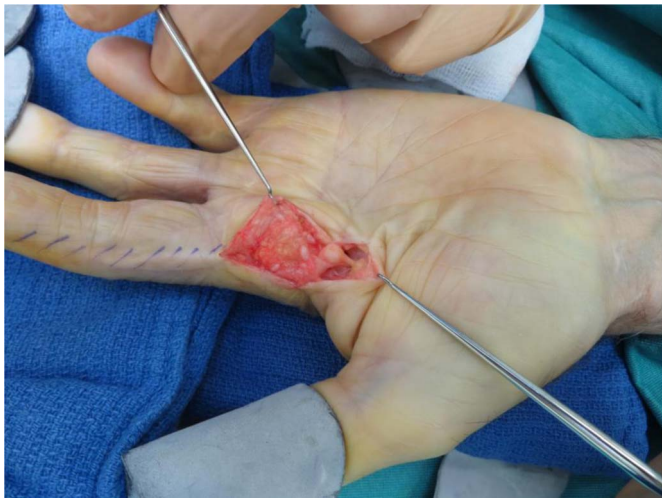

FIGURE 1. Symptomatic neuroma after ray amputation of index finger.

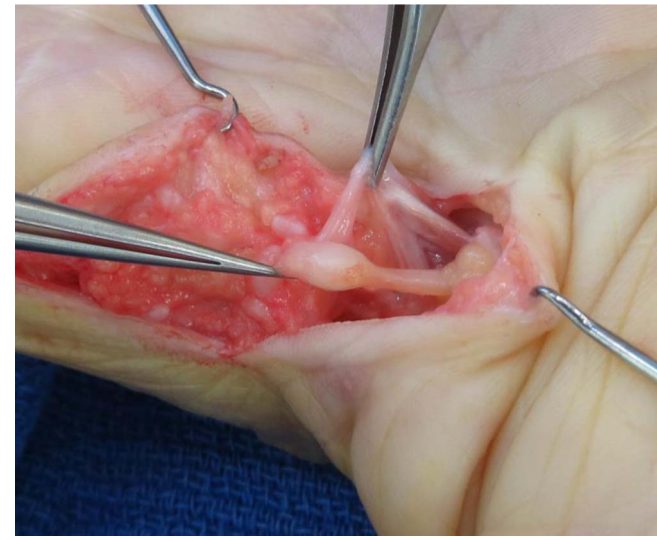

FIGURE 2. Close up of neuroma before resection.

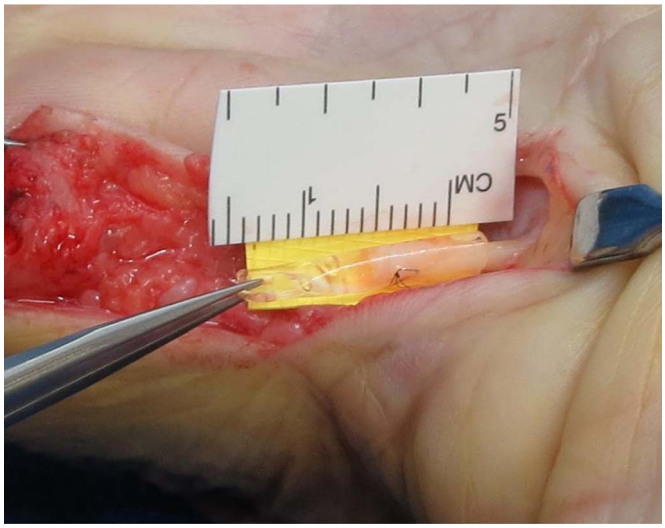

FIGURE 3. First suture placement to secure residual nerve stump in Neurocap.

Sample size was calculated to confirm a minimal VAS pain score reduction from 66 to 44 (at a scale of 0–100) based on previously collected but unpublished data (NCT02528266). To achieve a power of 0.80 and an α of 0.05 (2-sided), a necessary sample size of 46 patients was anticipated. The enrollment of minimally 69 patients was planned to compensate for a potential 1/3 dropout due to the long duration of the study.

Surgical Technique

Neurocap (Polyganics B.V., Groningen, the Netherlands) is a tubular device sealed at one end composed of the same biocompatible, bioresorbable copolyester composing the Neurolac nerve guide, Poly (68/32[15/85D/L] Lactide-ε-Caprolactone) (PLCL) (Fig. 1, Fig. 2, Fig. 3, Fig. 4). The size of the product is 3 cm in length and is available in different diameters for different sized nerves (1.5–10.5 mm). The correct device size is calculated intraoperatively based upon the diameter of the proximal nerve stump after resection of the symptomatic neuroma.

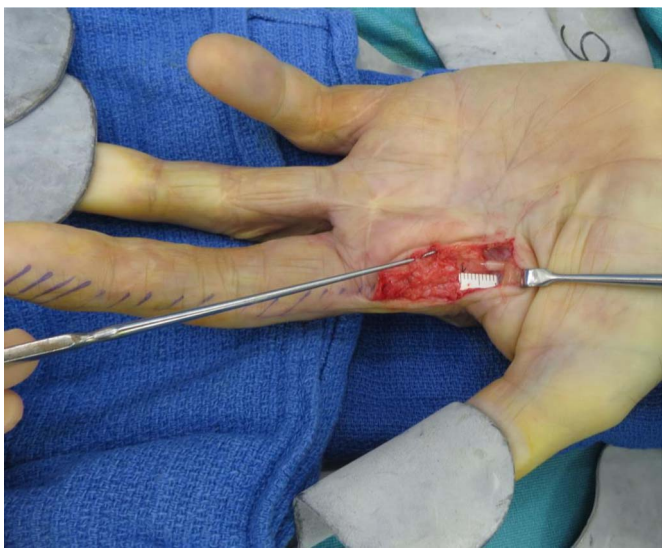

FIGURE 4. Anchor suture to stabilize Neurocap in wound.

The length of the device can be trimmed to accommodate final placement.

Prophylactic antibiotics and tourniquet were administered based on surgeon preference. Each neuroma was exposed, mobilized from surrounding tissue, and excised. The width of the nerve end was measured using a sterile ruler and a Neurocap of the appropriate diameter was selected. The device was soaked in 37°C saline solution to improve pliability and ease of suturing, and trimmed in length so that the nerve end could be securely inserted into the tubular portion of the device while maintaining a 5-mm gap between the nerve end and the end of the nerve cap. Two nonresorbable microsutures were placed 180 degrees apart between the tube edge and the epineurium. The capped nerve end was relocated under muscle or in adipose tissue, per surgeon preference, to ensure sufficient cushioning. In total, 23 surgeons performed the procedures.

Assessments

Initial screening included collection of demographic information, cause of neuroma formation, diagnosis and localization of neuroma, treatment history,

TABLE 2. Patient Demographics at Screening

Demographic	Population	
Age, mean [SD], y	46.8 [15.2]	
Gender, n (%)		
Male	46 (63.0%)	
Female	27 (37.0%)	
Neuroma location, n (%)		
Upper-limb	50 (68.5%)*	
	Hand and/or digits	40 (54.8%)
	Arm	10 (13.7%)
Lower-limb	23 (30.5%)*	
	Lower leg	22 (95.7%)
	Upper leg	1 (4.3%)
Comorbidities		
Musculoskeletal	19	
Cardiovascular	12	
Diabetes	3	
Autoimmune disease	21	
Other	21	
None	35	
Pain medication at screening, n (%)		
None	19 (26.0%)	
Paracetamol	20 (27.4%)	
NSAIDs	23 (29.9%)	
Neuromodulators	33 (42.9%)	
Opioids	34 (44.2%)	
Smoker, n (%)		
Yes	13 (17.8%)	
No	60 (82.2%)	
No. caps implanted per patient		
1	51	
2	17	
3	3	
4	1	

*In total, 73 patients were treated who received 92 Neurocaps. Several patients received Neurocaps on multiple nerves, mainly in digital implants. In some patients, more than 1 Neurocap was placed on 1 nerve, mainly in lower extremity implants.

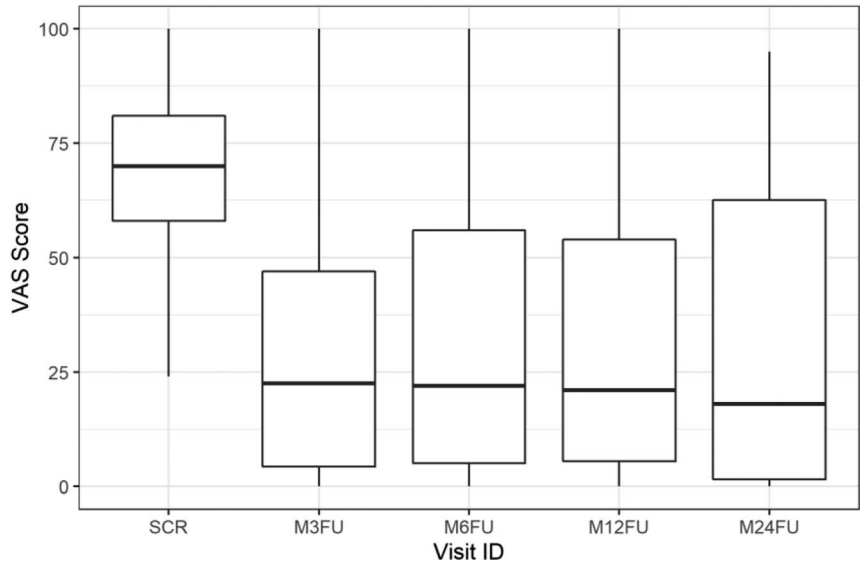

FIGURE 5. Absolute VAS scores at screening and each follow-up period.

workers compensation status, and pain medication usage. After localization by means of Tinel test, a local diagnostic block of xylo/lidocaine anesthetic was injected around the suspected neuroma. Preinjection and postinjection pain was assessed utilizing a VAS (0 = no pain; 100 = worst imaginable pain). Additional data collection included the Elliot neuroma score questionnaire including 5 questions regarding pain and scored on a scale of 0–20.[15] Functional assessments included subjective disability ratings of 3 patient-identified activities (for lower extremity neuroma patients—goals score) and the Quick Disability of the Arm, Shoulder, and Hand (QuickDASH) questionnaire (for upper extremity neuroma patients).[16,17] Pain and functional assessments and pain medication usage were reassessed at 3, 6, 12, and 24 months follow-up. During the complete follow-up period, all adverse events regardless of their relationship to the device or treatment were recorded. Surgeon focused data were obtained at the time of surgery by means of a questionnaire. Questions included ease of handling and application in comparison to earlier experiences and preferences.

TABLE 3. Fixed Effects Results From Fitting the Full Repeated Measures Mixed Effects Model

Covariate	Estimate of Effect	95% CI	*P*
Intercept	87.89	(55.69, 120.77)	<0.001*
3 mo	−41.46	(−48.84, −34.16)	<0.001*
6 mo	−39.10	(−46.37, −31.60)	<0.001*
12 mo	−37.76	(−45.49, −30.12)	<0.001*
24 mo	−38.48	(−47.14, −30.04)	<0.001*
Male	−5.16	(−14.60, 4.22)	0.33
Age	−0.17	(−0.51, 0.16)	0.36
Smoker (yes)	6.07	(−5.95, 18.12)	0.37
Diabetes (yes)	2.34	(−21.00, 25.31)	0.86
Cardiovascular disease (yes)	7.66	(−5.56, 20.93)	0.31
Musculoskeletal (yes)	3.71	(−8.58, 16.07)	0.59
Autoimmune disease (yes)	18.16	(−11.24, 47.76)	0.28
Adverse event (yes)	6.99	(−3.93, 17.96)	0.26
Digit (yes)	6.47	(−3.13, 15.97)	0.23
Hand (yes)	−13.55	(−37.89, 10.37)	0.32
Arm (yes)	−20.37	(−45.18, 4.30)	0.15
Leg (yes)	−15.48	(−38.86, 7.37)	0.24

*Significant at the <0.1% level.

Statistical Analysis

Data from VAS scores were analyzed using a repeated measures random effects model. Presence of comorbidity, the occurrence of adverse events, neuroma location, age, gender, and smoking habits were included as covariates. The relationship between VAS score, Elliot score, and function scores were investigated graphically, taking the follow-up time point into account. Where the primary VAS analysis indicated a significant relationship with any of the covariates, this relationship was further evaluated for additional pain measures. The changing characteristics of the pain data for the different visit time points were visualized to indicate the trend in medication use over time. In the subanalysis of amputee patients, independent *t* tests and Mann-Whitney *U* tests were used to identify significant differences between the scores reported for amputee and nonamputee patients. Data were analyzed statistically using R Version 4.0 and the lmerTest package was used for fitting and evaluating the mixed models.

RESULTS

Seventy-three patients (46 male; 27 female) were enrolled with a mean age of 47 ± 15 years. Fifty upper-limb and 23 lower-limb end-neuroma patients were included (Table 2), mostly located in the digits and lower legs. For 66 of 73 enrolled patients, the treated symptomatic neuroma had been present for more than 6 months at time of the study surgical treatment. Three patients had the origin of their neuroma between 4 and 6 months before their study surgery. In 4 patients, the origin of the neuroma was less than 4 months before their study surgery. Fifty of 73 treatments were revision patients that had received 1 or more prior surgeries for the neuroma before enrolling into the study. In total, there were 98 Neurocaps implanted. Of the 73 patients initially enrolled, 46 (63%) patients completed at 24-month follow-up.

The mean VAS score at screening was 70 ± 18 and decreased significantly to 31 ± 33 at 24 months ($P < 0.001$) (Fig. 5; Table 3). For 78.3% of patients, this implied an improvement of VAS score of ≥5 levels. A total of 30.4% of patients still had a VAS score ≥50 at final

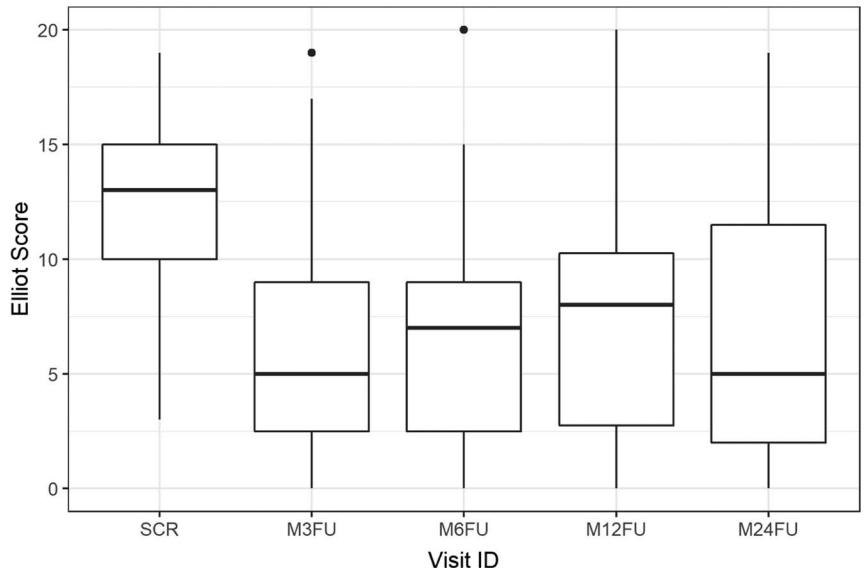

FIGURE 6. Absolute Elliot scores at screening and each follow-up period.

follow-up. The mean Elliot score at screening was 13 ± 4 and significantly decreased during 24-month follow-up to 7 ± 6 ($P < 0.001$). The mean QuickDASH score at screening was 56 ± 20 and significantly decreased during follow-up to 29 ± 29 ($P < 0.001$) (Fig. 7). The mean goals score at screening was 8 ± 3. This significantly increased to 12 ± 5 during 24-month follow-up ($P < 0.001$) (Fig. 8), indicating a significant decrease in functional disability. The most problematic activities reported preoperatively consisted of exercising, housework, driving, and activities that require fine motor movements. The VAS score had a strong significant positive correlation to the Elliot score ($r = 0.77$) (Fig. 6), a significant positive correlation to the QuickDASH score ($r = 0.76$) and a significant negative correlation to the goals score ($r = -0.75$), indicating that at lower VAS scores there should be higher QuickDASH scores and lower goals scores and therefore improved functionality.

TABLE 4. Summary Statistics for the VAS, Elliot, QDASH, and Goal Scores of Amputee and Nonamputee Patients

		VAS		ELLIOT		QuickDASH		Goals	
VISITID	Amputee	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Screening	No	69.0	18.5	12.7	3.8	59.3	18.7	7.2	2.7
	Yes	73.9	14.8	12.4	3.9	48.6	22.6	8.2	2.5
	Difference	4.9	−3.7	−0.2	0.2	−10.7	3.9	1.0	−0.2
3 mo	No	28.2	28.3	6.4	4.8	35.0	26.2	11.7	4.1
	Yes	29.2	25.5	5.6	4.7	22.7	22.6	13.4	4.0
	Difference	0.9	−2.7	−0.9	−0.1	−12.2	−3.6	1.6	−0.1
6 mo	No	31.9	30.9	7.3	5.5	37.4	28.6	11.5	4.4
	Yes	31.3	30.9	5.7	3.8	26.6	22.9	13.4	3.6
	Difference	−0.6	−0.1	−1.6	−1.7	−10.8	−5.7	2.0	−0.8
12 mo	No	30.1	27.6	7.8	5.4	40.4	26.7	11.7	4.5
	Yes	36.1	33.1	6.2	4.7	27.1	24.6	13.5	4.3
	Difference	6.0	5.5	−1.6	−0.7	−13.3	−2.14	1.8	−0.1
24 mo	No	29.8	31.9	7.4	5.8	34.6	30.8	11.6	5.0
	Yes	32.6	35.8	4.8	4.8	18.9	21.5	14.1	3.6
	Difference	2.8	3.9	−2.7	−1.0	−15.7	−9.3	2.5	−1.4

Postprocedure, patients had a trend toward decreased pain medication intake but more importantly they generally shifted toward lesser-impact medication such as paracetamol/acetaminophen and nonsteroidal anti-inflammatory drugs (NSAIDs). Of the patients who used medications preintervention, a majority of patients had lower use of NSAIDs (15 patients with lower dose—68% of those with any NSAID use), opioids (15 patients with lower dose—63% of users), and antineuropathic medications (14 patients with lower dose—50% of users) at the last recorded follow-up than at screening (Fig. 9).

There were 2 confirmed recurrent neuromas requiring surgical revision during the 24 months study period (one in the infrageniculate branch of the saphenous nerve and one in the palmar cutaneous nerve). Relevant adverse events noted included pain (13.7%), infection (2%), seroma (1%), hematoma (1%), allergic reaction (1%), and abscess formation (1%).

Eighteen of the included subjects had amputation-related neuromas. In total, there were 28 amputation-associated neuromas of which 22 were in the digits, 4 in the arm, and 2 in the leg. There appeared to be little difference in the average scores for both the pain and functionality compared with nonamputees, except for the QuickDASH score where patients with an amputation reported lower scores than those without an amputation (Table 4).

The surgeon focused questionnaire indicated ease of use and application of Neurocap comparable with other commonly used methods.

DISCUSSION

This study assessed the Neurocap device for the management of symptomatic end-neuromas. Clinical efficacy was demonstrated during a 24-month follow-up period by decreasing VAS pain scores, improvement in functional outcome scores, and decreasing pain medication requirements. Symptomatic neuroma recurrence was low, and the device was well tolerated by patients.

Neuropathic pain can become centralized in a poorly understood process sometimes thought of as central nervous system imprinting with some similarities to complex regional pain syndrome or phantom pain (after surgical amputation).[1,16] Deafferentation pain can be recalcitrant to all modalities, although addressing all related pain generators (such as neuromas) is still felt to be a critical component of any comprehensive treatment plan.[16,18,19] In this study, end-neuroma diagnosis was determined by a history of injury, systematic examination, and a

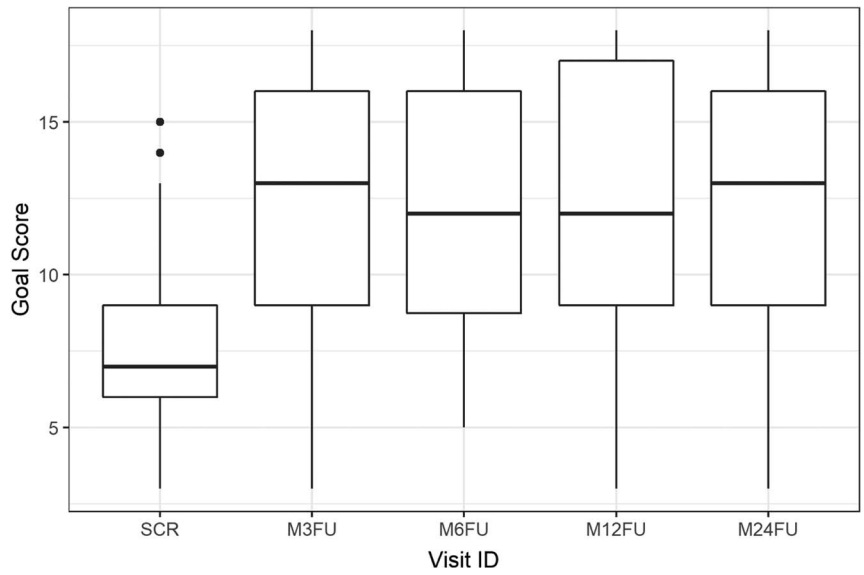

FIGURE 7. Absolute goals scores at screening and each follow-up period. The score is calculated as the sum of the 3 individual goal scores.

positive response to a local anesthetic block of the affected nerve proximal to the site of suspected neuroma.[2]

Numerous techniques have been described for end-neuroma management, but scientific data quality is generally low. A pooled data review from 54 studies on surgical management of neuromas included only 4 prospective studies.[9] There was no statistical difference between the different surgical treatment groups reported in their review. A meaningful reduction in pain was reported in 77% of patients across all surgical techniques. Neuroma excision and relocation can be effective in reducing pain, with over 70% of patients having meaningful pain reduction. This is in concordance with other reports estimating a surgical failure rate up to 30%,[1,20,21] whereas other reports high reoperation rates of up to 65%.[8,20] For some of these failures, we suspect unhindered neuron outgrowth and perineurial scarring could result in recurrent pain. In the current study, the addition of a Neurocap post neuroma excision seemed to improve efficacy as demonstrated by a 56% reduction in VAS pain score pain (70 to 31) maintained at 24 months. In addition, 67% of patients had a meaningful reduction in pain as measured by either a reduction of ≥30 VAS points or a VAS score ≤40.

We saw a reduction in the percentage of patients taking any medications as well as a reduction of patients taking multiple pain medications during 24-month follow-up. Pain medication overall and most profoundly opioid and use of antineuropathic medications were reduced compared with baseline. This trend indicated a shift toward less morbid and addictive pain medications such as paracetamol and NSAIDs. We acknowledge that patients may have self-medicated or obtained unreported opiate medications, although by analyzing changes in medication usage over the course of 2 years we would expect reporting biases to be consistent.

Despite supportive animal data, the technical challenges associated with capping procedures may account for limited clinical adoption.[10] Historically, silicone nerve caps were poorly fitted,

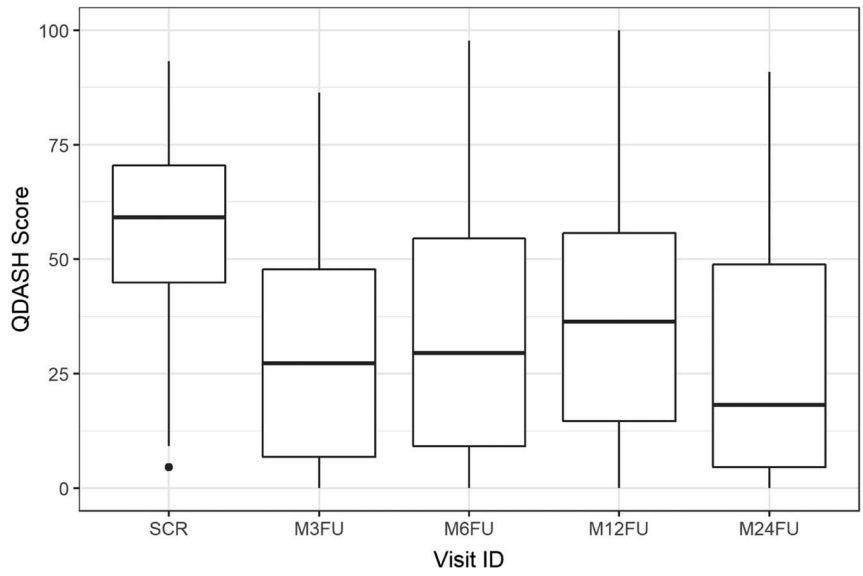

FIGURE 8. Absolute QDASH disability scores at screening and each follow-up period.

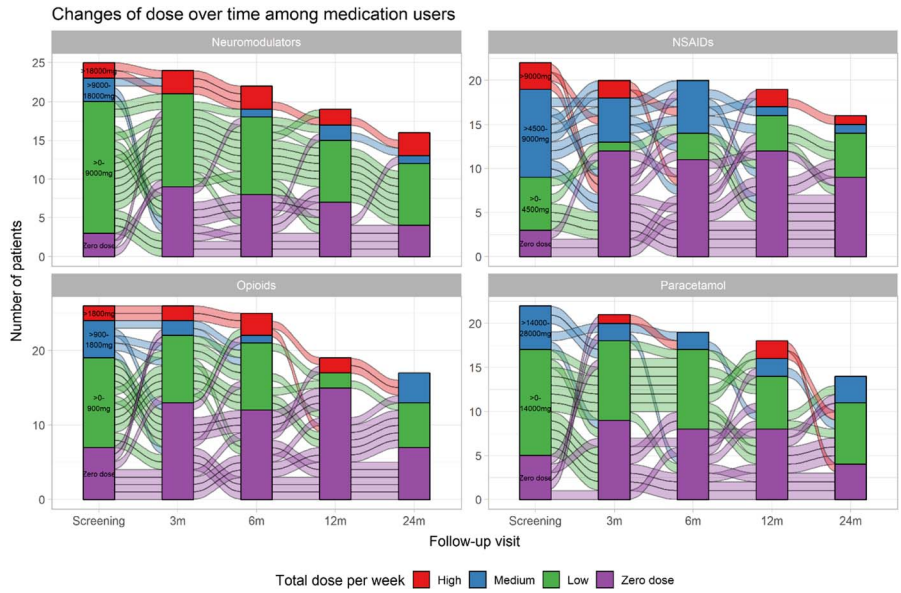

FIGURE 9. Line graph of changes in total pain medication dose at each visit, organized by medication type. Colored segments indicate number of patients with high, medium, low, and zero medication use at each visit, with exact category cutoffs indicated in the screening bar of each subplot. The colored flowing lines indicate the movement of a patient from a category at 1 visit to another category at the next.

allowing axon escape, as well as structurally hard and rigid causing secondary neural irritation and the need for unplanned surgical removal.[22] Neurocap is biotolerant and absorbable so that nerve irritation would be unlikely and, if present, would be transient.[13] This was not found to be an issue in the current study, and the revisions reported were not related to device irritation. Neurocap also differs from predicate devices in that a 5-mm void is maintained between the nerve end and the blind pouch. The resulting environment is not neurotrophic, does not support axon regeneration, and seems to inhibit robust axonal elongation. As demonstrated in a small animal study, the regenerating axons only grow a short distance and do not form the characteristic swirling pattern associated with neuroma formation.[13] Once capped, nerve ends were buried in a soft tissue envelope so that mechanical shielding may have played a role in the overall treatment effect, although the clinical outcomes are far superior to relocation procedures not incorporating the Neurocap.[1–3] Neuroma formation was not assessed in the current study, but the very low revision rate implies successful prophylaxis of symptomatic neuromas.

Lacking a suitable recipient nerve, TMR and regenerative peripheral nerve interfaces have emerged as strategies for end-neuroma treatment.[16,23,24] After neuroma resection, the proximal end is sutured to a freshly cut motor nerve at the nerve's muscle entry point in TMR. Although conceptualized to create amplified myoelectric signals to facilitate advanced prosthetic control for amputees, the procedure quickly became associated with a dramatic reduction in neuroma pain.[17] These procedures however can be technically demanding and require detailed knowledge of the motor nerve branching anatomy and longer and more expansive exposures. Regenerative peripheral nerve interface also prevents neuroma formation by providing free muscle grafts as physiological targets for peripheral nerve ingrowth, thus preventing symptomatic neuroma formation.[23] Nerve capping can be performed at the time of amputation or as in the current study in the management of established end-neuromas. Nerve caps generally require limited to no additional dissection and can be performed quickly and efficiently in almost any anatomic location. The favorable, surgeon-focused "ease of use" data collected in our study support this assertion, although the potential for bias cannot be excluded as participating surgeons were compensated.

The study was adequately powered and provided long-term follow-up on nerve capping as a treatment for an established symptomatic end neuroma. Short follow-up periods might miss delayed neuroma recurrences. Even symptoms of late recurrence would be expected before the 24-month end point in our study. The study population was diverse with regards to background and neuroma location and included both amputees and nonamputees.

The lack of a control group is potentially a weakness of this study, with no universally accepted criterion standard therapy; an acceptable control treatment strategy was not feasible. Also, the subjective nature of pain as the main primary outcome measure allows for potential bias. The use of VAS pain scores, while a purely subjective outcomes measure, is standard for this type of study. Currently, there is no objective measure of pain. Secondary outcomes points including the Elliot neuroma score and functional outcomes scores were meant to bolster the VAS findings and emphasized the role of chronic pain on daily activities and overall function. Functional limitation as a result or symptomatic end-neuromas is challenging to measure given the heterogeneity of the patient populations, neuroma location, neuroma symptom duration, and pain severity at baseline. The QuickDASH is a validated upper-limb questionnaire and was used in the assessment of the upper-limb neuroma patients. Pain medication usage was included as an additional objective outcome measure.

CONCLUSIONS

Our results demonstrate long-term device safety and efficacy with significant reduction of pain, pain medication use, and disability. Surgeon feedback on ease of use was comparable to standard surgical procedures. The results should be interpreted in context of the complexity to treat this patient group.

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