Surgical treatment of symptomatic neuromas: a feasibility study using the NEUROCAP® bioresorbable nerve capping device

Dear Editor,

Neuropathic symptoms secondary to neuromas, following traumatic or iatrogenic causes, can significantly affect the quality of life and socioeconomic integration of patients (van der Avoort et al., 2013). Many methods have been described to treat symptomatic end-neuromas, including pharmacological and surgical techniques, each with its own limitations. In general, surgical treatment involves excision of the neuroma and burying the nerve end within soft tissues or bone, with varying success rates. Repeat surgeries are often required (van der Avoort et al., 2013) and there is usually some degree of residual pain.

The use of synthetic nerve capping materials to limit pathophysiological axon regeneration have recently been developed to reduce the need for repeat surgeries. It is hypothesized that neural capping allows for epineural recovery within the device but reduces the regeneration of disorganized axons and formation of a bulbous mass that is susceptible to mechanical stimulation and painful adhesion to surrounding scar tissues (Yan et al., 2014). A recent study demonstrated NEUROCAP® (Polyganics, Groningen, Netherlands) to be effective in a case of digital end-neuroma (George et al., 2020). NEUROCAP® is a bioresorbable nerve cap (Figure 1), made of biocompatible co-polyester (Poly[68/32(15/85 D/L] Lactide-Caprolactone) or PLCL. In this cohort study, we assessed the safety, outcome and ease of use of NEUROCAP® to reduce the recurrence of peripheral symptomatic end-neuroma with a 12-month follow-up.

This prospective, multicentre, single-arm trial was registered at ClinicalTrials.gov (NCT02528266). Patients with upper-limb peripheral symptomatic end-neuroma were enrolled between February 2016 and March 2017 at three Dutch hospitals. Inclusion and exclusion criteria are listed at ClinicalTrials.gov. A total of 10 patients met the inclusion criteria. Eight patients had an end-neuroma of the superficial radial nerve (SRN) and two of the median nerve. Preoperatively, the locations of the end-neuromas were confirmed by Tinel’s test and a decrease in pain after lidocaine block, as demonstrated by a four-fold reduction in the visual analogue scale (VAS) for pain, from 80 to 20 ($p < 0.05$). Intraoperatively, the neuromas were excised, and the nerve end placed into the NEUROCAP® and secured with non-resorbable sutures. The nerve and cap were then surrounded with and secured onto the surrounding soft tissues. Postoperatively, the VAS pain score reduced from 73.3 at baseline to 17.3 at 6 weeks follow-up. An international neuropathic pain score system (Douleur Neuropathique 4 or DN4) was reduced from 6.4 to 3.3 and neuroma pain score (Elliot et al., 2010) reduced from 12.8 to 3.5. All pain scores remained similarly low throughout the 12 months follow-up (Figure 2). At 12 months, the mean VAS score was 22.1, DN4 score 3.4 and neuroma pain score 4.4. Disability of the affected upper limb improved, demonstrated by a decrease in Quick Disabilities of the Arm, Shoulder, and Hand (QuickDASH) questionnaire score from 51.6 at baseline to 20.0 at 6 weeks and 14.4 at 12 months (Figure 3).

Preoperatively, all patients used at least one type of painkillers. On average, the preoperative intensity of each type of neuropathic pain was moderate to severe and for one patient, the worst pain imaginable. After 6 weeks, only three patients required the continued use of painkillers, with the majority reported no pain or only pain of mild intensity. There were no adverse device-related effects, as assessed by an independent Data Safety Monitoring Board. One patient suffered an external trauma within 6 weeks postoperatively, resulting in a seroma, re-operation and removal of the NEUROCAP®. The patient continued follow-up until 3 months and decided to quit the study afterwards. At study exit, the patient had no neuropathic pain and his improved QuickDASH score remained.

**Figure 1.** The NEUROCAP® device.
There were two neuroma recurrences involving the radial sensory nerve, one after an external trauma and the other with an unclear origin; both of which were treated conservatively. Other adverse events that occurred were anticipated and included postoperative pain and numbness of the operated area, inherent to the healing process and did not require intervention.

Our results compared favourably with those of Regal and Tang (2019) and Yao et al. (2017), when focused on the SRN. The use of NEUROCAP® in our patients demonstrated a similar or better result regarding revision surgery rate and improvement of disability. The results were not superior to the technique of end-to-side repair of SRN neuroma, which resulted in pain-free follow-up of at least 16 months in three patients (Regal and Tang, 2019). However, the results of VAS score were comparable with muscle implantation or SRN neurolysis and interposition of acellular dermal matrix allograft (Yao et al., 2017). The major limitation in our study is the small sample size, and future studies should be further assessed within a larger patient group. Future studies should assess more long-term outcomes and compare different treatments for symptomatic end-neuromas, including treatment with the bioresorbable NEUROCAP®, to determine potential benefits for each treatment option. To this end, a prospective clinical trial with a larger group and 2-year follow-up is currently underway (ClinicalTrials.gov number NCT02993276).

**Acknowledgements** Statistical advice was received from H. Groen, MD PhD, epidemiologist affiliated to the Department of Epidemiology of the University Medical Center Groningen.

**Declaration of conflicting interests** The authors declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: MB was involved in device conception under patent EP3265142 / US20180339083. All participating surgeons (TS, TvM, MB) were contracted as investigator for the study. EdV declares to have no conflicting interests with
respect to the research, authorship, and/or publication of this article.

**Funding** The authors disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: the study was sponsored by Polyganics. Study fees covered additional efforts necessary for device implantation, study data registration and time for follow-up assessments that were not covered within standard of care. Patients were offered coverage of travel expenses for the follow-up visits that were not part of standard of care at their hospital. All study devices were provided by Polyganics.

**Ethical approval** The study was performed according to the Declaration of Helsinki and in agreement with the guidelines for conducting a clinical investigation and registered at ClinicalTrials.gov (registration number NCT02528266). Written Ethical Committee approval was obtained for all participating centres (UMCG 2016/009, MUMC 161001, MC Group 111010).

**Informed consent** Written informed consent was obtained from all subjects before the study.

**References**

Elliot D, Lloyd M, Hazari A et al. Relief of the pain of neuromas-in-continuity and scarred median and ulnar nerves in the distal forearm and wrist by neurolysis, wrapping in vascularized forearm fascial flaps and adjunctive procedures. J Hand Surg Eur Vol. 2010, 35: 575–82.

George S, Pohl U, Power D. Analysis of an end neuroma 6 months after capping with a bioresorbable polycaprolactone cap (NEUROCAP®) in a human model. Surg Case Rep. 2020, 3: 2–4.

Regal S, Tang P. Surgical management of neuromas of the hand and wrist. J Am Acad Orthop Surg. 2019, 27: 356–63.

van der Avoort DJ, Hovius SE, Selles RW et al. The incidence of symptomatic neuroma in amputation and neurorrhaphy patients. J Plast Reconstr Aesthet Surg. 2013, 66: 1330–4.

Yan H, Zhang F, Kolkin J et al. Mechanisms of nerve capping technique in prevention of painful neuroma formation. PLoS One. 2014, 9:e93973.

Yao C, Zhou X, Zhao B et al. Treatments of traumatic neuropathic pain: a systematic review. Oncotarget. 2017, 8: 57670–9.

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**Achenbach syndrome: a report of three familial cases**

Dear Editor,

Achenbach syndrome, paroxysmal finger haematoma, is a benign condition of unknown aetiology. It is uncommon, with less than 50 previously reported cases, mostly single case reports (Godoy and Tabares, 2019). It consists of spontaneous bruising and discoloration of the palm or the palmar surface of the digits and more rarely the toes, that may be preceded by pain and tingling for a few hours. The discoloration fades spontaneously within a few days. There is no reported association with trauma, occupation, vibration exposure or body habitus. There is no treatment other than patient reassurance.

I report three cases of Achenbach syndrome. The index patient is a 48-year-old right-hand dominant woman. She has a several year history of recurrent painful bruising of the palmar surface of all eight fingers (Figure 1). This occurs sometimes spontaneously and sometimes after lifting and carrying items, such as shopping bags. The frequency of episodes is every few weeks or months and the duration of symptoms is 1 to 3 days. Clinical examination is unremarkable. She is a non-smoker with no other bleeding tendency and no medical history. Previous coagulation investigations were normal.

The second patient, her mother, is aged 73, left-hand dominant and retired. Her symptoms started at the age of 70. All eight fingers are affected, predominantly in the right hand. The pulps of the fingers are unaffected. Symptoms occur every 2 to 4 months and last 1 or 2 days. She is a non-smoker.

The third patient, the sister of patient two, is aged 70, right-handed and retired. Her symptoms affect all the digits except the little fingers and thumbs, sparing the distal part of the pulp. The distal part of the pulp is spared.

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Figure 1. Patient one: the discoloration affects the palmar side of the fingers. The distal part of the pulp is spared.