A Pilot Multicenter, Prospective, Randomized, Subject-Blinded Comparative Study of Axoguard Nerve Cap® and Neurectomy for the Treatment of Symptomatic Neuroma and Prevention of Recurrent End-Neuroma Pain (REPOSE℠)

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Introduction

- The current standard of care for surgical neuroma management involves either traction neurectomy, which has a high rate of neuroma recurrence, or burying the nerve stump into adjacent muscle or bone.
- While burying can prevent mechanical stimulation that would cause pain, this procedure does little to manage the resulting regenerate and the subsequent neuroma that will form.
- Neuromas in the foot are a suitable model for neuromas throughout the body as the nerves in the foot are subjected to more mechanical stimulation than most other anatomical areas and therefore represent a worst-case scenario.

Overall Study Design

Study type: Pilot crossover to Comparative Parallel Group
- 101 subjects
- Up to 15 centers (US only)

Study Population: Adults with symptomatic neuroma in at least one nerve in the foot or ankle that cannot be repaired to a distal nerve end

Study Groups: Axoguard Nerve Cap vs Neurectomy

Current Study Design

Study type: Pilot

Study Population: Adults with symptomatic neuroma in at least one nerve in the foot that cannot be repaired to a distal nerve end

Study Groups: Axoguard Nerve Cap

Current Objective: To compare early pain scores at baseline (6 weeks pre-surgery), 3 months, and 6 months post-surgery in 15 patients undergoing surgery for symptomatic neuromas

Assessments Used: Visual analogue scale for pain (VAS) and the Patient-Reported Outcomes Measurement Information Systems (PROMIS) scales for physical function, pain, and fatigue.

Results

- 15 neuromas at baseline (12 female, 3 male)
- Age at baseline: 57 ± 13 years
- 12 participants completed 3-month follow-up
- 7 participants completed 6-month follow-up
- Decrease in VAS and PROMIS Pain, and Fatigue scores
- Increase in PROMIS Physical Function scores

Visual Analog Scale Scores

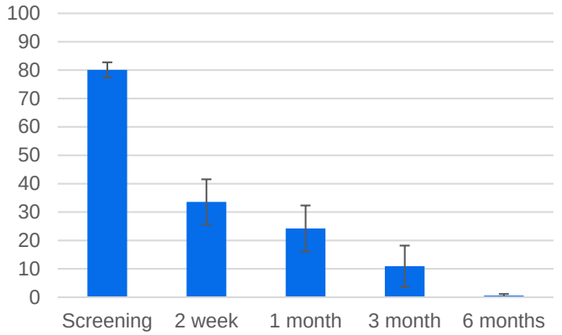

Figure 1. VAS Scores. VAS questionnaires were completed by all subjects at screening and each follow-up visit**.** Average difference from baseline to 6 months was 79.5 mm. Minimal Clinically Important Difference **(MCID)[1] = 20-27 mm**

PROMIS - Physical Function

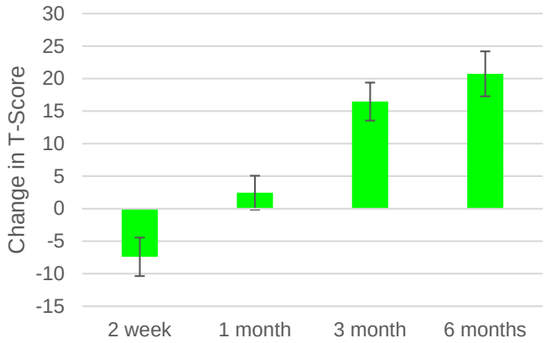

Figure 2. PROMIS Physical Function change in T-scores over time. From baseline to 6 months the average T-score increased by 18.5 points. **MCID[2-4] = 1.9 to 6 points**

Results

PROMIS - Pain Symptoms Present

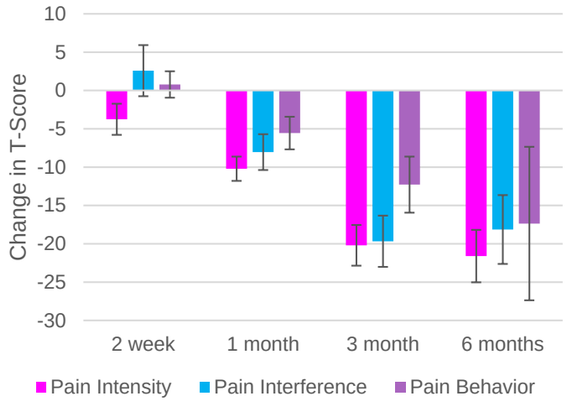

Figure 3. Pain Symptoms change in T-scores over time. From baseline to 6 months the average pain intensity T-score decreased by 20 points. **MCID[1] = 10-20% difference (5.5-10.9 points).** From baseline to 6 months the average change in T-scores for pain behavior over time show the T-score decreased by 17.3 points. **MCID[6] = 3.2 points.** From baseline to 6 months the average pain interference T-score decreased by 18 points. **MCID[2, 4-6] = 1.5-6 points**

PROMIS - Fatigue

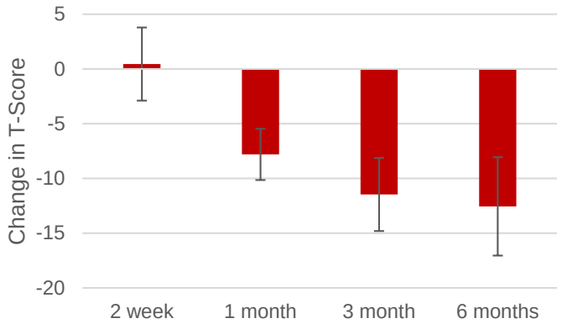

Figure 4. Fatigue change in T-score over time. From baseline to 6 months average T-score for fatigue decreased by 12.6 points. **MCID[2] = 3-5 points**

Conclusions

- The pilot phase of the REPOSE study is demonstrating that patients undergoing neuroma treatment in the foot using the Axoguard Nerve Cap are experiencing a reduction in pre-operative pain
- No Serious Adverse Events related to the Axoguard Nerve Cap were reported.
- Next stage of study is the comparative phase to compare pain reduction after neuroma treatment with the Axoguard Nerve Cap to pain reduction after standard neurectomy

Indications for Use

Axoguard Nerve Cap was designed to protect a peripheral nerve end and to separate the nerve from the surrounding environment to reduce the development of symptomatic or painful neuroma.

Contraindications

Axoguard Nerve Cap is derived from a porcine source and should not be used for patients with known sensitivity to porcine derived materials. Axoguard Nerve Cap is contraindicated for use in any patient for whom soft tissue implants are contraindicated; this includes any pathology that would limit the blood supply and compromise healing or evidence of a current infection.
Axoguard Nerve Cap should not be implanted directly under the skin.

NOTE: This device is not intended for use in vascular applications.

References:

1. Dworkin et al. (2008) Pain 9(2) 105-121
2. Yost. et al. (2011) Clin Epidemiology 64(5), 507-516.
3. Hays, et al. (2015) Ann Rheum Dis 74(1) 104-107.
4. Lee et al. (2017) Pain 18(9) 1096-1110
5. Chen et al. (2016) Pain Research 9 251-255
6. Askew et al. (2016) Clin Epidemiology 74, 103-111

Disclosures:

-Ivan Ducic, MD is the Medical Director of Axogen
-Damien Dauphinee, DPM; Craig Thomajan, DPM; and Stephen Frania, DPM are paid consultants for Axogen

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