Comparison of sacral neuromodulation leads exposed to pull forces in a controlled in-vitro environment.

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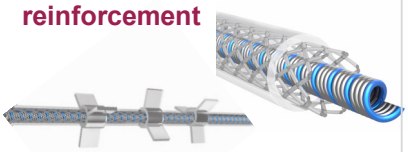
Aim of study

To evaluate **mechanical performance** of a finned sacral neuromodulation lead designed with braided reinforcement and stretch and recover properties compared to that of the currently commercial available tined lead.

Tined Lead

Finned Lead w/braid reinforcement



Study design, materials and methods

Five (5) standard tined leads, five (5) novel finned leads. Fixation potted in silicone for each sample.

Equipment

Instron Test System: ISN 01538 with testing software and accessories.

Testing procedure

Three tests were conducted:

1. Cyclic Elongation testing

All 5 samples pulled to defined elongation values of 1,2,3,4,5,10, 15,20,30,40,45 mm with return to start point between each cycle. *(Fig. 1)*

2. Anchor fixation testing

Fixation features were constrained in a silicone tube filled with silastic adhesive. *(Fig 2)*

3. Mechanical Failure testing

Leads were tested for lead body strength. Samples were tested to failure. *(Fig 3)*

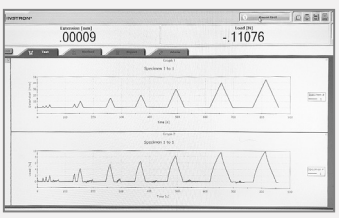


Fig 1: cycling testing graph

Fig 2: fixation test

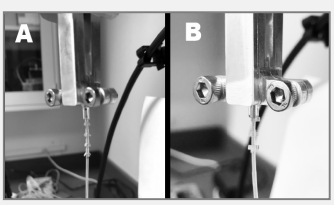


Fig 3: A)Tined B) Finned

Results

Test 1: Cyclic Elongation

- Finned reinforced lead stretched for 20 mm with **minimal peak force**
- Tined leads: at an elongation of 20mm the forces were **significantly greater**
- No samples failed the testing

Test 2: Anchor Failure

Similar force was required for anchor fixation to slip (lead separating from the external silicone tube at the fixation area) for both tined and finned leads.

- 1 tined lead failed electrically and mechanically following the test.
- Permanent lead length elongation.
  - finned leads (1.38%)
  - tined leads (5.74%)

Test 3: Mechanical Failure

- Tined leads failed at **27.1N** average force.
- Finned leads slipped at **46.8N** average force. (did not break)
- At **73% greater force** finned leads with reinforced lead bodies did not break and remained electrically and mechanically intact.

Interpretation of results

- The anchor fixation force is similar for both lead designs
- The finned leads recovers from elongation to a greater degree than the tined lead
- **Finned lead design with reinforced lead body does not break even at much greater forces than required to break the tined lead.**

Disclosure

The authors receive compensation for services to Nuvectra, Inc., which is developing products related to the research described in this paper. Opinions and conclusions herein are solely those of the authors themselves.

Nuvectra makes no claims regarding the opinions expressed herein.

The finned lead described in this presentation is not approved for commercial distribution in the European Union or the United States.

Clinical Possibilities

- Based on lead strength & performance this could have theoretical clinical relevance of:
  - Mitigating lead breakage
  - Mitigate against clinically significant lead migration
  - More consistent & complete lead extraction from the IPG pocket
- In-vivo studies are required to confirm these suggestions.