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.

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)

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.

Clinic 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.

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

Nuvecutra 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.