

## Aim of study

Examine extraction forces on a lead with novel features including finned fixation, stretch and recover lead design, and braid re-enforcement compared to the current commercial standard tined lead using an acute, in vivo animal model.

## Study design, materials and methods

- Acute sheep model
- Four (4) tined leads
- Four (4) finned leads

## Procedure

- Leads were implanted in the sheep sacrum under fluoroscopic control.
- Leads were tunneled laterally to the typically expected location of an implantable pulse generator (IPG). Pulling of leads occurred from this position in order to simulate a lead pull from the IPG pocket site. (Fig 1A & 1B)
- A strain gauge (Shimpo FGV-20XY) with stepper motor were used to capture the force and distance recorded to LabView Vi. (Fig 2)
- Lead pulls were observed externally and via lateral fluoroscopy.

## Lead Implant

### Fluoroscopic

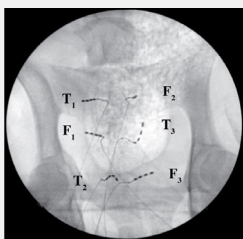


Figure 1A: AP fluoroscopy of the first 6 implanted leads F<sub>1</sub>, F<sub>2</sub>, F<sub>3</sub>, finned lead, T<sub>1</sub>, T<sub>2</sub>, T<sub>3</sub> tined leads.

### Externalized Leads

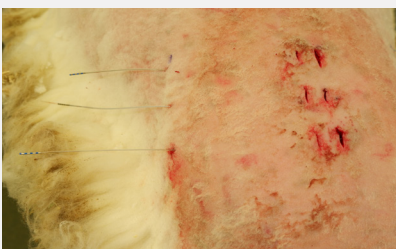


Figure 1B: Body of Sheep, leads tunneled to extraction point

## 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.

## Results

- 3 of 3 finned leads and 2 of 3 tined leads were explanted without failure.
- The tined lead in S2-right failed at 14.12N. The failure mode was a separation of the lead tip.
- Position S2-right was retested with a de novo tined lead which also failed at 13.49N. (Fig 3A)
- Position S2-right was retested with a de novo finned lead which did not fail, despite reaching a peak pull force of 19N. (Fig 3B)

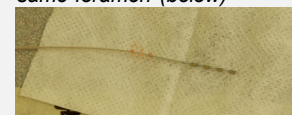


Figure 2: Pull Test setup



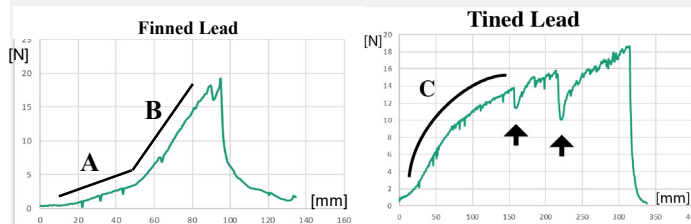
Fig 3A: Broken tined lead at extraction simulated from pocket site (above)

Fig 3B: intact Finned lead from same foramen (below)



**Finned** leads consistently stretch 4-5cm without observed migration. (Fig 4, Sec. A) After this, lead tip migration occurred. (Fig 4, Sec. B)

**Tined:** Due to the limited stretch design, increased forces resulted in prompt deformity and observed lead tip migration. (Fig 4, Sec. C)



## Interpretation of results

- The braided reinforcement and fin design allowed intact removal without retained fragments, in contrast to the tined lead.
- The tined lead fluoroscopic observation of pull visually transferred more directly to the lead stimulation tip consistently leading to tip movement at lower forces
- 2 of 4 tined leads were observed to fracture during extraction, this was not observed in any of the braid reinforced finned leads.

## Clinical Possibilities

A **finned sacral neuromodulation lead** designed to stretch with a **braid reinforced lead body** could have clinical relevance of:

- Mitigating lead fracture during extraction
  - Allow intact lead removal from the pocket
  - Reduce the rate of clinically significant lead migration.
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- Human studies are required to confirm these possibilities