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Impact of Activities of Daily Living on the Biomechanics of Indwelling Continence Care Devices: New Opportunities for Improved Patient Care (21358)

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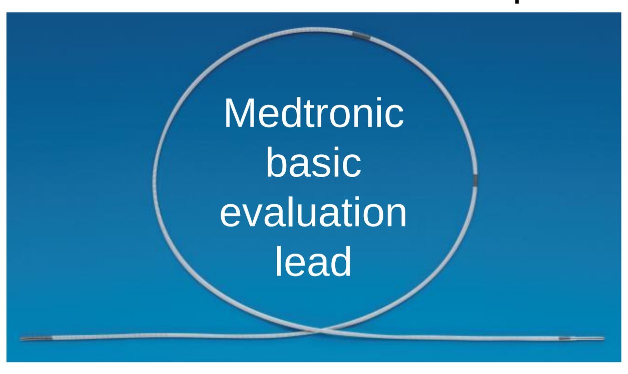
Introduction

Continence care patients have benefitted from sacral neuromodulation therapy for over 20 years and the aim of this study is to provide the first evidence that a redesigned basic evaluation lead can further improve the physician and patient experience.



Many patients considering sacral neuromodulation first undergo a therapy evaluation wherein stimulation is delivered to the sacral nerves via a temporary lead, enabling the patient to trial the therapy prior to receiving a permanent implant.

Lead dislodgement during the trial period has been identified as a possible cause of inconclusive trial response [1-3].

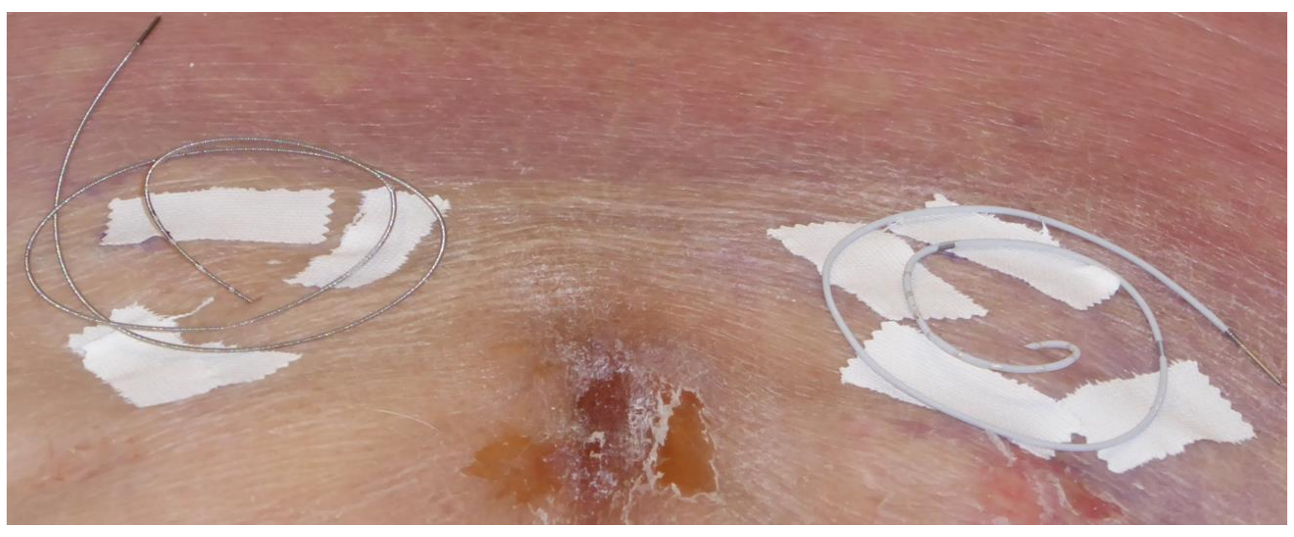
To reduce the potential for dislodgement, the InterStim™ trialing lead (commonly known as the PNE lead or temporary stimulation lead) has been redesigned to better accommodate patient movement and stabilize the tip electrode during therapy evaluation.

The hypothesis was that incremental tip electrode movement is lower during simulated activities of daily living in a cadaver when using the redesigned basic evaluation lead (new; Model 306001/306006) compared to the market-released lead (control; Model 305901/305906).

Methods

Specimens and Implant

- Ten cadavers were obtained from a bequest program and demographic information was collected for each specimen.
- A skilled implanter placed leads according to standard procedures into the left or right S3 or S4 sacral foramen using ultrasound or fluoroscopy and verified the location of the tip on lateral fluoroscopy. The figure below illustrates a typical implant configuration for a cadaver receiving both lead models.



- In a first cohort of five cadavers, the new basic evaluation lead was placed contralaterally to the control lead.
- In a second cohort of five additional cadavers, the new basic evaluation lead was implanted on the specimen's right or left side.
- Once leads had been implanted, the externalized portion of the leads were coiled, gauze was placed on top of each implant, and Tegaderm (3M) dressing was placed over both leads per typical implant procedures.

Cadaver Positioning

- Cadavers were alternately positioned in up to four postures and subjected to up to 4 tissue manipulations to simulate activities of daily living. A typical shearing challenge is shown in the figure below.

CT Imaging and Processing

- Cadavers were CT scanned after each challenge to measure lead movement and images were segmented in Mimics image processing software.
- Siemens Imageware reverse engineering software was used to register lead positions to a baseline scan using the patient's sacrum and measure incremental tip electrode movement relative to the previous cadaver challenge.

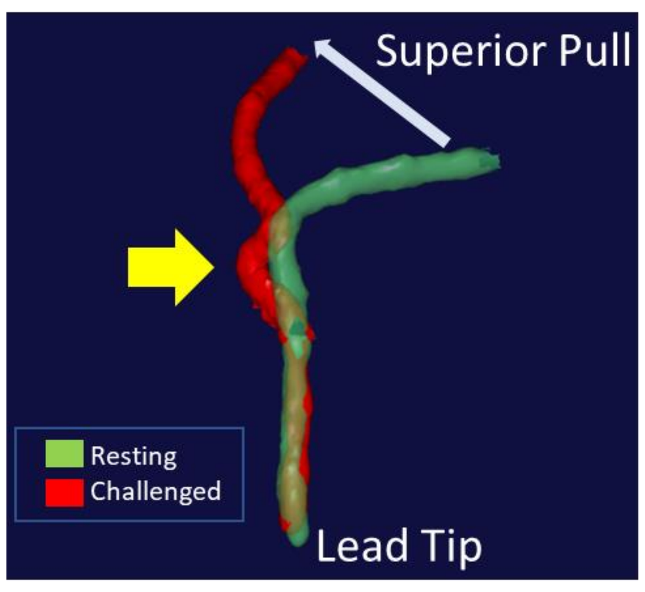
Statistical Analysis

- For this proof of concept work, no preliminary data were available and therefore power was not pre-specified.
- Since the order of challenges may have impacted the outcome of each experiment, a linear mixed effects model was evaluated using restricted maximum likelihood to compare the incremental movement of new and control lead tip electrodes and derive appropriate standard errors.
- A 95% confidence interval was derived for incremental tip electrode movement and assessed-values were computed using a t-statistic and Satterthwaite's approximation for degrees of freedom.

Results

Cadaver demographics were:

- Mean age was 83 years and 5/10 were female.
- Cadaver height was 67.3 ± 4.1 inches and weight was 163 ± 31.6 pounds.
- BMI ranged from 19.9 to 41.6 (average 25.5 ± 6.26).



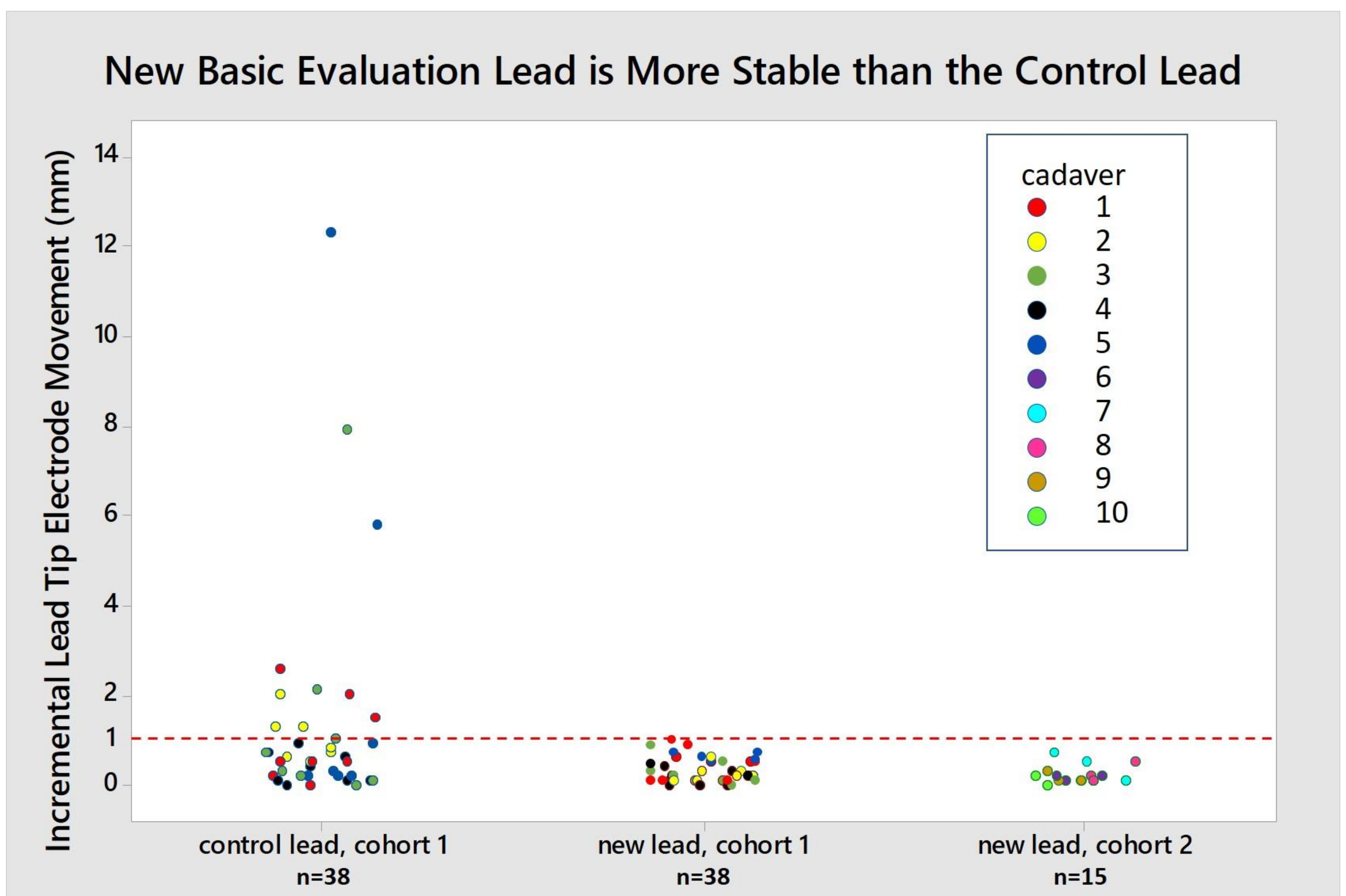
As shown in the figure to the left, the tip of the new basic evaluation lead remained stable moving from rest (green) to a challenge position (red) after a simulated activity of daily living.

The new basic evaluation lead experienced bending during challenge to maintain tip stability.

Summary statistics for both lead models and both cadaver cohorts are tabulated below (n = number of cadaver challenges).

Lead Type	**Incremental Tip Electrode Movement (mm)**		
Cohort 1	**Range**	**Mean ± SD**	**Median**
Model 306001/306006 (new, n=38)	0.0 to 1.0	0.34 ± 0.28	0.25
Model 305901/305906 (control, n=38)	0.0 to 12.3	1.32 ± 2.40	0.55
Cohort 2			
Model 306001/306006 (new, n=15)	0.0 to 0.7	0.23 ± 1.9	0.20

- Incremental tip movement after cadaver manipulation in the first cohort was 0.98 mm less for the new basic evaluation compared to the control lead [95% CI: -1.74 mm to -0.21 mm, p=0.015].
- After all challenges, cumulative tip electrode movement in each cadaver was between 2.1 and 19.5 mm (control; n=5 cadavers) and 0.3 to 1.9 mm (new; n=10 cadavers), respectively.



Incremental lead tip electrode movement in two cohorts of cadaver data. All of the incremental tip electrode movement in the new basic evaluation lead was at or below 1 mm (red line).

These results suggest:

- The new basic evaluation lead may improve tip stability and reduce the number of inconclusive trials experienced by patients during evaluation.
- Small tip movements in each cadaver are likely repeated hundreds of times during evaluation, potentially explaining dislodgement.
- There was no consistent body position that tended to create large (>5 mm) tip movements.
- Cumulative tip movement in each cohort one cadaver was consistently greater in the control lead compared to the new basic evaluation lead.

Limitations include using cadaveric tissue rather than living patients, relying on images with a 0.6 mm resolution, and a small sample size.

Conclusions

- Across various positional changes in a cadaver model, the tip electrode of the new basic evaluation lead demonstrated statistically significantly less incremental movement compared to the tip electrode of the control lead.
- These results suggest the new basic evaluation lead may improve tip electrode stability.
- The biomechanics of basic evaluation lead movement serve as input to a computational model that will allow manufacturers to determine the impact of anatomic variation, implant procedure, and design on performance.

References

1. Crites-Bachert MA, Mukati M, Sorial A, et al. Percutaneous nerve evaluation in women: lessons learned. Female Pelvic Med Reconstr Surg. 2011;17(6):293-297.
2. Shalom DF, Pillalamarri N, Xue X, et al. Sacral nerve stimulation reduces elevated urinary nerve growth factor levels in women with symptomatic detrusor overactivity. Am J Obstet Gynecol 2014;211:561.e1-5.
3. InterStim Temporary Lead Product Performance Summary (NDHF1534-161101); Medtronic data on file.