103

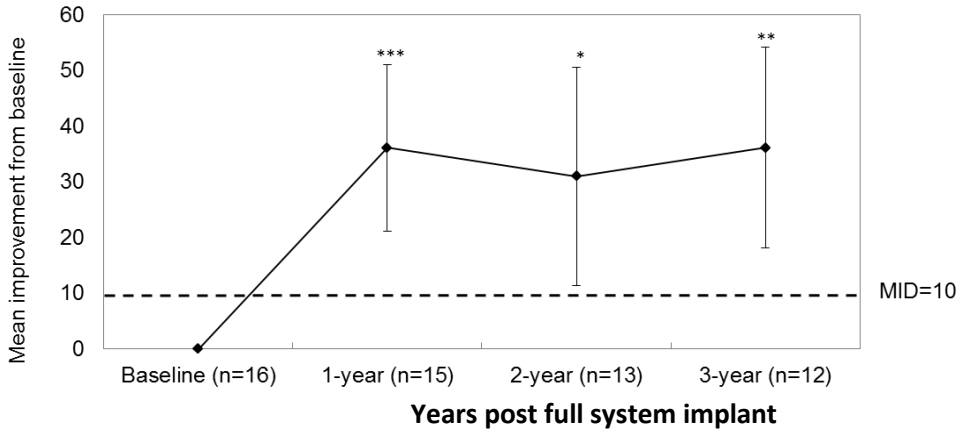
Noblett K[1], Mangel J[2], Comiter C[3], Bird E[4], Griebling T[5], Sutherland S E[6], Berg K[7], Kan F[7], Siegel S[8]
1. *University of California, Riverside,* ***2.*** *MetroHealth Medical Center,* ***3.*** *Stanford University,* ***4.*** *Scott and White Healthcare,* ***5.*** *University of Kansas, Kansas City,* ***6.*** *University of Washington, Seattle,* ***7.*** *Medtronic,* ***8.*** *Metro Urology*

SUCCESS OF A REPEATED TINED LEAD TRIAL IN A REFRACTORY OAB POPULATION

Hypothesis / aims of study
To determine the success of a repeat therapy evaluation after initial test stimulation failure and evaluate long term efficacy.

Study design, materials and methods
InSite is an ongoing, prospective, multicenter post-approval study. Subjects with bothersome symptoms of overactive bladder (OAB) including urinary urge incontinence (UI) or urgency-frequency (UF), who had not exhausted all medication options (failed at least 1 anticholinergic medication and had at least 1 medication not tried) were included. Subjects completed test stimulation with a tined lead and external neurostimulator for 14 days. Therapeutic success was defined as a UI or UF response; for UI as a ≥ 50% improvement in average leaks/day, for UF as a ≥ 50% improvement in voids/day or a return to normal voiding frequency (<8 voids/day) on a 3-day consecutive voiding diary. Subjects not meeting success were allowed to repeat test stimulation with a new lead implant at the discretion of the investigator. Those subjects meeting the definition of therapy success went on to receive an implantable neurostimulator. Therapy efficacy was collected using electronic voiding diaries. Quality of life was evaluated using the validated disease-specific International Consultation on Incontinence Modular Questionnaire (ICIQ-OABqol).

Results
Overall, 340 subjects underwent test stimulation with 272 (80%) going on to full device implant. Of the 68 subjects who failed the initial trial, 29 received an additional tined lead to undergo repeat test stimulation. Reasons for initial test stimulation failure in these 29 subjects were: 22 had not met therapy success criteria, 5 had the lead replaced due to adverse events, 1 had the lead replaced due to an adverse event and technical observation, and 1 was due to insufficient completion of the voiding diary. Mean age of this cohort was 59 ± 12.8 years, time since diagnosis was 10.2 ± 9.4 years, and 90% were female, with a median of 2 previously used OAB medications. Out of 29 subjects, 13 (45%) had both UI and UF symptoms, 5 (17%) had UI only, 10 (34%) had UF only, and 1 (3%) did not have baseline qualification available. Baseline leaks/day were 4.0 ± 2.4 for UI subjects (n=18) and baseline voids/day were 14.4 ± 5.3 for UF subjects (n=23).
Of these 29 subjects, 16 (55%) went on to receive a full system implant. The OAB therapeutic success rate was 86% at 1 year (n=12), 75% at 2 years (n=9), and 82% (n=9) at 3 years post-implant which is similar to the larger cohort. There were statistically significant improvements compared to baseline in Health Related QOL score at 1-year, 2-year and 3-years as displayed in the figure.



*p<0.05, **p<0.01, ***p<0.001

Error bars are 95% confidence intervals

MID: is the smallest score change that is perceived beneficial to patients and is often used to determine whether changes in scores are considered clinically significant. The MID for the OABqol subscales has been suggested to be 10 points.

Twelve device-related adverse events occurred in 6 subjects post full system implant through 3 years of follow-up, including 3 events of undesirable change in stimulation, 2 events of therapeutic product ineffective and 1 event of each in 7 other adverse event types.

Conclusion:
These results demonstrate that over 50% of patients who do not initially respond to a staged tined lead trial may respond to repeat test stimulation. The long term subjective and objective improvements are similar to those who responded to the initial trial.

Disclosures
Funding: Clinical study sponsored by Medtronic **Clinical Trial:** Yes **Registration Number:** ClinicalTrials.gov, NCT00547378 **RCT:** No **Subjects:** HUMAN **Ethics Committee:** Local Ethics Committees or Institutional Review Boards at each site. Western IRB. **Helsinki:** Yes **Informed Consent:** Yes