

# INTERSTIM® SACRAL NEUROMODULATION AND BOTOX® BOTULINUM-A TOXIN INTRADETRUSOR INJECTIONS FOR REFRACTORY URGE URINARY INCONTINENCE: A DECISION ANALYSIS COMPARING OUTCOMES INCLUDING EFFICACY AND COMPLICATION.

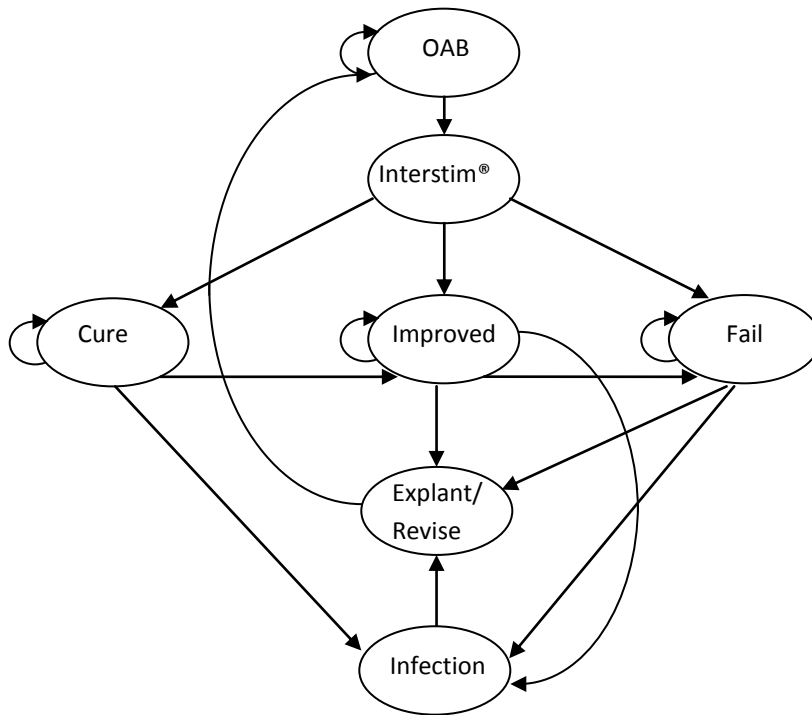
## Hypothesis / aims of study

Overactive bladder is a common disease for which current pharmaceutical treatment is often unsatisfactory. Antimuscarinic medications have been the mainstay of treatment, but discontinuation rates are often >75% at 1 year due to side effects of dry mouth and constipation. Newer modalities have been developed, including Botox® and Interstim® for cases where antimuscarinics are unsuccessful. Our objective was to compare Interstim® and intradetrusor Botox® therapies for urge incontinence refractory to antimuscarinic therapy.

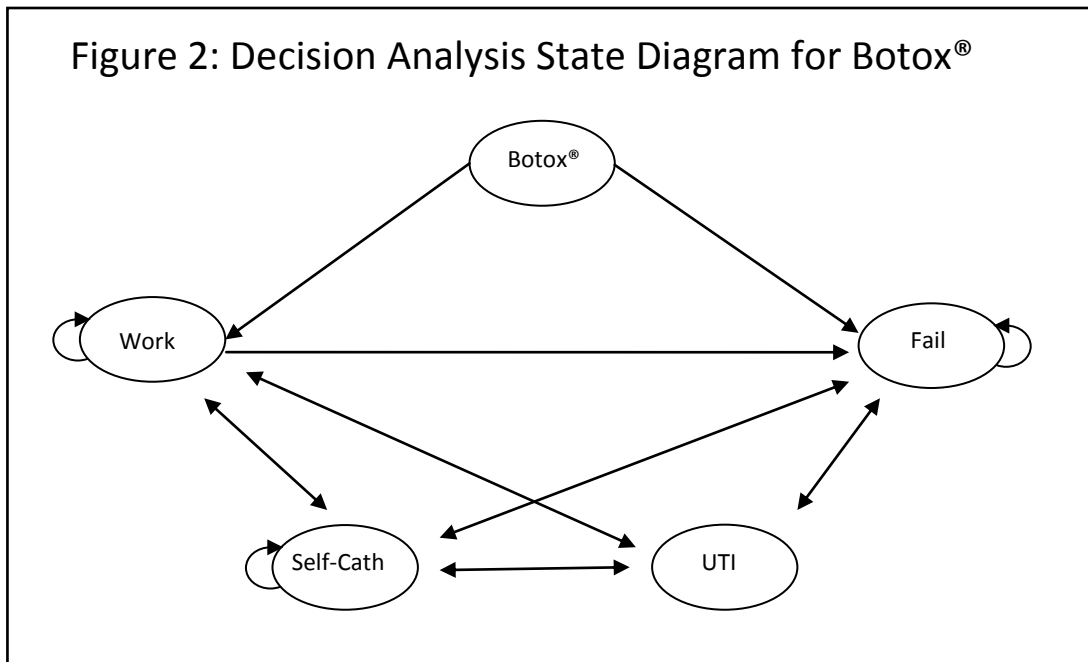
## Study design, materials and methods

A decision analysis model was constructed using values for efficacy and complications from the literature. Simplified state diagrams for Interstim® and Botox® are depicted in figures 1 and 2. The actual model is far more complex with multiple unpictured states to account for the full interplay of efficacy and multiple complications. Overall utility for the two operations was compared monthly for a period of 54 months. This time period was selected as it is the average Interstim® battery life. Multiple one-way sensitivity analyses for all utilities and all outcome probabilities were performed.

Figure 1: Decision Analysis State Diagram for Interstim®



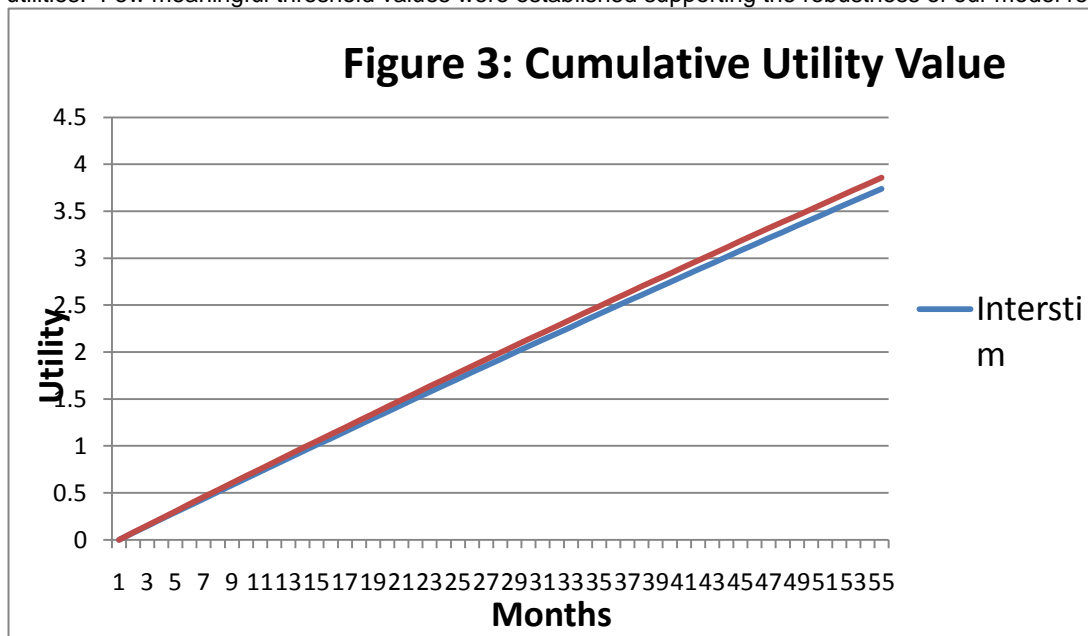
**Figure 2: Decision Analysis State Diagram for Botox®**



**Results**

For every month during the simulation the overall utility value was higher for Botox® injections than Interstim®. After 54 months the cumulative utility was 3.86 vs. 3.74 favoring Botox® for an average yearly quality adjusted life year (QALY) value of 0.86 vs. 0.83 (figure 3). All differences between the two surgeries were less than published minimally important differences (MID) for utilities. Few meaningful threshold values were established supporting the robustness of our model results.

**Figure 3: Cumulative Utility Value**



**Interpretation of results**

While Botox® has higher average QALYs at all time points, the differences are less than the MID. Therefore, the two operations are highly comparable with similar overall utility. Until appropriately powered randomized controlled trials are available, both operations are reasonable strategies for the treatment of urge incontinence refractory to antimuscarinic therapy.

**Concluding message**

In the setting of refractory urge urinary incontinence, Interstim® and Botox® are effective therapies with similar QALY outcomes when considering efficacy and complications.

<b>Specify source of funding or grant</b>	<b>We have no funding and no financial disclosures</b>
<b>Is this a clinical trial?</b>	<b>No</b>
<b>What were the subjects in the study?</b>	<b>NONE</b>