Hypothesis / aims of study
Electrical neuromodulation is a promising technology for the treatment of a variety of urological disorders. Peri-urethral and peri-anal electrical stimulation by implantable stimulators have been shown to be effective for the treatment of urinary and faecal incontinence [1, 2]. To further advance this technology it is necessary to understand whether and how the stimulating electrode can be accurately placed in targeted pelvic neuromuscular structures and to extract feedback signals for event-evoked, closed-loop stimulation. In the present study we tested the hypothesis that the stimulation electrode of an implantable peri-urethral stimulator (Accessa™) can be used to record pelvic floor/external urethral sphincter electromyography (EUS-EMG) in animals and these EMG signals are sensitive to electrode location and proximity to EUS or pelvic floor muscles.

Study design, materials and methods
Rats were anesthetized with either urethane (1.0 g/kg i.p.) or ketamine + xylazine (150 mg/kg + 30 mg/kg, i.p.). The bladder was catheterized and infused with room temperature saline (5 ml/hr). A vertical midline abdominal incision was made and the symphysis pubis was found and cut to fully expose the urethra. The stimulating electrode of Accessa™ was either placed onto the mid-urethra at the location of the EUS or had its position moved towards the bladder neck. Sensitivity to tissue interference was tested by placing a piece of adipose tissue between the electrode and the urethra. The Accessa™ electrode is a bipolar cylindrical electrode with a distance between the electrodes of 4 mm. Each electrode is 1.4 mm in diameter and 4 mm in length. After the electrode was placed, the bladder was infused and bladder pressure and EUS EMG signals were recorded using an Accessa™ electrode connected to a WPI ISODAM8A amplifier. The initial experiment was carried out in two rats anesthetized with urethane and the same experiment was subsequently repeated in at least three more rats anesthetized with ketamine/xylazine with similar results.

Results
A low frequency, low amplitude EMG signal was registered by Accessa™ electrode at baseline. Bladder filling with saline increased the amplitude and frequency of EMG signals. These changes correlated with an increase in bladder pressure. The EMG signals were largest when the Accessa electrode was placed onto or close to the EUS (Figure 1). These signals decreased when the Accessa™ electrode was moved slightly away from the sphincter (Figure 2). Placing a piece of adipose tissue between the EUS and the electrode diminished the EMG signals (Figure 3).

Representative external urethral sphincter (EUS) electromyography (EMG) recorded using the Accessa™ electrode. Left: The top trace is EUS EMG. The bottom trace is simultaneous bladder pressure. Right: A picture showing the Accessa™ electrode laid on top of the urethra with one of its electrodes placed approximately at the mid urethra and the second electrode placed more distal (not visible).
Figure 2. Representative external urethral sphincter (EUS) electromyography (EMG) recorded using the Accessa™ electrode placed near the bladder neck. Left: The top trace is EUS EMG. The bottom trace is bladder pressure. Right: A picture showing the Accessa™ electrode being moved proximally from the mid urethra.

Figure 3. Representative external urethral sphincter (EUS) electromyography (EMG) recorded using the Accessa™ electrode with a piece of adipose tissue inserted between the Accessa™ electrode and the urethra. Left: The top trace is EUS EMG. The bottom trace is bladder pressure. Right: A picture showing the Accessa™ electrode laid on top of a piece of adipose tissue inserted between the electrode and the urethra.

Interpretation of results
Electrical signals from the pelvic floor muscles or EUS seem to be reliably recorded using the Accessa™ stimulating electrode. Baseline EMG represents tonic activity of the EUS, as reported in the literature [3]. The increase in EMG signal amplitude and frequency and associated increase in bladder pressure suggests there is a strong correlation between bladder pressure and activity of the EUS, which may reflect continence or guarding reflex. Changes of the EMG signal, both in amplitude and frequency, when varying electrode placement, indicated that the Accessa™ electrode is sensitive to changes in electrode position relative to the EUS.

Concluding message
Our results suggest that the stimulating electrode of Accessa™ can be used to record EMG in rats. The frequency and amplitude of EMG signals varies with proximity of the electrode to the EUS. Recording pelvic floor or EUS EMG with the Accessa™ electrode may be used to aid in optimal lead placement and to provide feedback signals for event detection and closed-loop stimulation for neuromuscular therapies.

References

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Is this a clinical trial? No
What were the subjects in the study? ANIMAL
Were guidelines for care and use of laboratory animals followed or ethical committee approval obtained? Yes
Name of ethics committee Cleveland Clinic Institutional Animal Care and Use Committee.