Title of Entry: A Novel Trans-Urethral Electrode to Record EMG Activity of the Male Striated Urethral Sphincter

Innovation: The mechanism for continence in males is not completely understood. Until now, there has been no device for researchers and health professionals to investigate the specific function of the striated muscles within the male pelvic floor during functional tasks and upright body positions. Here we describe a new trans-urethral surface electromyography (EMG) electrode which has the potential to dramatically increase our understanding of the function of these muscles in both healthy males and also in men with altered pelvic floor musculature, such as those who undergo radical prostatectomy. This may, in turn, help to shape new treatment protocols for post-prostatectomy incontinence, which is a major side effect of the most common form of treatment for the most common form of malignant cancer in men.

Description: Recordings of EMG activity from the striated sphincter are generally made using concentric needle electrodes inserted via the perineum [1-2]. This technique has many limitations including position of subject (supine only), stability of recording (needle moves with any dynamic task), and pain/discomfort associated with the insertion. An alternative to concentric needle recordings is transurethral surface EMG. Until now this technique has been discarded on the basis of low quality recordings[3]. The challenges associated with this technique include placement of the electrodes in the appropriate orientation to the muscle fibres and fixation of the electrodes to ensure stability of the recording. Anatomically, the striated sphincter is described as an omega-shaped loop of striated fibres inserting dorsally into the perineal body and encircling the anterior and lateral aspects of the urethra [4]. Previous recordings have involved pairs of circumferential ring electrodes (which are at 90 degrees to the ideal orientation relative to the muscle fibres) mounted on 10 or 12 Fr urinary catheters[5]. These electrodes also have the potential to move. The lack of appropriate techniques to investigate the activity of the male striated pelvic floor muscles has left a significant gap in the knowledge of male pelvic floor function. With this in mind we aimed to design and validate a new trans-urethral surface electrode which provided optimal electrode-to-muscle fibre orientation and a method to stabilize the electrode. A novel electrode was fabricated from a size 6 Fr paediatric urinary catheter, 30 cm in length. Four strands of 75µm Teflon-coated stainless steel fine wire were inserted through small pinholes 15 and 25 mm from the tip of the catheter (Fig. 1A) that were fixed internally with a knot and threaded down the lumen to exit the catheter via pinholes in the rubber connector (Fig. 1B). Teflon was removed from the 10 mm of wire on the external surface of the catheter to form two pairs of recording surfaces. The four wires were placed at equal intervals around the catheter, with pairs separated by the two urine ports. A small dot of cyanoacrylate was placed over wire exit points to fix the wires, provide a smooth surface, and ensure the catheter was airtight. Approximately 5 cm of wire with 5 mm of Teflon removed from the end was provided for connection to the EMG amplifier. The challenge of stability of the catheter relative to the muscle was solved by gently suctioning the catheter to the urethral mucosa via the urine ports, at the site of the recording electrodes. Suction was provided from a syringe fitted with a spring inserted into the catheter connector (Fig. 1B). This simple device generated a negative pressure of ~20 mmHg. Subjects self-inserted the catheter using a standard aseptic technique. EMG recordings were bandpass filtered between 3 and 1000 Hz (50 Hz notch filter), amplified 2000 times, and sampled at 10 kHz. To investigate myoelectric properties of the striated sphincter activity, five healthy subjects performed a range of dynamic, upright tasks including voluntary efforts at 60% maximum voluntary contraction (MVC) (Fig. 2A) and MVC (Fig. 2B). Analysis of EMG data indicated high quality recordings using the novel electrode. Properties of the signal including mean and median frequency, and frequency range were typical of human striated muscle[6]. The effect of suction was evaluated by comparison of the EMG recordings with and without suction applied during a cough. Power in the spectrum at <20 Hz was nearly twice that during trials without suction, suggesting greater movement artefact. Median and mean frequencies demonstrated a leftward shift when suction was absent, highlighting the effect of suction on electrode stability. The stability of the recordings over time was evaluated by comparison of striated sphincter EMG during an intra-abdominal pressure MVC task at the beginning and end of the experiment, ~two hours later. Discrimination of single motor unit action potentials showed consistent motor unit morphology between time points, suggesting the position of the recording surfaces remained consistent. These data confirm the viability of high quality recordings of striated sphincter EMG with the novel electrode in stationary and dynamic tasks in males. The novel design circumvents some of the problems associated with concentric needle recordings and extends measurement possibilities. Future applications of this device could investigate the function of striated urethral muscles in men following prostatectomy in order to gain a physiological understanding of post-prostatectomy incontinence (PPI). PPI continues to affect 25% of men six months post-surgery however, little is known about the condition due to difficulties associated with recording from the urethral muscles. This new device may, for the first time, answer some of the questions associated with PPI and help to shape more specific and effective treatment protocols for such a debilitating side effect of the most common form of treatment for the most common form of malignant cancer in men.

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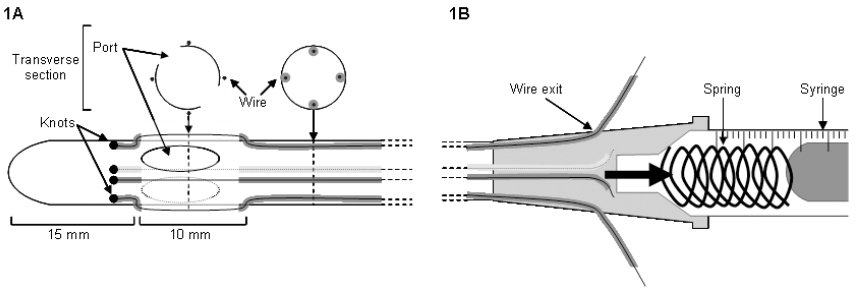
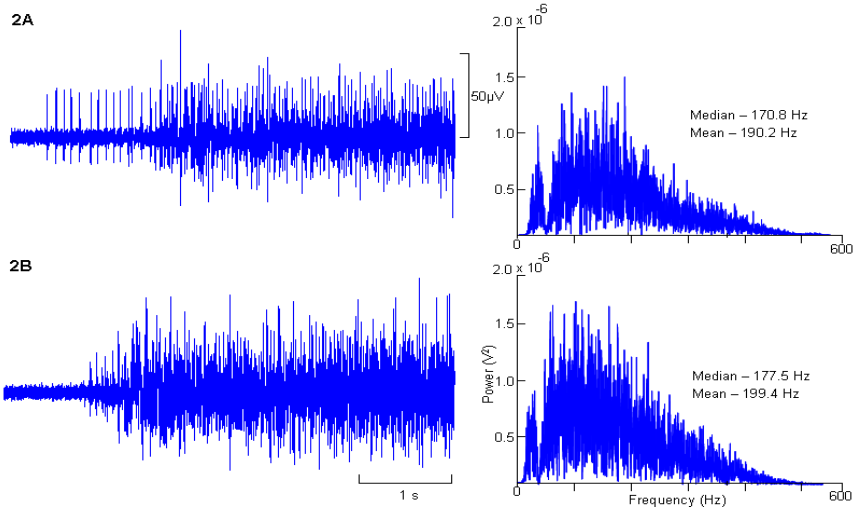
Supporting Material:

Figures



1. The design of the novel electrode. Individual wires are secured at the proximal end with internal knots and a dot of superglue over the respective pinholes, 15 mm from the tip (A). A 10 mm section of the Teflon insulation is removed to from the recording surface and the remainder of the wire is fed through another pinhole 25 mm from the tip down the lumen of the catheter to the distal end (B). The wires exited the catheter via pinholes in the rubber connector. When optimal position was determined the suction was applied via the spring-loaded syringe shown in (B).



2. Raw striated sphincter EMG recordings from the novel electrode with associated power spectral densities (PSDs) during a 60% MVC (A) and MVC (B). The reduced power at 50 Hz is due to the notch filter used to reduce the effect of electrical interference.

History of Dissemination - (Authors not included for anonymity of application):

1 - A Novel Trans-Urethral Electrode to Record EMG Activity of the Male Striated Urethral Sphincter. J Urology. 2009 (In Press)

2 - Viability of a Novel Electrode to Record Activity of the Male Rhabdosphincter. International Continence Society Annual Meeting, Cairo, Egypt, 2008.

References

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2 - Fanciullacci F, Kokodoko A, Garavaglia PF, Galli M, Sandri S and Zanollo A: Comparative-study of the motor unit potentials of the external urethral sphincter, anal-sphincter, and bulbocavernosus muscle in normal men. Neurourol Urodyn. **6**: 65, 1987.

3 - Brostrom S, Jennum P and Lose G: Motor evoked potentials from the striated urethral sphincter: a comparison of concentric needle and surface electrodes. Neurourol Urodyn. **22**: 123, 2003.

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5 - Nordling J, Meyhoff HH, Walter S and Andersen JT: Urethral electromyography using a new ring electrode. J Urol. **120**: 571, 1978.

6 - Basmajian J, De Luca, C.: *Muscles Alive.* Baltimore, Williams and Wilkins, 1985, pp 561.