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VALIDATION OF NOVEL PATIENT-APPLIED SURFACE ELECTRODE FOR TREATMENT OF FEMALE STRESS URINARY INCONTINENCE

Hypothesis / aims of study

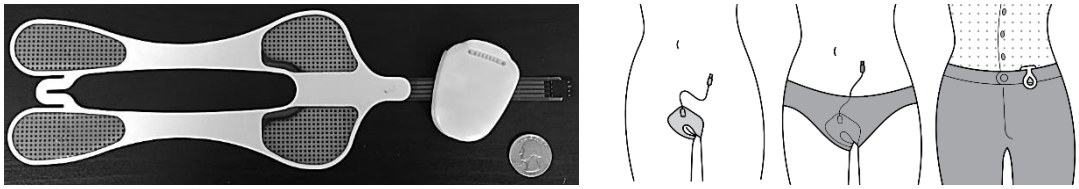
Electrical muscle stimulation (EMS) of the pelvic floor muscles (PFM) through use of intravaginal electrodes has been demonstrated as an effective tool in treating women with stress urinary incontinence (SUI). Unfortunately, many women opt-out of this invasive treatment, allowing incontinence symptoms to gradually worsen. This suggests the need for a means of delivering PFM stimulation in a manner that will be more readily adopted. Application of EMS proximate the perineal tissue has shown therapeutic promise when administered in a clinical setting [1][2], and recently our team had engineered this non-invasive treatment into a form factor suitable for patient-administered home use.

In this study we assessed the usability of a novel, patient-applied surface electrode designed to deliver EMS through the perineal region. Specific elements of the assessment included:

1. Validation of intuitive self-application, anatomic fit and comfortable removal of a one-size-fits-all device.
2. Identification of preferred candidate waveforms capable of comfortably stimulating the pelvic floor muscles.
3. Characterization of patient-to-patient variability of key EMS electrical parameters including impedance and stimulation current.
4. Formative human factors observations to inform optimization of user interface features.

Study design, materials and methods

The device comprises a disposable surface (i.e. transcutaneous) electrode and an electrical muscle stimulator, both custom build for this application. The electrode has an hourglass shape with four conductive regions and a central egress. The stimulator, provided in a compact wearable form factor, contains a microcontroller that allows programming of various candidate stimulation waveforms.



Left: Novel SUI electrode and stimulator use in study, Right: Pictoral representation of hwo device is worn.

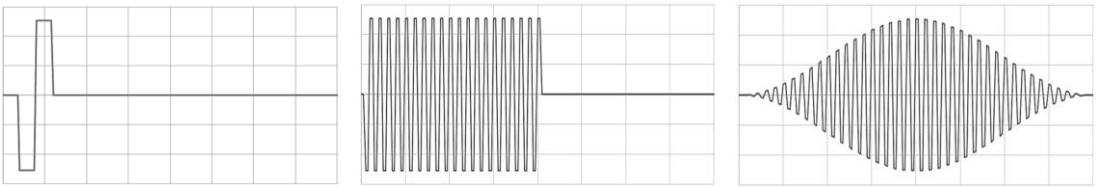
Eight subjects self-applied the device per textual and pictorial instructions. With the subjects fully dressed and seated in a chair, the voltage controlled treatment intensity was incremented while the subjects commented on the strength and comfort of the PFM stimulation. This was repeated with various waveforms and subjects provided comparative assessments. An adaptive approach eliminated the least effective waveforms from further consideration and allowed additional evaluation of derivatives of the more effective waveforms. At the end of the study the subjects completed a questionnaire. Throughout the study an oscilloscope and multimeter allowed direct measurement of treatment parameters including applied voltage (Vpp) and current (Irms).

All waveforms were delivered at a stimulation frequency of 50 Hz and provided alternating 6 second periods of contraction and relaxation with 1 second of ramping. In total, 7 waveforms were tested, each broadly classified as one of three types:

- Traditional Intravaginal – Single pulse bi-phasic square wave
- Burst Mode Alternating Current (BMAC) – Repeating bi-phasic square wave profile with 30-50% duty cycle
- Modulated – Repeating bi-phasic square wave with sinusoidal amplitude modulation

Results

- All subjects were able to apply, wear (~1 hour) and remove the device without difficulty or discomfort, even in the presence of pubic hair.
- Subjects identified a modulated waveform at 2000Hz modulation frequency as delivering the most comfortable muscle contractions. BMAC at 2000 Hz and 50% duty cycle was also favourably evaluated.
- Subjects reported initial perception of stimulation at 5.6±1.4 mA, comfortable PFM muscle contraction at 10.1±2.3 mA and an initial level of discomfort at 15.6±2.7 mA. This later level corresponded to peak voltage of 40-60V.
- System impedance (i.e. electrode + tissue) was calculated as 840±310Ω.
- Patient demographics varied widely (age: 25-70, BMI: 16-27, prior births: 0-3, incontinence symptoms: none-moderate) but no correlation with electrical performance measured was identified.



Left: Traditional Intravaginal Waveform, Middle: BMAC, Right: Modulated

Interpretation of results

- The physical characteristics of the electrode component (shape, flexibility, hydrogel adhesiveness) are suitable to accommodate a broad range of body types.
- PFM access through the perineal tissues requires a different stimulation waveform than conventional intravaginal therapies. Candidate waveforms familiar to orthopaedic applications (e.g. Modulated, BMAC) comfortably delivered stimulation energy across the skin-electrode interface and deep within the underlying musculature.
- The relatively low pain patient sensitivity to applied current (i.e. the current delta from initial perception of stimulation to discomfort) is desirable in that it reduces the risk profile of the device in patient-administered use scenarios.
- Measured impedance across the perineal tissue is within the 500-1000Ω range commonly cited for general use (i.e. orthopaedic) EMS applications [3]. This supports ongoing utilization of those devices as relevant baselines for development and testing.
- A homogeneous response across a diverse patient population supports pursuit of a simple treatment approach that does not rely on various compensatory factors that could overly complicate the system intent for home-use.

Concluding message

The findings validate device efficacy in comfortably contracting the PFM. Further, the device achieves this through a means that requires minimal patient instruction and which a woman can conveniently adopt as part of an at-home routine. Future work will move from single-session assessments to multi-week trials designed to show clinical efficacy in reducing incontinence systems. Based on pelvic floor therapy literature, successful treatment regimens are likely to comprise daily 20 minutes treatment sessions, with measureable improvement after 6-8 weeks. This promising technology, which aims to deliver an efficacious alternative to intravaginal SUI devices, will potentially lead to greater adoption and compliance rates among the 1 in 3 women affected by urinary incontinence.

References

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Disclosures

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