158

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FIRST IN PATIENT USE OF NOVEL SURFACE ELECTRODE FOR WOMEN

Hypothesis / aims of study

Non-surgical treatment of Stress Urinary Incontinence (SUI) involves retraining the pelvic floor muscles through active muscle contraction (i.e. Kegel exercises) and/or intravaginal electrical muscle stimulation (EMS). For patients, the former is challenging to execute correctly and regularly, and the latter presents psychological and physical barriers to use. Consequently, both solutions realize poor adoption and compliance rates, with fully two thirds of affected women simply enduring their SUI symptoms without ongoing treatment [1].

Recent clinical reports suggest that a pattern of surface (i.e. transcutaneous) electrodes placed in the suprapubic and ischial tuberosity regions are as effective as intravaginal electrodes at retraining the pelvic floor muscles [2]. This suggests the opportunity to redesign traditional EMS incontinence devices to eliminate the intravaginal probe and provide a product that women are more willing to adopt and use over a full course of treatment.

The aim of this study is to fabricate a surface electrode device suitable for pelvic floor muscle toning that can be (1) applied by a patient, (2) worn comfortably for multiple hours, and (3) used in conjunction with an absorbent pad. Further this feasibility study aims to demonstrate proof-of-concept efficacy of this wearable therapeutic device on a patient with SUI symptoms. We propose that a device which discreetly delivers treatment throughout the day and without interruption of normal activity poses a significant opportunity to improve patient adoption and compliance of a known therapeutic modality.

Study design, materials and methods

The novel surface electrode has been designed to deliver deep EMS through the skin of the perineal tissue. The wearable therapeutic device is a single electrode with four electrically conductive regions fabricated from carbon film, carbon fiber leads and hydrogel, and located at the corners of the 170mm x 90mm device such that the anterior conductive pair engage the suprapubic tissue and the posterior conductive pair are proximate the ischial tuberosity. The conductive regions are interconnected by layers of non-woven tape that serves to electrically isolate them from one another as well as the non-patient contacting surfaces. Further, a midline egress provides a pathway for bodily fluids to pass to an underlying absorbent pad. An electrical adaptor was fabricated to connect the four conductor ribbon cable exiting the electrode to a commercially available interferential current generator (Intensity Select Combo, Roscoe Medical) with a beat frequency of 50Hz and adjustable intensity (i.e. current) level.

A single female patient, 42 years of age and with moderate SUI symptoms, performed the usage test with consent. A baseline modified 1-hour pad test was performed on Day 0 and Day 73 and comprised the following steps:

1. Empty bladder
2. Weigh and apply absorbent pad
3. Drink 500ml of water
4. Wait 30 minutes
5. Perform 20 minutes of high-intensity aerobic activity
6. Weigh pad and report weight increase.

The subject was trained on proper device placement and use of the generator. She was instructed to wear the device “at her convenience” and “as needed” for up to two 20-30 minute treatment sessions per day, up to five times per week for the duration of the 12-week assessment. The subject was instructed to maintain a log to record usage time/date.

Results

On Day 0 the 1-hour pad test measured 49.8g of leakage. Over the first 6 weeks the subject averaged 120 minutes/week of treatment. Over the last 4 weeks the subject averaged 45 minutes/week of treatment. On Day 73 the 1-hour pad test measured 3.4g of leakage, representing a 93% reduction in leakage.

Interpretation of results

The 93% reduction in leakage is within a range comparable with SUI studies utilizing intravaginal EMS, albeit on the higher end of that range. Treatment dosing early in the study (120min/week) substantially exceeded dosing levels common with in-clinic administration of EMS, which typically consists of two 20 minute sessions per week (40min/week). During the latter half of the study, the subject reported that she was experiencing notable improvement in continence and self-elected to use the device less frequently. This “maintenance” use is wholly compatible with the proposed self-administered treatment device and is a further potential benefit relative to in-clinical treatment.

Concluding message

By providing an EMS technology solution that eliminates the intravaginal probe, that facilitates multiple convenient treatments, and that presents as a discreet, unobtrusive therapy, women suffering from SUI will be more likely to pursue and complete medical treatment. Successful proof-of-concept device fabrication and first-in-patient use support the need for a larger clinical study.

References
1. 1. “Women’s Health: U.S. Markets for Female Urinary Incontinence Therapies.” February 2014. MedTech Insight web site. http://www.medtechinsight.com/ReportA472.html. (Accessed March 12, 2014).
2. 2. Correia, CN; Pereira, VS; Hirakawa, HS; Driusso, P; “Effects of surface intravaginal electrical stimulation in the treatment of women with stress urinary incontinence: randomized controlled trial”, Eur J Obstet Gynecol (2013).

Disclosures
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