



Neuromuscular Electrical Stimulation (NMES) of the Pelvic Floor Muscles using a Non-Invasive Surface Device in the Treatment of Stress Urinary Incontinence (SUI); A Pilot Study

Introduction

Results from studies using transvaginal NMES in the treatment of SUI are somewhat equivocal^{1,2} and, moreover some patients can find the treatment objectionable. This study evaluated a novel approach which purports to deliver superior activation of the pelvic floor muscles from an array of external garment integrated electrodes surrounding the pelvic area.

Aims

The purpose of this study was to investigate the clinical efficacy of a novel external stimulation device in the treatment of women diagnosed with Stress Urinary Incontinence (SUI).

Methods

Treatment comprised of a 30 minute session of NMES, 5 days per week for 12 weeks. The first treatment was delivered in the clinic where activation of the pelvic floor was confirmed by ultrasound imaging. Subsequent treatments were self administered by the patient at home. Outcome measures were collected at baseline and at 4, 8, 12 and 26 weeks follow-up. Measures included a stress-test following a 1-hour standardized bladder filling protocol and a 24-hour pad weight test (PWT). Patients also completed IQOL and MESA questionnaires and kept a bladder diary. Finally, pelvic floor muscle strength was evaluated using the modified Oxford score.

Results

Fourteen SUI patients completed a 12-week training program using the device. Results showed a reduction in the mean (SD) urine leakage on the 1-hour and 24-hour pad weight tests from baseline to Week 12 of 41.6g (43.92) to 5.8g (13.19) and 21.8g (19.41) to 5.6g (5.16) respectively. 86% of patients had attained a greater than 50% improvement in the 1hr PWT at week 12 while 57% were defined as dry (<2g leakage). This improvement in patient symptoms was reflected in the quality of life scores during and following intervention (See Figure 1&2). Secondary measures indicated a trend towards a reduction in the mean (SD) number of incontinence episodes per day, from 2.5 (2.81) at baseline to 1.3 (1.83) at week 12. Finally, it was noted that scores on the modified Oxford Scale improved following treatment indicating an increase in pelvic floor muscle strength.

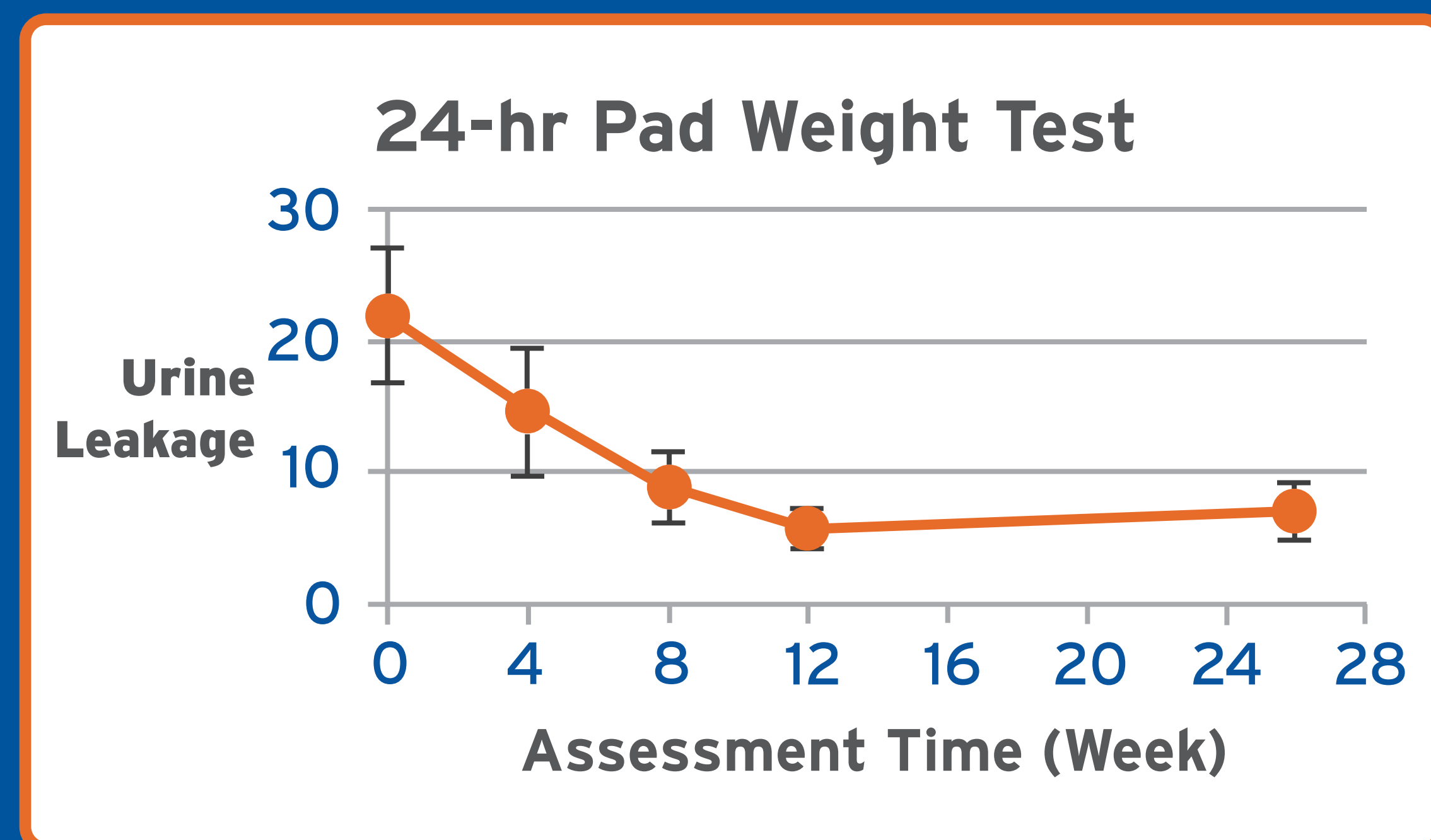


Figure 1 - Mean Patient Scores on 24-hr PWT over time.

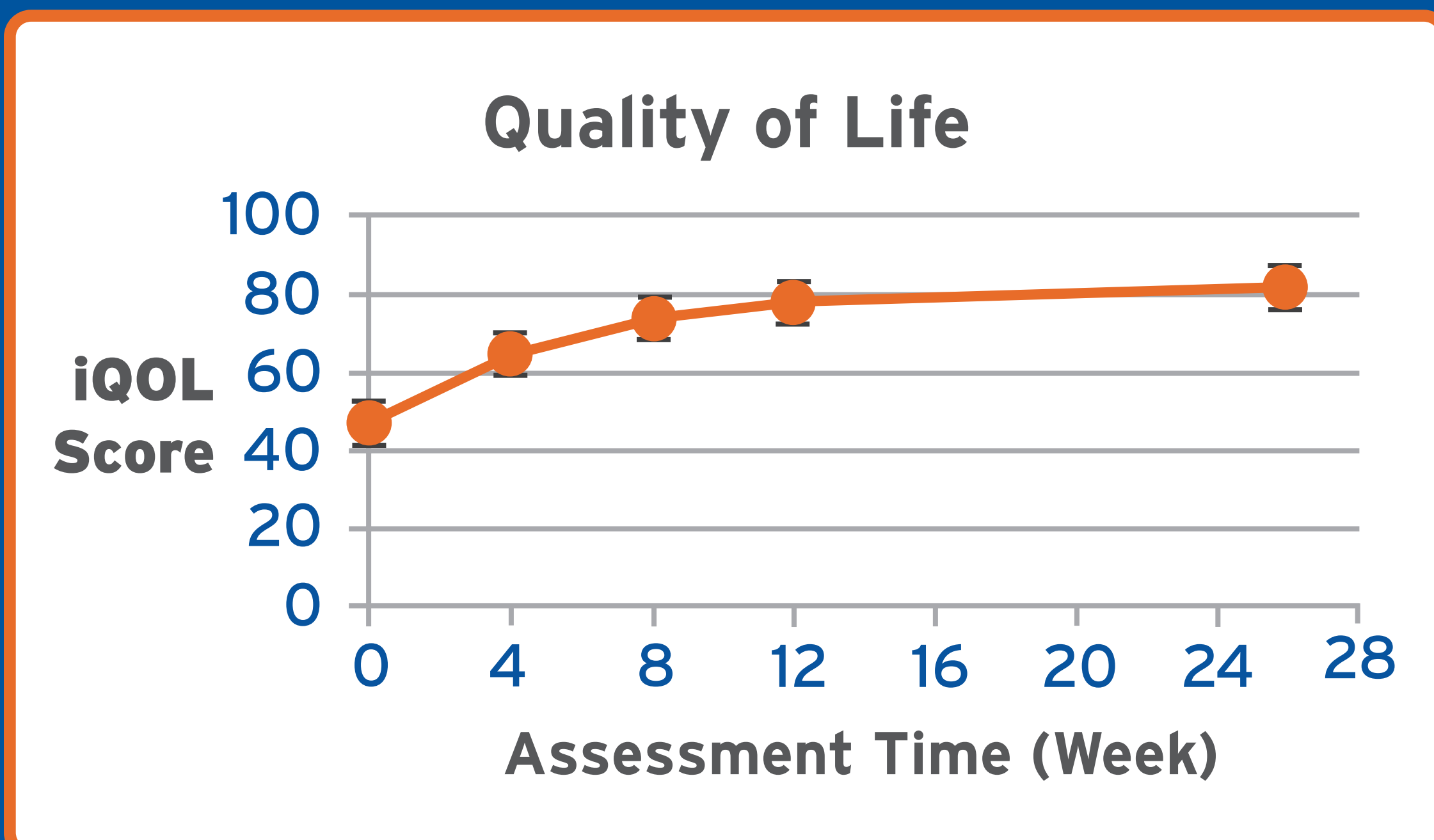


Figure 2 - Mean Patient Scores on IQOL Questionnaire over time.

Discussion and Conclusions

Overall, the 12 week treatment resulted in a significant improvement in patient outcomes with results being maintained at 6 months. The application of stimulation within an externally applied garment avoids the requirement for an invasive vaginal probe. This preliminary data has highlighted the potential of this novel method of treatment for SUI and further larger RCT studies are warranted.

References

1. Bo, K., Talseth T, Holme, I. (1999). "Single blind randomised controlled trial of pelvic floor exercises, electrical stimulation, vaginal cones, and no treatment in management of genuine stress incontinence in women." *BMJ*; 318:487--93
2. Castro, R. A., R. M. Arruda, et al. (2008). "Single-blind, randomized, controlled trial of pelvic floor muscle training, electrical stimulation, vaginal cones, and no active treatment in the management of stress urinary incontinence." *Clinics (Sao Paulo)* 63(4): 465-72

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