Novel Pelvic Floor Treatment with Mechanotherapy: Long-term Follow-up Quality of Life Results in Women with Stress Urinary Incontinence

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OBJECTIVE

Pelvic Floor Muscle Training (PFMT) is the standard of care for nonsurgical treatment of SUI. Enhancements to improve the efficacy of PFMT are needed, especially in women who are not interested in or are not candidates for surgery. The aim of this study was to evaluate if mechanotherapy (MT) applied to pelvic floor muscles (PFM) in conjunction with PFMT improves continence in women with SUI.

METHODS

This abstract presents long-term quality of life (QoL) data from a previously reported prospective, randomized, controlled, double-blinded, cross-over trial (P-SUIT) that included 119 women with Stress Urinary Incontinence on an intent-to-treat basis. The novel device used for this study (Flyte®, Pelvital, Inc., Minneapolis, MN, USA) is an intravaginal wand that provides MT via preloading of the PFM and with specifically tuned mechanical pulses with biofeedback, shown to provide incremental benefit in two studies (Figure 1). This mechanotherapy facilitates therapeutic changes in the local pelvic muscles and interstitial tissues, as well as modulation of afferent and efferent neural communication with the reflexive sacral plexus pathways and conscious control centers of the brain. This results in neuromuscular facilitation and motor learning. Subjects performed 5 mins of Flyte therapy that includes Kegels, for 12 weeks. Endpoints were assessed at 6 and 12 weeks, at which time Control subjects crossed over to the Intervention arm. The Primary Endpoint was 24-HR Pad Weight. QOL was assessed during the 12-week protocol with continued voluntary assessments every 6 months for 24 months using the validated Urinary Incontinence Quality of Life (I-QOL) and the International Consultation on Incontinence Questionnaire – Urinary Incontinence - Short Form (ICIQ-UI-SF) questionnaires.

Figure 1. The Flyte Urinary Incontinence Device

STUDY RESULTS

IQOL

The I-QOL includes 22 items that assess the subject's feelings regarding their incontinence, and seven items that assess the characteristics of the subject's incontinence, e.g., duration, severity, frequency. It is scored according to a weighted formula, with a *higher score* demonstrating better quality of life.

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Highly significant improvements were noted in IQOL scores from Baseline through 12 weeks, as previously published (Figure 2). When stratified by Baseline Pad Weight Severity, significant improvements were observed at all levels of Baseline Pad Weight Severity (Figure 3). These improvements in IQOL were maintained through the 24-month follow-up (Figure 4).

NOTE: Higher score demonstrates improvement

Figure 2.

I-QOL Full Cohort

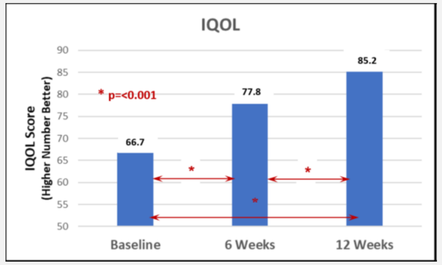


Figure 3.

I-QOL Stratified by Baseline Severity

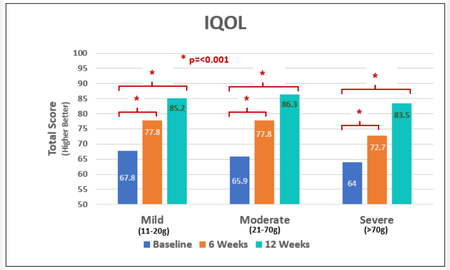
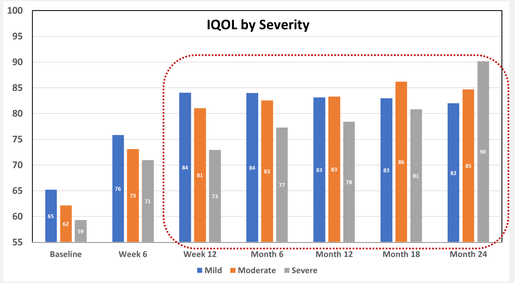


Figure 4. I-QOL Long-term Follow-up



ICIQ

The ICIQ-UI-SF includes six items that assess the frequency, estimated volume and the degree that incontinence interferes with the subject's life. The total from items 3-5 are summed to create a total score. A *lower score* denotes fewer symptoms.

Highly significant improvements were noted in ICIQ scores from Baseline through 12 weeks, as previously published (Figure 5). When stratified by Baseline Pad Weight Severity, significant improvements were observed at all levels of Baseline Pad Weight Severity (Figure 6). These improvements in ICIQ were maintained through the 24-month follow-up (Figure 7).

NOTE: Lower score demonstrates improvement

Figure 5.

ICIQ Full Cohort

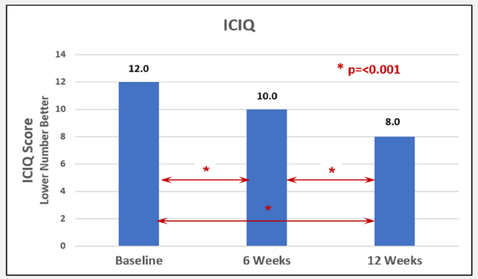


Figure 6.

ICIQ Stratified by Baseline Severity

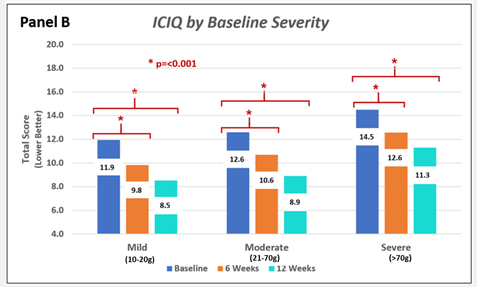
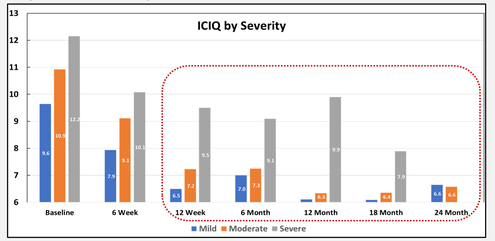


Figure 7.

ICIQ Long-term Follow-up



24-HR Pad Weight

24-HR pad weight was the primary endpoint of the study. Continence was defined as <10g/ Post hoc analyses (previously published) are presented below. Very significant improvements were noted from Baseline through 6 weeks follow-up, with incremental improvement noted from 6 to 12 weeks (Figure 8). When stratified by Baseline Pad Weight Severity, significant improvements were noted in women with all levels of leakage (Figure 9).

Figure 8.

24-HR Pad Weight (Full Cohort)

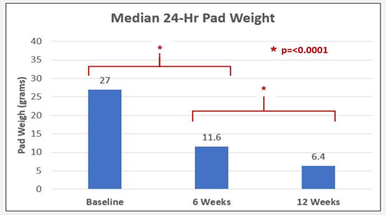
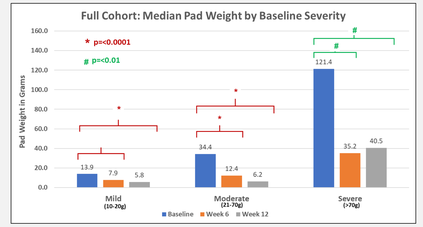


Figure 9.

24-HR Pad Weight Stratified by Baseline Severity (Full Cohort)



CONCLUSION

Flyte Mechanotherapy resulted in effective, non-invasive therapeutic improvements in quality of life as assessed by the IQOL and ICIQ QoL instruments. These benefits were sustained over the two-year follow-up.