A randomised controlled trial of the PelvicToner Device in female stress urinary incontinence

D. Delgado, M. Drake
Bristol Urological Institute, Southmead Hospital, Bristol. UK.

Correspondence to; Professor Marcus Drake, Southmead Hospital, Bristol, BS10 5NB, UK.
Tel +441179595690, Fax +441179502229, e-mail marcus.drake@bui.ac.uk

ABSTRACT

Introduction and Hypothesis: *Pelvic floor muscle training (PFME) is first line treatment for female urinary incontinence, requiring a regime of regular voluntary pelvic floor contractions without resistance. The PelvicToner device (PTD) is an approach to PFME, enhancing pelvic floor strengthening and endurance by offering intravaginal resistance. The objective of this study was to compare standard PFME with PFME using the PTD.*

Methods: *40 women, aged at least 18 years with symptoms of pure stress or stress-predominant mixed urinary incontinence were randomly assigned to participate in the two groups. They were evaluated throughout treatment using International Consultation on Incontinence Questionnaires (ICIQ), bladder diaries and other subjective outcome measures for symptom improvement.*

Results: *Both groups showed statistically significant symptom improvement post treatment, based on ICIQ responses. There was no significant difference between groups regarding improvement in SUI. Some women reported easier use and favoured the confidence derived from the biofeedback.*

Conclusions: *The PTD is not inferior to standard PFME. It is a safe and well tolerated adjunct to PFME, which increases patient choice and may promote subsequent compliance and sustained efficacy.*

Keywords: pelvic floor muscle training, stress urinary incontinence, randomised controlled trial.

INTRODUCTION

Urinary incontinence, though not life threatening, can be very distressing, with significant physical, psychological, economic and social implications for the well-being of affected individuals. The estimated prevalence of urinary incontinence in middle-aged and older women ranges between 30% and 60% (increasing with age), with approximately half of these women being classified as having stress urinary incontinence (SUI). Pelvic floor muscle exercises (PFME) training was first advocated as a treatment for SUI in the 1950's following Arnold Kegel's reports of an 84% associated cure rate [1]. Subsequent research has endorsed these findings, demonstrating that women with SUI who carry out PFME are more likely to report cure or improvement and fewer leakage episodes per day than controls [2].

In its guidelines for the management of female incontinence [3], the UK National Institute of Clinical Excellence (NICE) recommend PFME as a safe and effective first line treatment for women with stress or mixed urinary incontinence. PFME training typically involves helping the woman confidently to identify her pelvic floor and then carry out a self-administered regime of unresisted pelvic floor contractions according to a provided schedule. Explicitly, PFME needs to be taught formally by a suitable trainer, with proper assessment that pelvic floor contraction is successfully being achieved, followed by a conscientious regime of regular exercises over a period of several months. Success rates are lower if formal teaching is not provided, or if PFME is not consistently undertaken over a sustained period. Adjunctive measures such as electrical stimulation, weighted vaginal cones and biofeedback which focus on overcoming some of these issues are not universally advocated as they have yet to produce sufficient evidence of efficacy.

Despite widespread acceptance and support amongst clinicians for this seemingly straightforward conservative therapy, women with SUI often find PFME to be problematic. Two particular issues are:

i) Lack of confidence in successfully identifying the pelvic floor muscles

ii) Compliance issues associated with the requirement to commit to a daily regime of PFME in the longer term

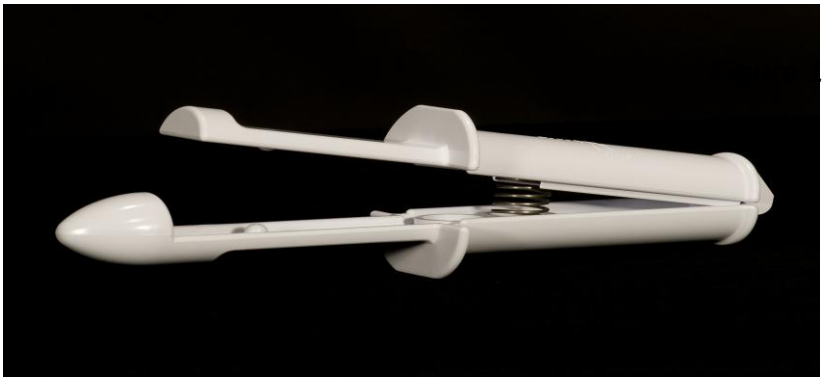
In addition, provision of formal training for PFME is patchy; many women do not have access to a suitable trainer, receive no feedback as to whether they are contracting their pelvic floor, are not informed of the need for adhering to the recommended regime and are not followed up.

We hypothesised that using the PelvicToner™ device (PTD) to introduce resistance against the pelvic floor contraction intravaginally may facilitate PFME training, improve muscle strength and aid women in successfully complying with PFME. To test this hypothesis we devised a randomised controlled study to investigate the efficacy, acceptability and patient satisfaction with the PTD as an adjunct to PFME.

METHODS

The PelvicToner device

The PTD (Solution Project Magement, UK) has been designed to increase the strength of pelvic floor contractions by providing intravaginal resistance. The PTD comprises two limbs held apart by a stainless steel spring (Figure 1). Once placed intravaginally, the closure of the two limbs of the device provides biofeedback, as the woman consequently knows that she is successfully contracting her pelvic floor. The PTD gives the option to increase the resistance over time as pelvic floor strength increases in stages, achieving this by; providing different strength springs, moving the spring position to alter leverage, and by adding an additional spring. Increasing PTD resistance was not undertaken in this study in view of the consequent complexity of analysis.



The PelvicToner device.

Methodology

A single centre, parallel group, randomised controlled study was carried out. Prior to screening potential subjects were sent a four day bladder diary (Figure 2) to complete, detailing their voiding frequency, the incidence of SUI and urge incontinence (UI) episodes and the volumes of urine voided. Women over 18 years of age with symptoms of pure SUI or stress-predominant mixed urinary incontinence (a minimum of three stress urinary leaks per week based on bladder diary), who had not undergone surgery for incontinence, were recruited between February and December 2008. Study interventions took place within North Bristol NHS Trust secondary care facility.

Exclusion criteria comprised; pregnancy / < 12 weeks post partum, taking Duloxetine Hydrochloride, recent or recurrent urinary tract infection, neurological disease, post void residual $\geq$ 100mL and significant pelvic organ prolapse. The ability to perform a voluntary pelvic floor muscle contraction was confirmed in all subjects (pre-randomisation) using a perineometer (Peritron 9300V). Subjects with a voluntary increment of $\leq$ five centimetres of water were excluded (n= 2) and offered a referral to a specialist physiotherapist for intensive instruction in PFME +/- biofeedback.

Day 1 Today's Date	day month year □□ /□□ / □□		
Time hh/mm	Toilet [**A/B**]	Volume [ml]	Leak [**C/D**]

Figure 2. *Excerpt from four day bladder diary*

Please record the time and write in the appropriate column the following:
A *in the toilet column when you voided in the toilet during waking hours*
B *in the toilet when you had to get up from sleep to void*
C *In the leak column when you had an accidental leakage caused by an activity such as coughing, sneezing, laughing, running, exercising or lifting*
D *in the leak column when you had an accidental leakage caused by a sudden strong need to urinate that you could not reach the toilet in time*

Randomisation

The randomisation sequence was generated independently of the investigator; randomisation slips were placed into opaque, sequentially-numbered envelopes, which were sealed until interventions were assigned. Participants were enrolled by a urology research nurse who administered the intervention based on the randomisation. Due to the nature of intervention, blinding of both subject and nurse as to treatment group was unfeasible.

52 subjects were randomly assigned to one of two interventions

1. Standard Treatment (ST) i.e. unresisted PFME alone
2. The PelvicToner Group (PTG) i.e. PFME employing the PTD.

Following randomisation, subjects in both groups underwent a one hour session with a health care professional, in which they were individually informed of the anatomy and function of the pelvic floor muscles and how to contract them correctly. All subjects were given a PFME leaflet specifically adapted for the study to refer to at home. Subjects in the PTD group additionally were given a PTD, together with written and verbal instruction on its use.

Subjects were instructed to carry out a standardised PFME regime consisting of five 'quick' and five 'slow' (sustained), high intensity pelvic floor contractions daily over a 16 week period. Participants were advised to hold the sustained contractions for as long as possible, relaxing their pelvic floor muscles for an equivalent time before repeating the process. To ensure the groups were comparable, all subjects were instructed to carry the PFME regime in the supine position as this is necessary when using the PTD. Subjects in the PTD group were instructed to use the PTD concurrently whilst executing the PFME regime. After two weeks, all subjects were followed up by telephone in order to answer queries and reinforce technique, with further review taking place at 8 and 16 weeks following commencement of treatment.

In order to minimise inconsistencies between subjects in the PTD group, women were given the lower resistance spring only and instructed to use it in the first (i.e. weakest) position of resistance (nearer the hinge) throughout the treatment period. This was necessary to simplify data analysis, but the PTD has the option to increase device resistance progressively, as alluded to above.

Outcome Measures

The primary outcome measure was comparison of subject-reported improvement between treatment groups. Improvement was defined as positive change in subject response to question 11 of the ICIQ-FLUTS questionnaire when administered at screening and on completion of the treatment period. ICIQ-FLUTS 11a) Does urine leak when you are physically active, exert yourself, cough or sneeze?

Response: Never, occasionally, sometimes, most of the time, all of the time. Question 11b) How much does this bother you? *Response: Bother score 0 – 10 ('0' - 'not at all', '10' - 'a great deal').*

Secondary outcome measures included subjective reports of 'cure', defined as the response of 'never' to question 11a ICIQ-FLUTS following the treatment period. Other measures included; the ICIQ-UI Short Form and ICIQ-LUTSqol questionnaires, the Patient Satisfaction Question (PSQ), Global Perception of Improvement (GPI), and Estimated Percent Improved (EPI). Subjective opinions regarding satisfaction and acceptability of treatment were also sought throughout the study period. Subjects were re-issued these questionnaires at eight weeks (post randomisation) and at treatment completion (16 weeks).

Statistical Analysis

Patient responses to key items on the questionnaires were cross-tabulated against randomly allocated treatment groups at baseline and follow-up, and an assessment of group differences was undertaken using Pearson's chi-square test of association. For the primary and secondary outcome measures an assessment of the percentage of patients reporting "an improvement", "no change", or "a worsening" over the duration of the study was undertaken within treatment groups and 95% confidence intervals were reported. Trends over time within each group were investigated using the Sign test for repeated measures and a comparative assessment of changes between randomised groups was conducted using the chi-square test of association. For ordinal measures, a comparison between groups was undertaken using the Mann Whitney test. For ordinal changes over time, the Wilcoxon test was applied to carry out the comparison.

As there is no previously published research investigating the efficacy of the PTD, it was not possible to calculate a sample size based on expected statistically significant differences between groups. Therefore a proposed sample of 30 subjects in each group was derived from similar studies.

RESULTS

Baseline Demographics

65 subject screenings took place resulting in 52 randomisations. In total 40 subjects completed the treatment period; the remaining 12 dropped out predominantly due to time constraints and/or ill health (ST: n=19, PTG: n= 21). The mean (range) age of participants was 49.6 years (36 – 68), and mean (range) duration of symptoms five years (6 months – 30 years). 36 out of 40 subjects had children, with an average parity of two. There was no significant demographic difference between the two groups.

Based on the four-day bladder diary completed prior to screening;

- 10 subjects reported mixed urinary incontinence (range 1-6 urgency incontinence episodes)
- The remaining 30 subjects presented with pure SUI, reporting an average of seven SUI episodes over the diary period (mean of five, mode of four, range 3-20).

On analysing participant responses to the ICIQ-FLUTS, ICIQ-LUTSqol and the ICIQ-UI Short Form questionnaires there were no significant differences between the groups in relation to the frequency of urine leakage, pad use and the overall impact of urinary symptoms on everyday life (ICIQ- UI Short Form question 5 –see Figure 3) at baseline.

Outcome measures

In analysing the primary outcome measure, 52.4% (n=11/21) in the PTG and 52.6% (n=10/19) receiving ST reported symptom improvement following the treatment phase. No subjects in the PTG (n=0) and 10.5% (n=2) subjects in the ST group reported 'cure'. There was no statistically significant difference between the groups at any time point for either of these outcome measures.

Following the treatment period, subjects were asked to complete an assessment of their Global Perception of Improvement (GPI) i.e. to rate how they felt about their symptoms following treatment. 75% subjects in both the PTG and the ST group reported feeling 'better' or a 'much better' after the treatment period (Table 1).

***Table 1* Global Perception of Improvement (GPI)** Question**:** Overall, do you feel that you are…?					
	Much Better	**Better**	**About the same**	**Worse**	**Total**
PelvicToner	9 (45%)	6 (30%)	4 (20%)	1 (5%)	20 (100%)
Standard Treatment	7 (35%)	8 (40%)	2 (25%)	0 (0%)	20 (100%)

Other measures of subject-reported improvement included responses to question 5 of the ICIQ- UI Short Form questionnaire (Figure 3). Both groups showed significant improvement in overall symptoms, but the extent of improvement reported between groups was not significantly different.

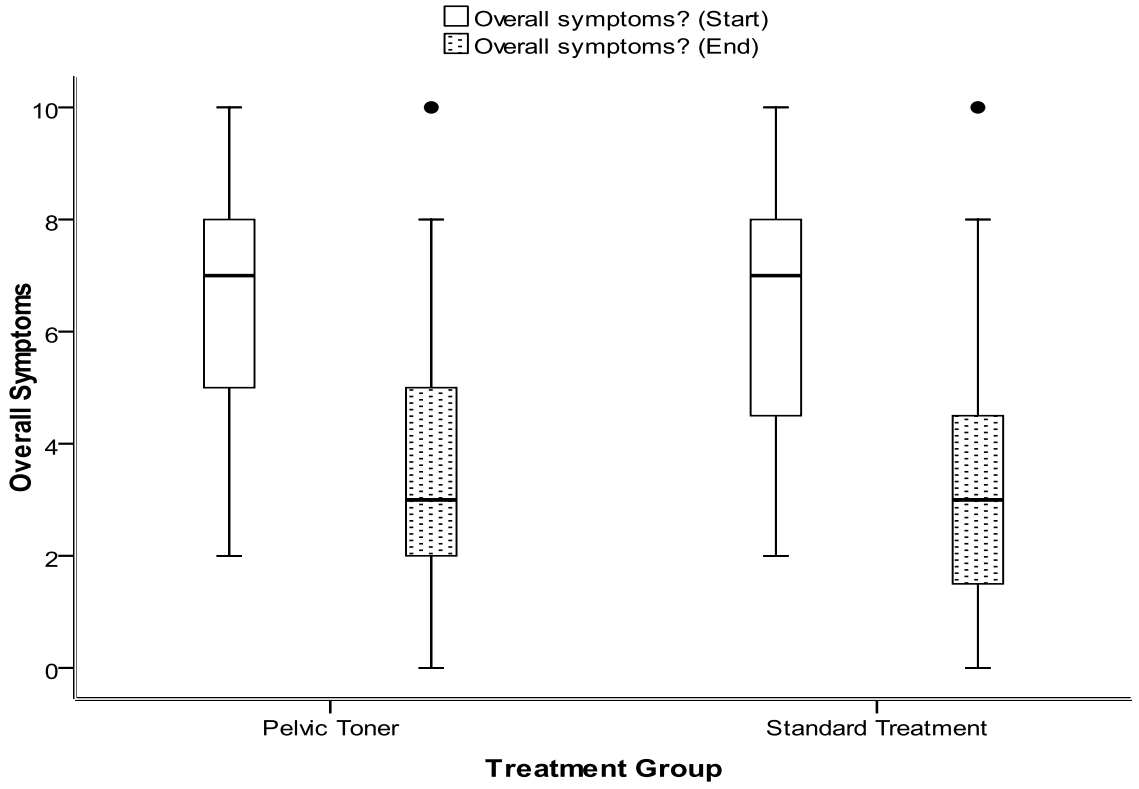


Figure 3. *Distribution of responses to question 5 of the ICIQ-UI Short Form at baseline (week 0) and treatment completion (week 16). The question asks; "Overall, how much does leaking urine interfere with your everyday life?" Response options range from 0 (not at all) to 10 (a great deal).*

User feedback on the PelvicToner

All subjects reported the PTD easy to use when questioned at treatment completion. 86% (n=18) gave the device a satisfaction rating $\geq$ 7/10 (0 = dissatisfied, 10 = very satisfied). Common reported themes included;

- That the PTD helped to isolate and focus on contracting the correct muscles
- That the PTD helped sustain motivation to keep going with PFME

One lady remarked that the PTD increased her confidence by providing '…something tangible to measure the squeeze'.

DISCUSSION

NICE [3] and the International Consultation on Incontinence (ICI) [4] both support supervised PFME as first line treatment for SUI and stress-predominant mixed urinary incontinence, and this is accepted as standard of care. The current study shows that use of PTD is not inferior to standard of care. This contrasts with other adjunctive devices used for PFME or training.

For skeletal muscle, resistance to contraction represents a loading that requires additional contractile effort, and is an element of strength and endurance training. For pelvic floor function, contractile endurance is important for sustaining continence throughout the day and by introducing intravaginal resistance, the PTD will facilitate development of endurance strength of pelvic floor activity. Speed of response to enable a rapid contraction in anticipation of imminent physical stress is another important facet, which is why the PFME regime incorporated “quick” pelvic floor contractions. PFME regimes combining speed and endurance training appear to offer the prospect of improving symptom severity in SUI.

Compliance with PFME regimes in the longer term is essential to achieve benefits, and healthcare professional input at the outset is appropriate for ensuring contractions are done correctly, and to reinforce the need to sustain compliance over a sufficient duration. Such input is generally given in an initial consultation and follow up after a few months. In reality, many people may find it difficult to reproduce unaided at home what they may successfully have achieved with the healthcare professional providing positive feedback. Where a woman is not confident that she is correctly contracting her pelvic floor, she is less likely to comply with the PFME routine. As elicited in user feedback, the PTD did deliver confidence to women that they were correctly contracting their pelvic floor, and this may be helpful encouragement when a woman is starting out on a regime of PFME.

Standard of care advocated by NICE and the ICI is supervised PFME training, but the reality of service provision often falls short of this. In some places, women may not be advised about PFME at all, or simply be given a leaflet about PFME, with no assessment of correct muscle contraction. In this setting, the biofeedback given by the PTD may be particularly helpful to demonstrate to the woman that she is carrying out the PFME appropriately. Another group of women who may benefit are those who do not consult their physician and wish to maintain confidentiality regarding their SUI symptom.

The study was not powered to show clinical superiority for the PTD-supplemented group over standard PFME. This would have required large numbers of patients in both treatment arms and was not realistic in the context of limited grant provision for the project. The study received corporate financial input (see Conflict of Interest statement below) from a comparatively small company. It is unusual for a small device company to invest in clinical research, and the financial commitment engaging in clinical research represents a major financial commitment for a small company, as it is a considerable part of their operating capital. Such research is of considerable benefit to the patients- a step which device companies rarely undertake, partly explaining the paucity of clinical evidence in conservative and surgical management of SUI. The cost of fully financing a large clinical trial is likely to be unrealistic for many device companies. Until better access to the large research funding needed to underpin acquisition of clinical evidence in SUI management is available, women will continue to have to make decisions with insufficient clinical evidence to guide their treating physicians.

CONCLUSION

Subjective clinical outcome of PTD-aided PFME is not inferior to standard PFME. The PTD aided women to identify their pelvic floor confidently. It is a safe and well tolerated adjunct to PFME, which increases patient choice and may promote subsequent compliance and sustained efficacy.

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CONFLICT OF INTEREST

Funding was provided by Solution Project Management, UK. The design, data collection, analysis and writing up were independently undertaken by the investigators, with no corporate input.