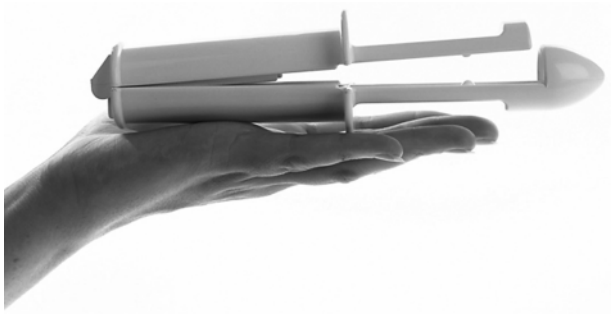
Product reviews

PelvicToner

Solution Project Management Ltd, Bristol, £29.99
ASIN: B002WBTS44



The PelvicToner is an intravaginal device that can be used during pelvic floor muscle (PFM) training. This review discusses not only the product, but also the information that was received with it:

- a research paper by Delgado & Drake (2010);
- a fact sheet for National Health Service (NHS) staff; and
- a patient information leaflet.

Research paper

A randomized controlled trial of the PelvicToner in participants with female stress urinary incontinence was undertaken by Delgado & Drake (2010) and published as an exclusive on the *BJU International* website. Fifty-two women were randomized to either a PelvicToner group (PTG) or standard treatment (ST), and advised to carry out PFM exercises (PFMEs) daily with (PTG) or without (ST) the PelvicToner device (PTD). Data for 40 women (PTG = 21, ST = 19) were analysed. Similar numbers (PTG = 52.4%, ST = 52.6%) reported an improvement. The conclusion was that:

> "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." (Delgado & Drake 2010, p. 1)

Critical analysis of "A randomised controlled trial of the PelvicToner Device in female stress urinary incontinence" identified the following issues:

- The title is not completely accurate since 10 of the 40 participants (25%) had stress-dominant mixed urinary incontinence. As far as can be determined, none of the subjects had undergone urodynamics and all symptoms were self-reported. It is unclear how exactly the sample was recruited.
- All the participants were assessed vaginally using a pressure biofeedback device (Peritron 9300V Perineometer, Cardio Design Pty Ltd, Oakleigh, Victoria, Australia), and two were excluded because of no or very weak contractions. Following randomization, the subjects all attended a one-hour education session with a healthcare professional that covered anatomy and physiology, PFM function, and PFM contraction. In my view, this is very different from a member of the public buying a PelvicToner over the counter, or obtaining one on prescription, when they may receive little or no advice, nor any form of objective PFM assessment.
- Both groups were followed up by telephone after 2 weeks, and again after 8 and 16 weeks (it is unclear if the latter two interviews were by telephone or face-to-face). Again, this is different from "usual practice" if one were using a PelvicToner.
- The advice on PFMEs (with or without the device) was to perform five quick and five slow contractions daily while lying supine (since this is the position in which the PelvicToner is used). I do not regard this as a "standard PFME".
- There were some inaccuracies within the results section (e.g. Table 1; Delgado & Drake 2010, p. 5) of the version of the paper that I received from the company. The numbers cited did not appear to add up, i.e. there seemed to be results for 20 women in the ST group ($n = 19$) and 17 in the PTG ($n = 21$). However, this information has been amended on the version that is currently downloadable from the *BJU International* website.
- The authors report user feedback from the PTG (e.g. it helped to isolate the right muscles and contributed to motivation), but no comments from the ST group are included, which seems inequitable.

- Within the discussion, the suggestion is that standard care consists of an initial assessment and "follow up after a few months". To the best of my knowledge, this is not the case, although practice varies throughout the UK.
- The study was supported financially by the company concerned, but this is clearly acknowledged within the text and identified as a conflict of interest.

In summary, my concerns in relation to this paper are that the "standard treatment" was not what I would consider to be typical. In particular, I am not aware of anyone who advises five quick and five slow squeezes a day. I am satisfied that the PTG did obtain similar results to the ST group. However, this was after vaginal assessment and one hour of education/advice, and the participants were followed up twice before the final review at the end of the study. This is not, I believe, reflective of normal practice with the device. I am disappointed that there was no reported feedback from the ST group and that the comments from the PTG were also limited.

Fact sheet for NHS staff

I was also sent a copy of the company's fact sheet, which is not referenced. Again, I have reviewed it critically because it is designed for healthcare professionals, and so, I believe, should be as evidence-based as possible.

- Within the introduction, it is claimed that the device offers "much improved patient outcomes in all those situations where pelvic floor muscle exercises are recommended". This is not, as far as I can see, supported by Delgado & Drake (2010), nor to the best of my knowledge, any other studies.
- The document also claims that the device encourages users to carry out and maintain a PFME programme "in the most effective way possible". Again, I am unaware of evidence to support this statement.
- Under a section on clinical justification, the cost for "urodynamic training" is given. I assume this should be testing, not training, and I do not think it is relevant. The fact sheet also states that, "The PelvicToner offers the equivalent treatment to supervised PFMT [PFM training] plus biofeedback at a cost of £15.00." I do not believe that this assertion is justified by the research presented (Delgado & Drake 2010), which showed that the outcome for the PTG after vaginal assessment, exclusion of women who could not contract their PFMs (or had a very weak contraction), one hour of education and advice, and regular follow-ups (after 2, 8 and 16 weeks) was equivalent to that achieved by the ST group.
- The document states that Delgado & Drake (2010) used "a total of 10 × fast pull-ups and 10 × slow pull-ups", which is incorrect. It was, in fact, five of each.

In summary, I feel that there are some inaccuracies in the fact sheet, which might mislead the reader.

Patient information

I would question some statements within the patient information leaflet that comes with the device:

- It suggests that a healthy pelvic floor could "discourage pelvic disease and menstrual problems". I am not aware of any evidence to support this.
- The leaflet states that half of all women "will suffer urinary continence problems". This is higher than the figure normally suggested in the literature (Buckley & Lapitan 2010).
- In more than one place in the leaflet, it is erroneously suggested that the pelvic floor and pubococcygeus muscles are the same thing. Perhaps this is not too important an error in a patient leaflet, but it would be good to correct it.
- Bø *et al.*'s (1999) comparison of PFMEs, neuromuscular stimulation and vaginal cones is mentioned because the results of this study showed that PFMEs were superior. However, in that research, the PFME group performed eight to 12 squeezes three times a day and attended an exercise session for 45 min every week. After the initial assessment, the other groups used stimulation or cones (following the manufacturers' instructions) with only a monthly check-up appointment with the researcher to monitor progress, and therefore, had less contact with a healthcare professional. For this reason, I do not feel that the study can be compared with that of Delgado & Drake (2010).
- With reference to the above point, the patient information leaflet goes on to state that the Delgado & Drake (2010) paper "noted that the PelvicToner was superior to other products on the market and offered several advantages over the best treatment offered by the NHS". I believe that this statement is unjus-

tified: the device was not compared to other treatments and the comparison was with what the researchers referred to as ''standard care'', not ''best treatment''.
- The paper by Delgado & Drake (2010) is incorrectly listed as ''Drake'' and the reference lacks detail, so it would be difficult for the reader to find it with an Internet search.
- Under the heading ''How to use the PelvicToner'', there are instructions on how to contract the PFMs. However, there is no mention of what to do if you can't.
- In the instruction about the number of repetitions, the leaflet does not mention how many seconds these should take, just that patients should begin with three sets of 30 repetitions and build up to six sets. I am not sure how these figures were reached, but I believe that many women would be unable to achieve them. There is no mention of doing fewer, if necessary.
- Under ''Frequently asked questions about the PelvicToner'' it is stated that, ''Many midwives advise that pelvic floor exercises should not be carried out during pregnancy.'' I believe that this statement is incorrect, and it certainly contradicts the advice given by the National Institute for Health and Clinical Excellence (NICE) in the urinary incontinence guideline (NICE 2006) quoted in the Delgado & Drake (2010) paper, and on the fact sheet for NHS staff.

In summary, the patient information leaflet does not suggest what to do if, for example, you cannot contract your PFMs, are unable to tolerate the device or your symptoms do not improve. I believe that it would be good to suggest that patients see a healthcare professional such as a women's health physiotherapist. As with the fact sheet, I feel that there are some inaccuracies, which might mislead the reader.

Trial of the device

I found the instructions fairly straightforward, but we should not necessarily assume that a member of the public would feel the same way. Although I was worried that the device might ''nip'' the vaginal mucosa, it did not. I could feel the device *in situ*, but was unsure whether I was closing it or not, and I had to look down to check. Even though I thought that I might be able to hear it when it shut, this was not the case. I progressed through different combinations of springs and could feel the resistance increase. When I tried to get the PelvicToner to close without contracting my PFMs, I was unable to do so, and therefore, I think that the device is a fair indicator of a PFM contraction. I wonder if it would be tolerated by most women. Although I found it comfortable, I can imagine that, for example, women with significant atrophic changes or those recovering from a vaginal delivery might not.

In summary, I found the device comfortable and could close it by contracting my PFMs. I could feel that I had to work harder as I added stronger or additional springs. Cleaning was straightforward.

Closing remarks

I feel that, in places, the evidence presented by Delgado & Drake (2010) has not been interpreted accurately in the company's literature, which might mislead the reader.

I do feel that, for some women who are under the care of a specialist physiotherapist or other appropriate healthcare professional, the device might be considered as an adjunct to supervised PFMEs. However, the evidence presented (Delgado & Drake 2010) does not demonstrate that this would add any value in terms of outcome.

The PelvicToner is available directly from the manufacturer (www.pelvictoner.co.uk) or from Amazon (www.amazon.co.uk). The recommended retail price is £29.99 (+£2.00 P&P). The NHS price is £15.00 (+VAT), and the device is available on prescription. For more information, contact Solution Project Management Ltd, 1 Westmoreland Road, Redland, Bristol BS6 6YW (e-mail: admin@spml.biz; tel: 0117 974 3534).

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My PFF: the new lights by TENA pelvic floor fitness app

TENA, Stockholm, available to download free http://www.lightsbytena.co.uk/mypffapp

Many apps containing information about and exercises for the PFMs are available for a variety of smartphones, including ''Kegel Kat'', ''Kegel Muscle Exerciser'' and now ''My PFF''.

The ''My PFF'' app is available to download free for the Android and iPhone, and it provides the user with information about the importance of PFMEs and encouragement to perform these. There are three video tutorials that simply and concisely explain the location and function of the PFMs, and the exercises recommended. This could have been enhanced by letting users know what to do if they are experiencing difficulties or struggling to locate their PFMs.

One tutorial recommends that users perform PFMEs three times a day. However, the reminder provided by the app only gives the option to prompt the user once a day, which is the minimum suggested. This part of the app could have been improved by allowing customers to set multiple reminders if a greater number of daily sets are desired.

In terms of the actual exercises set, the short squeezes seem to vary in length and are perhaps slightly too long. When timed, these seem to last between 4 and 9 s, which many women may struggle to hold for initially. The length of the short squeezes may need to be reduced in order to exercise the fast muscle fibres. The interactive aspect of the long squeeze is beneficial since it accurately measures the user's contraction, but there is no numerical value to the length of the hold, which makes it harder for the user to perceive a change. This is seen in the ''My Progress'' section because, although differently coloured dots indicate a change in ability, these do not allow for as much feedback in terms of length of hold. Perhaps attaching a numerical value to the long squeezes and including this in ''My Progress'' would more effectively highlight improvements. Also, if the user performs more than one set of exercises a day, only the most recent workout is recorded in this section, and therefore, perhaps including all workouts might be more indicative of any improvement.

In terms of the number of sets and repetitions, only three short squeezes and one long hold are considered a daily workout, but ACPWH indicates that patients should perform 10 long holds and 10 short squeezes three times a day. Although this may not be possible for many women, perhaps the option of increasing the number of repetitions of each exercise could be included to allow users to individualize their workout.

''My PFF'' provides good motivation to do the exercises and informative daily tips throughout its sections. The app is simple and easy to use, and gives novice users a good foundation on which to begin doing their PFMEs. For the more experienced user or for those who want more out of the app, several options could be included that would be beneficial for all women.

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