Received: 3 May 2019 | Accepted: 18 June 2019

DOI: 10.1002/nau.24099

ORIGINAL CLINICAL ARTICLE

Neurourology and Urodynamics ICS SUFU WILEY

Scientific evidence for pelvic floor devices presented at conferences: An overview

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Abstract

Aims: An increasing number of diagnostic and therapeutic medical devices are available to help patients and physicians manage pelvic floor symptoms in women. Many of these are presented at scientific conferences, and in the absence of a gold standard for evaluation, marketing has become more prominent than scientific evaluation. The goal of this study was to (a) provide an overview of pelvic floor devices for women that have been presented at recent annual meetings of leading scientific societies and (b) to summarize and review the scientific evidence underpinning these devices.

Methods: Manual searches were performed of all abstracts presented in 2016 and 2017 at annual meetings of the International Continence Society, the International Urogynecological Association, the European Association of Urology, and the American Urological Association. The exhibition floor of the 2017 International Continence Society was also searched. Subsequently, literature searches of both the MEDLINE and Embase databases were performed in November 2018 to identify original full-text publications related to the identified devices.

Results: We identified 11 devices from these sources, which were mainly used for the control of urinary incontinence. Only seven of these pelvic floor devices were covered by publications, with no full-text records identified for the remaining four devices.

Conclusions: Sample sizes were small and there was a lack of convincing evidence for most devices. Despite this, many devices were available in the market. Our findings indicate that the process for introducing these new devices

This study was presented as an ePoster and oral presentation at the early career session of the annual meeting of the ICS held in Philadelphia, 2018.

is in stark contrast with the strict requirements for introducing new drug classes.

KEYWORDS

congresses as topic, pelvic floor disorders, urinary incontinence, vices

1 | INTRODUCTION

Pelvic floor dysfunction refers to a variety of disorders or diseases caused by impairment of the structural elements of the pelvic floor and affects approximately a quarter of adult women.[1] The dysfunction can have a profoundly negative effect on the quality of life,[2,3] and can lead to significant economic burdens.[4,5] Guidelines often advocate pelvic floor muscle training (PFMT), with or without supervision, as a first-line conservative treatment.[6-8] Pelvic floor devices have therefore been developed and are used as auxiliary aids for this training or as alternative treatments.[9-11] Given that some of these are relatively new devices, no gold standard has been developed against which they can be evaluated, with development and marketing gaining a more prominent role in their distribution and use than proper scientific evaluation. In Europe and America, this is compounded by the lack of a need for clinical data on effectiveness before being granted marketing approval.[12]

Scientific meetings offer fantastic opportunities for developers and scientists to present their devices and work to professionals and the promotion of these devices at meetings has grown. Therefore, we aimed to (a) provide an overview of pelvic floor devices for women that have recently been presented at the annual meetings of leading scientific societies and (b) to review the scientific evidence underpinning these devices.

2 | METHODS

2.1 | Search strategy

All abstracts presented at the annual meetings of the International Continence Society (ICS), the International Urogynecology Association (IUGA), the European Association of Urology (EAU), and the American Urological Association (AUA) in 2016 and 2017 were manually searched. Screening of titles and abstracts for inclusion was conducted independently by two authors, while another two authors attended the exhibition floor of the 2017 ICS annual meeting to identify devices. We did not register this overview on the PROSPERO website, because our aim was not to conduct a formal systematic review.

2.2 | Study selection

We included devices designed to support the diagnosis and/or treatment of any pelvic floor dysfunction in women. Devices were excluded if they were (a) solely intended for use in male subjects or (b) relied on a physician for placement. Any disagreement on inclusion or exclusion was resolved through discussion between two researchers.

2.3 | Data extraction

Data extraction was independently performed by two researchers. For all identified devices, we extracted the following information from the manufacturers' website or brochures: type of device, target condition, and availability. We then conducted literature searches of both the MEDLINE and Embase databases in November 2018 to identify any scientific evidence concerning each device. Rather than conducting a full search, we looked for full-text publications by entering the names of the authors listed on the abstracts and the names of each device. Original publications were obtained when possible, and the reference lists of each included article were manually searched to find other relevant publications. Finally, we collected full-text publications, summarized the evidence, and ranked them by study design, using the pyramid of evidence.[13] We did not assess the risk of bias in the included studies because the number of randomized controlled trials was expected to be low. Moreover, a systematic assessment of quality was considered to be beyond the scope of this study.

3 | RESULTS

3.1 | Device inclusion and study identification

In total, we identified eleven eligible pelvic floor devices (Figure 1). The literature search uncovered 10 original full-text publications, but these only referred to seven of

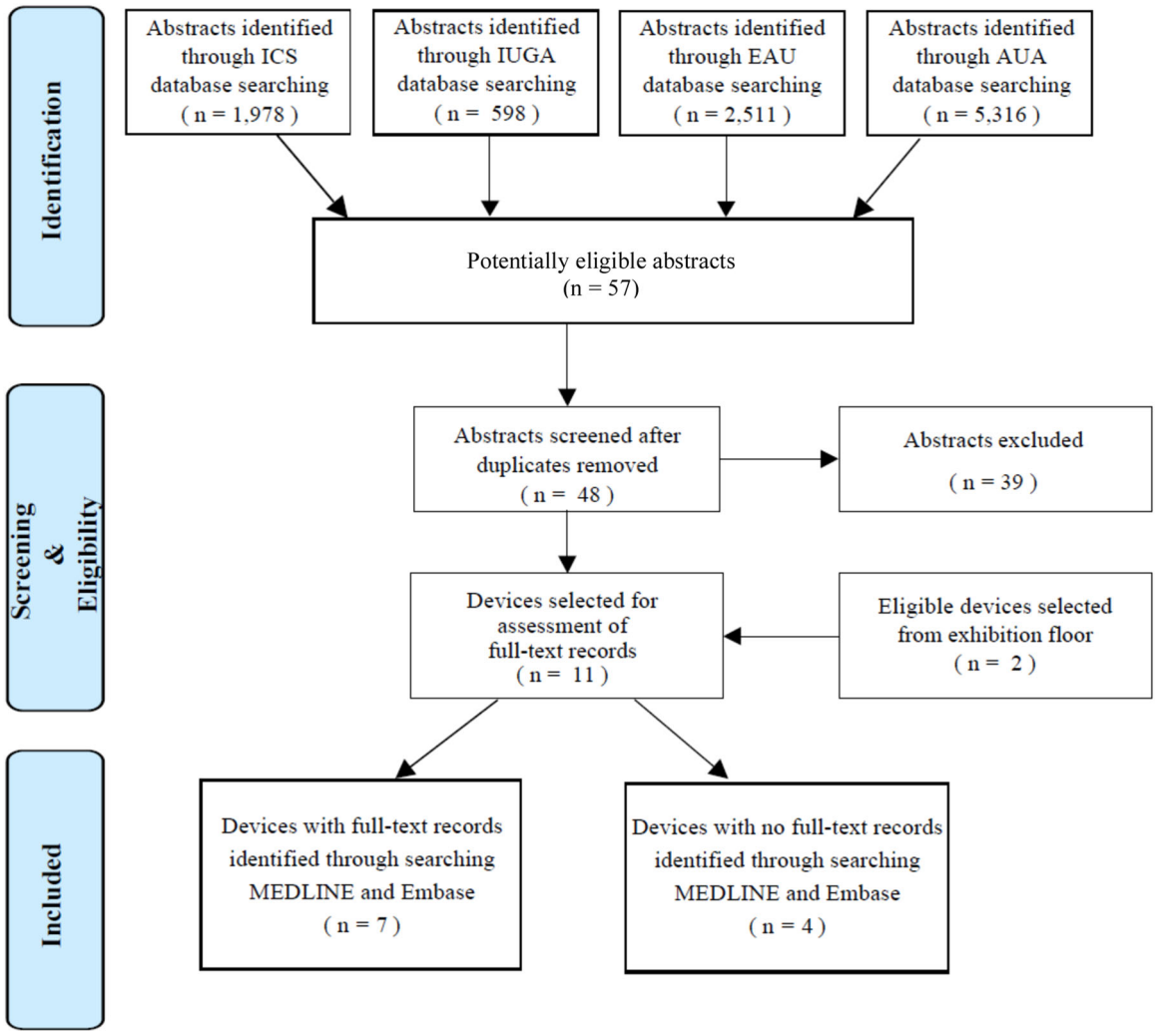

FIGURE 1 Summary of abstract search, screening for relevant devices, and identification of corresponding full-text records. AUA, American Urological Association; EAU, European Association of Urology; ICS, International Continence Society; IUGA, International Urogynecology Association

the devices. No full-text publications were available for the remaining four devices. The details of the devices are summarized in Table 1.

3.2 | Overview of the evidence for pelvic floor devices

In the following text, we present the evidence available from full-text records for each device. The devices are ranked by study design, according to the pyramid of evidence.

3.2.1 | The MAPLe device

This is an electromyography-electrode device that can provide functional electronic stimulation. It was developed for diagnostic and therapeutic use in patients with urinary incontinence (UI), fecal incontinence (FI), overactive bladder (OAB), pelvic organ prolapse (POP), and pelvic pain. One diagnostic study of 229 healthy volunteers published in 2013 determined the device's reliability.[14] The device was tested anally in men or vaginally and anally in women among four groups of volunteers. Test-retest reliability was performed on a random group of volunteers from all groups by calculating the intraclass correlation (ICC). Demographic data or other information from these volunteers was not described. The ICC was reported to be moderate (0.5-0.7) in six cases, good (0.7-0.9) in fourteen cases, and excellent (>0.9) in one case. However, no objective comparisons of the measurements were made against other commercially available probes because of reported differences in shapes and sizes.

In 2017, a randomized controlled trial was performed to assess the device for the treatment of OAB (n = 58).[15] The effectiveness of biofeedback-assisted pelvic muscle

TABLE 1 Summary of the identified devices: aims, usage, and available full-text records

Device	Condition	Diagnostic or therapeutic	Available for	Presented at	Abstract number	Full-text records
MAPLe	UI, FI, OAB, POP and pelvic pain	Both	Caregivers	ICS 2017	217	Reliability study[14] and RCT[15a]
Diveen	SUI	Therapeutic	Patients	Exhibition floor	–	Phase III trial[16]
VPT/VKD	SUI	Therapeutic	Patients	ICS 2016	259	Pilot study[17]
IncoStress	UI and POP	Therapeutic	Patients	ICS 2016	411	Pilot study[18]
Magneto Stym	UI, FI, and PP rehab	Therapeutic	Caregivers	Exhibition floor	–	Pilot study[19]
Peritron+	Voiding dysfunction	Diagnostic	NA	EAU 2017	1123	Diagnostic reliability study[20]
Pericoach	SUI, FI, and POP	Therapeutic	Patients	IUGA 2017	171	Case studies[21-23]
Elitone	SUI	Therapeutic	NA	ICS 2017	467	No full text
Elvie	SUI, SD, and PP rehab	Therapeutic	Patients	ICS 2016	211/213	No full text
Panasonic EU-JC70[b]	SUI	Therapeutic	Patients/ caregivers	ICS 2017	887	No full text
IVPSD	Unknown	Diagnostic	NA	ICS 2016	414/538	No full text

Abbreviations: EAU, European Association of Urology; FI, fecal incontinence; ICS, International Continence Society; IUGA, International Urogynecology Association; IVPSD, intravaginal pressure sensor device; MAPLe, Multiple Array Probe Leiden; NA, not yet available; OAB, overactive bladder; POP, pelvic organ prolapse; PP rehab, postpartum rehabilitation; SD, sexual dysfunction; SUI, stress urinary incontinence; UI, urinary incontinence; VPT/VKD, vibrance pelvic trainer/Vibrance Kegel device.

[a]The reliability study was diagnostic and the randomised controlled trial (RCT) was for treatment.

[b]Horseback-riding machine.

therapy with the MAPLe (intervention group) was compared against simple instructions on toilet behavior and lifestyle (control group) in women with OAB. The intervention group received weekly half-hour sessions by a pelvic floor therapist for nine consecutive weeks. Compared with the control group, the authors found significant improvements in the intervention group across several outcome measures, including the Pelvic Floor Inventories, the King's Health Questionnaire, 24-hour voiding diaries (urgency, $P = .008$), the daily use of pads ($P = .03$), and 24-hour pad tests.

3.2.2 | The Diveen device

This is an intravaginal, tampon-like device designed to treat stress UI by supporting the urethra and bladder neck. We found a single prospective randomized parallel-group trial from 2012 that compared the effectiveness of 2 weeks' treatment with an intravaginal tampon device against no treatment for women with stress UI (n = 55), using the Urinary Symptom Profile questionnaire.[16] The authors found a greater decrease in the primary outcome, incontinence episode frequency, in the treated group (mean −31.7%) than in the control group (mean −7.6%) in the intention-to-treat analysis ($P = .0023$). Mean symptom scores also decreased to a greater degree in the treated group compared with the untreated group for stress UI ($P = .0043$), OAB ($P = .016$), and dysuria ($P = .043$). There were no statistically significant differences in pad-test variations between both groups ($P = .4$).

3.2.3 | The Vibrance Kegel device

This is a T-shaped biofeedback tool intended for use in diagnosis and treatment of stress UI. The abstract reported on a randomized controlled trial conducted among 40 women with stress UI who were randomly divided into two groups. This abstract contained no updates from an earlier abstract presented in 2012[24] or a full-text article published in 2015.[17] In this study, one group received PFMT alone and the other group received PFMT with biofeedback from the Vibrance Kegel device. Both groups underwent 16 weeks of PFMT during which they were treated individually by a physiotherapist in monthly sessions lasting 20 minutes. Assessments were made at baseline, four, and 16 weeks, using the Australian pelvic floor questionnaires and the modified Oxford scales for pelvic floor muscle strength. Although the number of patients with improved pelvic muscle strength was significantly higher in the treatment group

after four ($P = .027$) and 16 weeks ($P = .003$) of continued therapy, no significant differences were observed in symptom scores or subjective cure rates at the end of the study.

3.2.4 | The IncoStress device

This is another intravaginal tampon-like device used to treat UI and POP. An abstract of a randomized pilot study that included 80 women were presented at ICS 2016 and was subsequently published as a full-text paper in 2018.[18] Women with different types of UI were randomized to a control group (receiving standard care and advice on pelvic floor exercises and/or bladder retraining) or to an intervention group (receiving usual care plus the use of the IncoStress device) in a 1:2 ratio. Disease-specific outcomes were assessed and compared between groups at 3- or 6-months follow-up. Median Incontinence Quality of Life scale score improved from 42.4 at baseline to 68.2 in pooled follow-up data in the intervention group and from 45.5 to 53.0 in the control group. Median Female LUTS Questionnaire score in the intervention group decreased from 14.5 to 12.5 and from 15.0 to 14.0 in the control group. However, because of the mixed-methods feasibility study design, presented data were incomplete and lacked formal statistical comparison, giving the results little weight.

3.2.5 | The Magneto Stym device

This is a chair used for functional magnetic stimulation in UI, FI, and postpartum rehabilitation. One preliminary study of 10 men and 10 women with UI was published as a full-text paper in 2018.[19] In this study, outcomes of urodynamic tests and three life-stress questionnaires were compared pretreatment and posttreatment. The authors reported significant improvements in cystometric capacity, maximum urethral closure pressure, urethral functional length, and pressure transmission ratio in patients undergoing twice-weekly treatment for 3 weeks. Median values in symptom scores on all three questionnaires also showed significant reductions after 3 weeks ($P < .01$). Unfortunately, there was no control or comparison group.

3.2.6 | The Peritron+ device

This handheld device is attached to urethral catheters to measure intravesical pressure. A diagnostic validation study of 10 patients with voiding dysfunction was presented at ICS 2017 and published as a full-text paper in 2018.[20] In this study, intravesical pressures were measured at three different bladder volumes (50, 100, and 200 mL) in supine and sitting positions and compared to standard urodynamics in adult female patients with a history of nonneurogenic (n = 9) or neurogenic (n = 1) OAB. The device was judged to be comparable to standard urodynamics when recorded intravesical pressure differences between both methods were no larger than 3 cmH_2O. For all measurements, the absolute difference in mean intravesical pressure values was within this limit. No statistically significant difference was found between measurements with standard urodynamic equipment and the Peritron+ device. However, there have been no clinical studies and it is not yet in the market.

3.2.7 | The Pericoach device

This is another intravaginal biofeedback device that is intended for the treatment of stress UI. We found three different case reports that described the device's benefits. The first reported improved quality of life, with decreasing scores on the Pelvic Floor Impact Questionnaire Short Form 7 after use.[21] The second reported decreased POP symptoms based on the Pelvic Floor Disability Index and POP-Distress Inventory scores.[22] The last-reported improvement in the Pelvic Floor Distress Inventory Short 20.[23] Abstracts were also presented in 2017, included one reporting a randomized controlled trial with 47 women and one reporting a trial with 51 women. In both abstracts, the efficacy of the device was evaluated over 20 weeks by comparing a control group who performed PFMT to an intervention group performing exercises using the device. Both abstracts reported improvements in different questionnaires. However, it was unclear whether these were two separate trials or two reports of the same ongoing trial. No full-text records of these trials were available.

3.2.8 | The Elitone device

This is a surface electrode device intended to treat stress UI that is purported to work through electrical muscle stimulation of the perineal region. An assessment of device usability was presented in an abstract at ICS 2017. Seven different waveforms of electrical stimulation with gradually increasing voltage were tested in eight women. The participants were asked to describe the first perception of initial muscle stimulation, the most comfortable level of pelvic floor muscle contraction, and the most comfortable waveform. Details of these were presented in the results, but we found no full-text publications. This device was not available for sale at the time of writing.

3.2.9 | The Elvie device

This intravaginal biofeedback device is intended for postpartum rehabilitation, stress UI, and sexual dysfunction. One abstract used data from a cohort of 1182 female users to assess the benefits of the device for research use. General conclusions were drawn from these data, such as the observation that childbirth significantly impacted pelvic floor strength and that this effect was attenuated with increasing age. In another abstract, authors reported a positive impact of the device on the frequency of PFMT based on data from a web survey completed by 417 users. To date, no full-text publications are available.

3.2.10 | The Panasonic EU-JC70 device

This is a horseback-riding fitness machine that aims to treat stress UI. Details of the device and its efficacy in a study of 24 women were presented in an abstract at ICS 2017. The authors reported that there were significant increases in vaginal squeeze pressure, as assessed by perineometer, and improvements in symptom scores after thirteen weeks of training in the intervention group compared to a control group. However, we found no full-text publications.

3.2.11 | The IVPSD

At the ICS 2016 meeting, an IVPSD (intravaginal pressure-sensing device) was presented in two separate abstracts. These abstracts describe bench and in vivo testing of this device in four women. The authors report the reliability and repeatability of the device for measuring vaginal pressure profiles at rest and during exercise. Again, however, there have been no full-text publications and the device has not been made commercially available.

4 | DISCUSSION

In this study, we aimed to give an overview of the evidence base for pelvic floor devices for women, as presented at scientific meetings in 2016 and 2017. Eleven devices, mainly intended for the treatment of UI, were presented at these meetings. Although we found full-text publications for seven devices, our searches yielded no such evidence for four of the devices.

The MAPLe device was supported with data from peer-reviewed journals. By contrast, the evidence for all other devices was, at best, limited. These findings are consistent with those of a systematic review from 2011, reporting that adding (bio)feedback to PFMT could have a beneficial effect in women with UI. However, the authors reported that risk of bias was high in most included trials and that further research was necessary.[11] A more recent systematic review on mechanical devices for UI in women found little to no evidence of effectiveness over no treatment,[9] supporting our findings that only a limited evidence base is provided for new pelvic floor devices.

Interestingly, despite there only being pilot studies or case studies in most cases, seven devices were commercially available for patients or caregivers at the time of writing. An explanation for this scarcity of evidence is that the requirements for medical devices tend to focus on safety rather than effectiveness. In Europe, medical devices can be marketed after receiving a Conformité Européenne (CE) mark, with different performance and reliability testing standards applied depending on the regulatory class assigned to a device. Similarly, in the United States, the Food and Drug Administration (FDA) applies different levels of control when assessing the safety and effectiveness of a new device depending on the regulatory class. If a new device is shown to be substantially equivalent to an existing legally marketed device, clinical tests of safety and effectiveness are usually unnecessary.[12] Although the FDA provides thorough guidance for medical devices intended to treat UI,[25] these are nonbinding. Given that many perineometers, electrical continence devices, and other vaginal devices are readily available in the market, new pelvic floor devices can receive FDA-approval or clearance by demonstrating substantial equivalence.

4.1 | Strengths and limitations

To the best of our knowledge, this is the first study to have explored the evidence base for medical devices presented at scientific meetings. However, the overview was incomplete because we limited the search to the scientific meetings of only four scientific societies in 2016 and 2017. We also acknowledge that we may have failed to identify publications submitted to scientific journals not covered by our searches, although we did try to explore the gray literature by extracting data from the manufacturers' websites. Also, we are unfortunately unaware of the number of users for each device and whether devices are reimbursed in different countries. Costs, either for patients or for the health care system, should ideally also be taken into account when applying these devices. Another weakness is the lack of a clear definition of what constitutes a pelvic floor device. Although eligible devices were discussed among the authors, no firm definition was agreed upon and the decisions were subjective. Nevertheless, this approach did allow us to perform manual searches of abstract

databases without being restricted to specific keywords. The major differences in device types, target conditions, and study designs meant that we could only rank devices by the level of evidence and could not provide comparative assessments. Moreover, there are no clear guidelines or gold standards for the evaluation of such devices; in future research, we must ensure that both are available to facilitate clinically relevant assessments of evidence quality. The lack of structured assessment of potential bias may also be considered a weakness, but given that our main finding was that there is a paucity of evidence in peer-reviewed publications, adding such assessment would probably have added little.

5 | CONCLUSION

Despite the clear limitations of this study, we showed that there is a lack of evidence for most of the devices presented in abstracts at scientific meetings. Nearly all devices presented in this overview lacked future supporting data from full validation or clinical studies. We found that our work, therefore, raised several important questions that went beyond the scope of the overview, and to which we are unable to offer meaningful answers. For example, do the CE and FDA systems offer routes by which medical companies can circumvent the rigor of peer review? Are abstract presentations that receive no further formal follow-up a way of gaining a degree of undeserved scientific validity, or are they simply an effective way to present data that might not otherwise be published? Although performing trials and publishing the results in peer-reviewed journals may be costly, time-consuming, and may fail to deliver the desired outcomes, only by thorough evaluation can we ensure the delivery of good clinical care. We believe that overviews such as this offer a means by which the wider scientific community can monitor the scientific merit of devices. In the long term, however, better regulatory mechanisms are needed.

ACKNOWLEDGMENT

We thank Dr. Robert Sykes (www.doctored.org.uk) for providing editorial services.

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How to cite this article: te Brummelstroete GH, Loohuis AM, Wessels NJ, Westers HC, van Summeren JJGT, Blanker MH. Scientific evidence for pelvic floor devices presented at conferences: An overview. *Neurourology and Urodynamics*. 2019;38:1958-1965. https://doi.org/10.1002/nau.24099