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EQUIPMENT REVIEW

Handheld biofeedback devices to enhance pelvic floor muscle training

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Abstract
In recent years, there has been an increase in the number and variety of devices that utilize biofeedback to monitor pelvic floor muscle (PFM) function, and as an adjunct to PFM training. The goal of this paper is to provide an overview of the handheld biofeedback units that are available in the UK. This subgroup is of particular interest because of the relatively low prices of such devices, and the wide availability of these to the public for direct purchase and home use. The author offers her personal analysis of and insights into the modes of operation, points of difference and clinical applications of these units. Research and development in this field is discussed, and reflections on how POGP members might continue to lead in the use of this modality are presented.

Keywords: biofeedback, medical devices, pelvic floor muscle training.

Introduction

Background

A perineometer is defined as "an instrument which measures the strength of contractions of the vaginal muscles" (Merriam-Webster 2020).

It has been 70 years since the American gynaecologist Dr Arnold Kegel described the use of a perineometer to measure and treat pelvic floor dysfunction in women (Kegel 1951). Professor Linda Cardozo, our organization's previous president, and Professors Paul Abrams and Stuart Stanton, her well-known colleagues, were early pioneers who explored its impact on detrusor instability (Cardozo *et al*. 1978). The Bristol women's health physiotherapy team described a "new" perineometer for the treatment of genuine stress urinary incontinence (UI) in the early 1980s (Shepherd *et al*. 1983).

Use of biofeedback in clinical practice

A skilled physiotherapist relies on her excellent assessment, teaching and motivational skills to coach patients on how to attain an improvement in pelvic floor muscle (PFM) function. In most cases, no equipment is needed to bring about a positive change.

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Within a clinic, biofeedback is a modality that is used to understand, identify and quantify dysfunction. Both in the clinic and at home, it is also a tool employed to enhance patient awareness of muscle position and function, effort during PFM training (PFMT), and the importance of adherence to a training programme over time (Herderschee *et al*. 2013).

Recently published results of the 24-month OPAL [Optimizing PFMT for Adherence Long term] trial (Hagen *et al.* 2020) found no evidence of any important difference in the severity of UI between the PFMT plus electromyographic biofeedback and PFMT alone groups. These results support the most recent National Institute for Health and Care Excellence (NICE) guidelines (NICE 2019) for the non-surgical management of UI and pelvic organ prolapse in women, which state that that routine use of electromyographic biofeedback with PFMT should not be recommended:

> "Do not use perineometry or pelvic floor electromyography as biofeedback as a routine part of pelvic floor muscle training." (NICE 2019, p. 14)

> "Electrical stimulation and/or biofeedback should be considered for women who cannot actively contract pelvic floor muscles to aid

> motivation and adherence to therapy." (NICE 2019, p. 15)

However, while there is multidisciplinary recognition that the first-line treatment for women with stress or mixed UI should be a trial of supervised PFMT of at least 3 months in duration (NICE 2019), there is now the need to deliver this gold standard of care in a world that limits face-to-face contact with patients as a result of overwhelming patient caseloads and pandemic-related restrictions. Nevertheless, physiotherapists may still wish to utilize biofeedback in clinical practice for bespoke patient needs in clinically reasoned circumstances.

Aims and objectives

The present review is intended as a pragmatic overview of the current products and devices that are available in the UK. It is intended to complement a review of neuromuscular electrical stimulation (NMES) units that was published in this journal 2 years ago (Savage 2019), but is not to be taken as a good practice statement.

In the context of pelvic health physiotherapy, biofeedback can range from the extremely simple approach of placing the patient's own finger into the vagina or anus, or the ubiquitous Educator stick (Neen Educator Pelvic Floor Exercise Indicator, Performance Health International Ltd, Huthwaite, Sutton-in-Ashfield, Nottinghamshire, UK), to the use of: vaginal balloon devices to provide manometric biofeedback; vaginal or anal electrodes to pick up electromyographic signals from the muscles; Bluetooth devices incorporating patented force sensors; or ultrasound visualization of the pelvic organs by means of abdominal, vaginal or anal transducers.

The present review does not cover the ultrasound options, or extend to the larger fixed biofeedback units. Ultrasound is widely used in pelvic health research and clinics, but there is not yet a home-use option available for patients. Fixed biofeedback units have been a feature of UK physiotherapy departments for some time, and are also used as a treatment modality for bladder and bowel disorders by occupational therapists in the USA. It is hoped that another POGP member might undertake a similar review of these alternative, clinic-based options in the near future.

This review will cover only the subgroup of handheld biofeedback units that are commonly used to enhance PFMT. These are of particular interest because of the relatively low prices of such devices, and their wide availability to the public for direct purchase and home use.

The products discussed below are not the only ones available, but those that the present author was able to obtain to trial within the time constraints of this project

Table 1 compares units in terms of a variety of categories: the mechanism of action, i.e. mechanical, electromyography (EMG), manometry or other sensor system; the type of feedback the user will receive, i.e. visual, auditory or vibrational; whether these can be used during pregnancy; operation by cables or Bluetooth; and the ability to be utilized in a telehealth capacity through remote data collection and clinical integration software. The prices of the units are also listed.

The following sections provide brief impressions of each device. These notes are based on the present author's personal observations, clinical reflections and user experiences, and are an attempt to give each device that she had access to due consideration. The intention is to help readers to think more deeply and critically about the available options when they make choices or recommendations both for their own and their patients' needs.

A review by the present author of the process of CE marking and regulation of medical devices, the Chartered Society of Physiotherapy (CSP) quality assurance standards (CSP 2013), UK advertising standards (ASA 2018), and the safety regulations (MHRA 2018) regarding medical devices in the UK may be a helpful companion piece (Savage 2018). An overview of how clinicians can and should work alongside medical device companies to develop products for patients is also useful (Gordon 2019).

It is understandable that physiotherapists can feel nervous about giving advice or making recommendations about equipment. However, the CSP quality assurance standards recognize that giving advice about products is a holistic part of what it means to be a physiotherapist (CSP 2013), and as discussed previously, physiotherapists are ideally skilled to offer unbiased, clinically reasoned advice to the general public (Savage 2018).

Traditional biofeedback devices

Mechanical

The simplest and cheapest device is the Neen Educator Pelvic Floor Exercise Indicator (Fig. 1). The inert white plastic body is small and solid,

Table 1. Characteristics of the handheld biofeedback devices: (N/A) not applicable; (EMG) electromyography; (LCD) liquid crystal display; (PC) personal computer; (NMES) neuromuscular electrical stimulation; (ETS) EMG-triggered stimulation; (RCT) randomized controlled trial; and (PFMT) pelvic floor muscle training

Device	Type of feedback	Single- or multiple-user capacity	Training programme for user to follow	Strengths	Notes	Wireless option	Telehealth capabilities	Use during pregnancy	Research	Additional functionality	Price	UK supplier
Mechanical												
Neen Educator Pelvic Floor Exercise Indicator	Visual/mechanical	Single-user vaginal device	No	Cheap, "find and feel"		N/A	N/A	No			£10.99	Multiple distributors
Neen Periform+ (used with indicator stick)	Visual/mechanical	As above	No	Cheap, "find & feel"	Used alone, no measurements, but also compatible with EMG biofeedback devices	N/A	N/A	No		Compatible with EMG biofeedback devices	£17.99	Multiple distributors
Manometry												
PFX/Peritron	Visual, simple dial	Multiple-user capacity for with detachable sensor	No	Medical-grade silicone elastomer anal and vaginal sensors available	Units no longer manufactured, but replacement sensors still available	No	No	Unknown			£73.00 (anal sensor)	Win Health Medical Ltd
Kegel8 Biofeedback Pelvic Trainer	Visual, LCD of rising and falling bar chart	As above	Audio-guided training programme, not customizable	Simple concept, small sensor, clear instruction booklet, patient-focused "scoring" system	"[W]ith normal use[,] probe should last around 6 weeks", latex-covered sensor	No	No	Instructions tell patients: "do not use during pregnancy unless directed by a doctor"			£94.99 (including VAT) replacement sensors £14.99	Kegel8
iEase Pelvic Floor Muscle Exerciser with On-Screen Biofeedback	As above	Single-user device, replacement sensors not offered	As above	As above, except uncertain about instruction booklet provided	Identical to the cheaper Kegel8 Biofeedback Pelvic Trainer	No	N/A	As above			£190.00	NineLife
Epi-No Delphine Plus	Visual, simple dial	Single-user vaginal device	Instruction booklet only, short video on website	Licenced for use during pregnancy and 5-year shelf life	Dual functionality for antenatal perineal stretching	No	No	Licensed for use during pregnancy	UK distributor reports that she has spent 6 years trying to find a group to engage in research using this device with frequent false starts	Serves as a birth trainer to stretch perineal tissues	£99.99	Epi-No UK Ltd (owned by Teresa Gernon)
evoStim P	Visual and auditory	Multiple-user capacity using compatible vaginal or anal balloon probes	Customizable guided training programme of work–rest trials for user to follow	Comes with a vaginal balloon probe with electrodes enabling dual functionality for biofeedback and NMES, 25–35 mm in diameter	Compatible with medical balloon probes	No	No	Limited by electrode choice		Serves as an NMES device with an appropriate vaginal electrode	£262.80	Win Health Medical Ltd and Kegel8
EMG only												
NeuroTrac Simplex	Visual (coloured lights) and auditory (beeps), above or below threshold option	Multiple-user capacity, compatible with electrodes with pigtail connectors*	As above	Useful belt clip and auditory feedback for "hands-free" functional training (e.g. in standing)	Manufacturer's instructions very difficult for a patient to follow, available to hire from de Smit Medical (www.desmitmedical.com)	No	No	Limited by electrode choice		PC Software (free) expands data collection, larger screen view	£238.00	Several distributors
Neen Peritone	As above	As above				N/A	N/A	As above			£214.99	Several distributors
Nu-Tek Maxi Plus 1	Visual (bar chart or line graph) and auditory	As above	As above	Colour LCD, choice of bar chart or line graph	Manufacturer's instructions very difficult for a patient to follow, audio cue is spoken word, can be changed to French, Dutch, Spanish or Italian	No	Potential for some remote functionality with purchase of additional software	As above		PC software (approximately £200)	£126.50	Win Health Medical Ltd

EMG with NMES												
NeuroTrac Myoplus Pro	Visual and auditory	As above	Customizable guided training programmes, choice of line graphs, bar charts and animated games.	Animated games	Intuitive touch screen, PC software (free) expands data collection and storage, and enables a larger monitor to be used	No	Yes	As above		NMES and ETS	£416.99	Several distributors
Nu-Tek Levator Elite	Visual and auditory	As above	Customizable programmes, same as Nu-Tek Maxi Plus 1	Consistent interface for all models in the Nu-Tek range makes operation easy	Manufacturer's instructions very difficult for a patient to follow, PC Software (£200) expands data collection and storage, and enables a larger monitor to be used	No	Potential for some remote functionality with purchase of additional software	As above		NMES and ETS	£264.00	Win Health Medical Ltd
Pelvic floor trainers												
Elvie Trainer	Visual on smartphone app	Single-user vaginal device	Guided training through gem games, strength and endurance skills, automated progression in response to performance	Petite device, cosmetically appealing, award-winning design elements	Scores in "LVs", no clinical interaction with device, patient-facing, keep antenna in line with phone	No wires, connects with smart phone app via Bluetooth	No	Yes	Various trials of the technology and effectiveness during the development stage		£169.00	Several distributors
Vibrance Pelvic Trainer	Sensory, vibration	As above	Guided training, audible cues to follow contract–relax cycles	Most petite device, no phone app required	Instruction to perform two sets of 50 clenches twice a day could encourage overuse, difficult to keep in place even supine, also functions as a mechanical resistance training device by adding plastic sleeves	N/A	N/A					
KegelSmart	No information to patient	As above	Vibrations tell user when to squeeze	Discreet, simple trainer	Automated progression of training programme number, or repetitions and endurance in response to performance, guided trainer only, not a biofeedback device	No wires	No	Instructions state: "pregnant women should check with their doctor"	Short report of an RCT of the device as an adjunct to PFMT		£140.00	iMEDicare UK Ltd
Telehealth biofeedback devices												
kGoal/PelviFly (manometry)	Visual, all animated "games" (e.g. butterflies, rockets and balls, rather than graphs), and sensory (vibration) on smartphone app	As above	Basic plan, three to five times per week, preset challenges and monthly test, with telehealth package multiple customizable options for assessment and training	Entertaining animated games change the experience from a clinical one to a patient talking point, strong emphasis on telehealth services	Glitchy connectivity with iPhone, kGoal is one of the larger vaginal sensors, can also be used for vibration therapy (distinct to feedback), training course for clinicians, subscription model	No wires, connects with smart phone app via Bluetooth	Extensive: integrated hardware, smartphone app, real-time data transfer, clinic portal for data storage and management, automated media communications to user (e.g. reminders) and chat facility	Website states: "we don't recommend using kGoal during the first trimester, after the bag of waters has opened, or for the first 6 weeks after delivery"	Various trials of the technology and telehealth effectiveness during the development stage		£189 with basic plan, UK subscription model for telehealth capacity being developed	Pioneer Medical Europe Ltd
PeriCoach (force sensors)	Visual, line graphs following templates, with audible cues on smartphone app	As above	Twice daily preset challenges, training programmes fully customizable by clinician once telehealth portals set up	Clear, intuitive visual (and audio) feedback in classic graph format	Little variety of feedback, graphs only, no further costs after purchase	As above	Integrated hardware, smartphone app, real-time data transfer, clinic portal for data storage and management, and direct communication with the user	Website states: "The PeriCoach is safe to use during a normal pregnancy as it does not deliver any energy into the body"	As above		£145.00	Several distributors

*Compatible with all vaginal stimulation probes with connector leads fitted with universal 2-mm female sockets, i.e. pigtails (e.g. the Periform Plus, Neen Anuform and Nu-Tek vaginal probes), and nickel-free vaginal probes with gold-plated electrodes (i.e. the Kegel 8 Glide, Perisize4, Optima3, Minima, Novatys, Classica and all Perisphera vaginal probes).

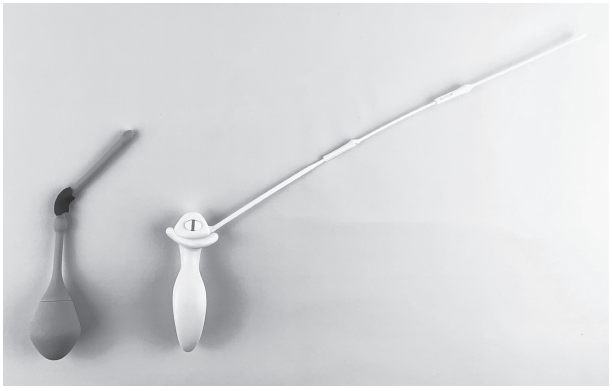

Figure 1. (Left to right) The Kegel8 Vaginal Cone and Neen Educator Pelvic Floor Exercise Indicator.

and some dexterity is required to attach and maintain the position of the indicator stick during insertion. The movement of the stick is not extensive, but the way in which it moves is sufficient to let patients know when they have performed a correct PFM contraction. No measurement is involved. Patients can be directed to perform their prescribed PFMT with the Educator in place. Visual cues will allow them to see broadly whether they are maintaining a contraction and/or creating a precontraction before a rise in intra-abdominal pressure. This device can be successfully used when lying or standing. The Educator stick has been used as a relatively inexpensive "take home to find and feel" tool for many years, but there does not appear to have been any further development in the product or use in clinical trials. Widely available, it gets four stars on Amazon.co.uk. Although the stick is long, it can be difficult to see it over an ample bust or protruding abdomen. (N.B. Its cousin is the EMG/NMES-compatible Neen Periform+ sensor, which was designed and developed by POGP leading light Jo Laycock, and comes with an indicator stick included.)

At one time, Kegel8 promoted the use of their lightest vaginal cone (Fig. 1) as a so-called "indicator wand" because its unique design also allows a compatible indicator functionality. However, although this device is still available as part of a pack of three vaginal weights (Kegel8 Vaginal Cones, Savantini Ltd, Kingston upon Hull, UK), it is no longer marketed or sold separately in this way because the manufacturer found that consumers were confused. Nevertheless, if a patient already has a set of Kegel8 cones, this could be a useful feature to highlight.

Manometry

Simple manometry devices offer the next-lowest prices and basic exercise options.

Many departments may still have the PFX (Laborie Medical Technologies, ULC, Mississauga, Ontario, Canada) or Peritron perineometers (Cardio Design Pty Ltd, Oakleigh, Victoria, Australia). These products offered interchangeable latex-free vaginal and anal sensors. Manufacture of these units ceased approximately a year ago, but the UK distributor (Win Health Medical Ltd, Jedburgh, UK) still offers replacement sensors, and these will still be produced for a few more years.

Both cosmetically and functionally, the Kegel8 Biofeedback Pelvic Trainer (Savantini Ltd**)** updates the basic manometer concept (Fig. 2). The latex-coated vaginal probe is relatively small, and can be disconnected from the handheld unit. The sensors can be purchased separately, which allows several individuals to use the same device. The instruction manual has clear, picture-led, patient-facing instructions. The large, liquid-crystal display (LCD) shows pressure activity by means of a simple bar graph. There is a guided programme of the ubiquitous "fast" and "slow" patterns of PFMT, and clear beeps indicate when to squeeze and relax. The unit generates a "score", and changes the pattern presented at the next session depending on this mark. As such, it serves as a useful pelvic trainer device as well as a simple biofeedback unit.

It should be noted that the Bia iEase Pelvic Floor Muscle Exerciser with On-Screen Biofeedback (Bia Health, Toronto, Ontario, Canada) appears to be an identical item for twice the price.

The Epi-No Delphine Plus (Epi-No UK Ltd, Northampton, UK) was designed and is primarily marketed as a third-trimester perineal stretching tool, and has a patented waist for this purpose (Fig. 2). However, as one of the few products licenced for use during pregnancy, it has dual functionality as a basic manometer and PFMT tool. The pressure sensor cannot be detached,

Figure 2. (Left to right) The Kegel8 Biofeedback Pelvic Trainer, Epi-No Delphine Plus and evoStim P.

making this a single-user device. However, with a suggested shelf-life of 5 years, these units seem to be bought directly and extensively by antenatal women, and the owner of the company takes pride in the fact that she has a gallery of "vaginismus" babies (T. Gernon, personal communication).

Clinicians who want a more sophisticated manometry device should explore the deceptively titled evoStim P (BeacMed SRL, Portalbera, Italy), a battery-operated handheld unit that offers dual functionality as both a biofeedback gauge and an NMES unit (Fig. 2). The interchangeable vaginal and anal balloon probes are made of medical-grade silicone. The product also comes with a vaginal balloon probe that is equipped with ring electrodes to allow for a seamless transition between the biofeedback and NMES functions. The instruction booklet is reasonably clear, and there is a user-friendly interface. The detected pressure value is not presented numerically, but rather, displayed on an LCD as a series of concentric circles or a linear bar graph. The goal for the user is to activate all 20 circles of the target, including the central one, or all 40 segments of the linear bar graph. Baseline contractions zero the feedback and calibrate the target. There is also an audible feedback signal. The preset work–rest patterns are programmed for a 30-min exercise cycle, but all the parameters can be customized. The evoStim P does not offer any personal computer (PC) software, but this handheld unit is large enough that you could view the screen alongside a patient.

Electromyography-only units

The Neen Peritone (Performance Health International Ltd) and NeuroTrac Simplex (Verity Medical Ltd, Braishfield, Hampshire, UK) are almost identical (Fig. 3). These devices have been available for over 20 years.

Both visual and auditory biofeedback are provided, and users can watch numerical readouts in millivolts. More useful, especially for those who struggle with small screens, are the bright lights that cross the front of the units diagonally. These change from orange to green as a threshold is crossed. This can be set automatically by a preworkout contraction or manually by the therapist, and then locked in place.

A device with very similar features, the Nu-Tek Maxi-Plus 1 [Nu-Tek (Hong Kong) Ltd, Hong Kong, China], retails at a compatible, and at present, notably cheaper price (Fig. 3). The colour LCD offers numerical readouts and also either

Figure 3. (Left to right) The Nu-Tek Maxi Plus 1, Nu-Tek Levator Elite, NeuroTrac Simplex and NeuroTrac Myoplus Pro with examples of the required accessories.

bar charts or line graphs depending on the mode chosen (i.e. patient or therapist, respectively).

These EMG-only units connect with wires to any of the large selection of vaginal and anal probes with "pigtail" connecting cables that are available on the market.

When initially switched on, these battery-powered, handheld EMG units can be used for "free-flow" EMG biofeedback, which allows the user to take as much time as needed to explore the required skills. A guided exercise programme involving a single work–rest pattern runs after the user presses the "START" button. Although the programme is preset to a 5-s work, 5-s rest cycle that is repeated five times, clinicians can change the parameters, but not mix the pattern. The guided programme on the NeuroTrac Simplex and Neen Peritone units is led by a rather subtle system of beeps. The voice commands issued by the Nu-Tek Maxi-Plus 1 are significantly clearer, and available in four European languages.

All three devices also offer auditory feedback that is ideal for aural learners and the visually impaired. Users can focus on maintaining regular beeps above the threshold, or for down-training, below it. The present author finds the auditory feedback option provided by the units in her clinic particularly beneficial for training patients to do functional movements. This is because the handheld unit can be put to one side on the stand included with it (within the limit of cable length), allowing users to practice standing/lunging and other functional movements. The NeuroTrac Simplex and Neen Peritone have belt clips, and clothes can be worn while using these devices.

Considered as patient-facing products, these EMG units are simple to use, robust, versatile,

and an ideal way to enhance both foundational and functional PFMT in the home setting. However, the devices do look and feel clunky, and have a lot of wires compared to modern personal trainers (see below). Furthermore, the manufacturers' instruction booklets are from a bygone era of impenetrable technical specifications, complex tables and tiny fonts! Patients will certainly benefit from your support while trying to understand these products, and learning how to achieve optimal usage. Clinicians themselves may need to allocate some time to getting to grips with the instructions while *not* being watched by a patient!

Software can link the units to a PC in order to store data and access relatively limited further training templates, but this is not compatible with Mac systems. The licences for the NeuroTrac Simplex and Nu-Tek Maxi-Plus 1 are free and approximately £200, respectively. Neither company has updated their software packages recently. These are awkward to download, and again, because of archaic instructions, will take some time to understand. However, this could equip a department with both patient-facing and clinician-friendly EMG biofeedback at relatively little cost in comparison to a traditional fixed unit. The respective software licences also work with the other, higher-level models in each range (see below).

Combined EMG/stimulation units

At an understandably higher price point, both the NeuroTrac and Nu-Tek ranges offer combined EMG/NMES or EMG-triggered stimulation (ETS) devices: the NeuroTrac MyoPlus Pro (Verity Medical Ltd); and the Nu-Tek Levator Elite [Nu-Tek (Hong Kong) Ltd] (Fig. 3). These products are compatible with the same software licences.

As with the manometric evoStim P (see Fig. 2 above), this form of dual functionality could be particularly helpful when a patient is very weak, or prone to overusing accessory muscles as she fatigues. In such instances, the clinician could move the patient seamlessly from NMES to biofeedback to NMES again, and with the same versatility of electrode choice as described previously.

Although the NeuroTrac MyoPlus Pro does not have as familiar an interface as the NeuroTrac Simplex, the instructions are clear, and straightforward touch-screen menus make it easy to navigate intuitively. Even as a stand-alone unit without the addition of the free optional software, this device offers the user considerably more EMG choices. There is a selection of openly displayed work–rest patterns, various preset and customizable templates, and "games". An early example of the "gamification" of biofeedback training, the NeuroTrac MyoPlus Pro offers: rabbits that run up and fall down hills; a plane to fly over mountains; and a flower that opens and closes. Although the visual concepts may feel a little childish, these are curiously compelling. There is a specific programme for downtraining, the rose relaxation game, which shows: microvolts numerically and as a real-time bar chart on one side of the screen; and a large flower with petals that open and close, and the words "stay relaxed" on the other.

The EMG functionality of the Nu-Tek Maxi-Plus 1 and the Nu-Tek Levator Elite models is exactly the same; the latter is literally a combined unit. Patients who learn to use one of these devices will need only minimal further knowledge/technical ability to use the other. A patient working with a PC-driven Nu-Tek Levator Elite unit in the clinic could then use the simpler and cheaper EMG, and/or the standalone Nu-Tek Maxi-Plus 1 model, for consistent home use with a familiar interface. The Nu-Tek software offers some basic telehealth functionality by enabling the transfer of data between a clinic and a home user via a smartphone, but the present author was unable to test this.

As previously mentioned, the clinical capacity of both of these small combined EMG/NMES units is further increased by Bluetooth connection to compatible software. The software packages offer data collection and storage, and clinical reports, as well as the more obvious benefit of the patient and clinician being able to view the biofeedback on a larger shared screen during a rehabilitation session in the clinic.

For a standard clinic that is not involved in research and does not deal with enormous numbers of clients, the functionality of either of these units could be on a par with the vastly more expensive fixed-unit options.

Pelvic trainers

The Autumn 2016 edition of this journal (No. 119) featured detailed product reviews of a range of single-user pelvic trainers, i.e. the KegelSmart (Burke 2016), Elvie (Igualada-Martinez 2016), PeriCoach (Nellist 2016) and kGoal (Wolujewicz 2016). This section offers updates on these devices.

Elvie Trainer

Five years ago, the Elvie Trainer (Chiaro Technology Ltd, London, UK) was a market leader in Bluetooth technology and smartphone compatibility (Fig. 4). It stood out then as a product that had been designed from the ground up as a female-focused solution to real-world needs, and still does now. Dr Kay Crotty consulted on the initial development, and other POGP members have been involved in subsequent research and development projects.

Although often described as expensive when it was first launched, it is notable that the cost of the Elvie Trainer has barely changed (then £149, now £169). All such patient-facing products are now similarly priced, and compatible with the other modern wearable devices that we take for granted, such as fitness trackers and watches. In theory, as with some other continence devices, it is now available on the National Health Service, but social media discussions with POGP members suggest that these units remain hard for patients to access.

Elvie uses patented technology, a force-sensitive resistor with a tri-axial accelerometer, to deliver real-time information about both muscular force and direction, respectively. The instruction booklet is tiny, but all the information is replicated and animated on the clear website (www.elvie.com/support/elvie-trainer). The internal "pebble" is smooth, easily washable, petite (with an optional extra cover to make it larger), and easy to place correctly because the Bluetooth antenna remains external. An Internet connection is needed to set up the free app, but thereafter, it operates via Bluetooth.

This is, as intended, a patient-facing rather than clinical device. The feedback is purely visual: a pale-green "gem" moves in response to contraction and relaxation of the pelvic floor. The user is given a series of sequential tasks that physiotherapists will recognize as a mix of maximal contractions, endurance holds, quick-response activities and tests of muscle strength. A woman working with an Elvie Trainer will be given an alert if she is bearing down when training, and advised to seek a full assessment. The progression through exercises is entirely automated by the device, so the user cannot choose the exercises.

A pilot study by POGP member Sinéad McCarthy found a positive correlation between the known inter- and intra-rater reliability of data derived from real-time transperineal ultrasound and the Elvie Trainer in a small sample of asymptomatic adult women (McCarthy & Khan 2017). This research established the latter device's ability to identify a correct contraction or incorrect Valsalva manoeuvre.

Figure 4. (Left to right) The Elvie Trainer, KegelSmart, Vibrance Pelvic Trainer, PeriCoach and kGoal/PelviFly.

The present author contacted the manufacturer, Chiaro Technology Ltd, about developments over the past 4 years. There have been no major changes in the device itself or any further clinical studies. However, changes to the app (e.g. improving the connection speed, updating the exercises to include difference versions for increased variety as users progress through the levels, new languages and in-app support) have been directly informed by the usual commercial product research and development channels, such as user feedback, reports from customer care teams about common problems/questions and proactive market research. Customer support appears to be swift, and reviews throughout social media remain positive.

KegelSmart

Like the previous reviewer (Burke 2016), the present author found the biofeedback element of the KegelSmart device (Intimina, Stockholm, Sweden) (Fig. 4) to be minimal. The product vibrates to tell the patient when to contract and then when to release, which is effectively a vibration-led guided programme. It does not vibrate in response to the user's activity. The manufacturer claims that the KegelSmart is designed to measure the strength of a contraction, and then automatically adjust the work–rest pattern from levels 1 to 5. However, this measurement information is not made available to the user or the clinician, and neither is any data about the changes in the patterns. The similar look but lower cost of the KegelSmart to the

Elvie Trainer, may lead some purchasers to think, as the present author originally did, that they are buying a cheaper version of the same sort of unit. The KegelSmart could be useful as a mid-priced "find and feel" product, or perhaps, for "follow through" as a device that a patient could work with discreetly to regularly perform a guided PFMT session.

Vibrance Pelvic Trainer

This product (Fig. 4) has been available for as long as those featured in the journal 5 years ago (Burke 2016; Igualada-Martinez 2016; Nellist 2016; Wolujewicz 2016). The Vibrance Pelvic Trainer [Bioinfinity (M) Sdn Bhd, Kuala Lumpur, Malaysia] could be described as the converse of the KegelSmart. The device emits a beep to tell the user when to perform a contraction, and then vibrates in response to this. The sensor head is the most petite of all the devices reviewed, which may be its most useful clinical feature if a non-intimidating sensor is required. It is very easy to make the Vibrance Pelvic Trainer vibrate in your hand, but even as an experienced pelvic floor exerciser, the present author struggled to get a consistent response unless she physically held the device in contact with her posterior vaginal wall. It would be very easy to resort to overactivity in an attempt to make the unit work. The Vibrance Pelvic Trainer is top-heavy, and therefore, inclined to tilt up and difficult to retain in standing. There is no visual feedback or data collection. Progression is by adding "stiffness" to the device with plastic sleeves, so that a "stronger" contraction is required to activate the vibration response. Like the KegelSmart, it should be classified as a "guided trainer" rather than a clinically useful biofeedback tool. As with the KegelSmart, if a patient had already bought one, the present author would work with her to utilize the Vibrance Pelvic Trainer's value as a tool for exercise adherence and motivation.

Telehealth biofeedback devices

Although directly available to the public, the newest telehealth biofeedback products are not intended to be used as standalone devices. These are not comparable with the pelvic trainers discussed above, and are capable of far more than the latter. The units described below were developed by biomedical engineers and physiotherapists, who collaborated in order to create telehealth/e-health solutions for pelvic floor issues.

PeriCoach

Although the website dedicated to the PeriCoach Kegel exerciser (www.pericoach.com) has a US bias, this is an Australian-led product (Analytica Ltd, Brisbane, Australia) (Fig. 4). It was built from the ground up by a female-led engineering team, who worked in close collaboration with Australian women's health physiotherapists and medics. The system has undergone prototype development, testing and clinical trials.

The internal device is purchased for a one-off fee, and there is also a free Bluetooth-connected smartphone app. The elegant pale-blue probe utilizes patented sensors to measure both the force and direction of a PFM contraction. The PeriCoach comes with a discreet case that also charges the device.

The user is asked to perform calibrating strength tests, and then given automatically generated templates to follow. Real-time auditory and visual feedback in the form of coloured line graphs is provided. The reactivity is sharp and use intuitive, although the measurements and data given are rather hard for patients to understand. The templates follow typical automatically progressed "quick" and "slow" patterns, which may feel a little lacking in variety in the long term, but equally, make for a pleasantly unfussy and useful tool. A patient is typically given 3–5 min of exercises to perform daily. The interfaces throughout the website, app and portals are softly coloured, clear and professional in appearance. Features such as a bladder diary and pad record are a little clunky, but useful add-ons.

The user can set up an online portal in order to view her saved data. She can also authorize her physiotherapist to view and interact with her progress via a compatible portal for clinicians. Healthcare professionals signing up to the PeriCoach platform can choose to have a public profile, which will allow them to be found by the general public, or opt to have only private interactions with specified patients. With portal access, a physiotherapist can view and change a patient's exercise programmes remotely, and also send messages to support adherence or arrange appointments. Clinicians are provided with the functionality and connection for free, and can purchase devices on a wholesale basis. The manufacturer suggests that healthcare professionals could provide their patients with a programme of treatment, and they can tailor this however they like. Such a programme includes the purchase of the device itself, and subsequent telephone portal

consultations and a clinic appointment. Upgrades to the PeriCoach are offered to active users for free, and Version 3 is the current one. According to the manufacturer, it has a replacement life of 2 years, but it has been known to last for longer.

kGoal/PelviFly

When it was first reviewed in this journal (Wolujewicz 2016), the kGoal (Minna Life, Inc., San Francisco, CA, USA) was a simple, standalone manometry device (Fig. 4) with a Bluetooth connection to a smartphone app. This provided a similar patient-facing experience to the Elvie Trainer. Since then, the biological engineering team who developed the device at Stanford University, Stanford, CA, USA, have collaborated with a Polish physiotherapy-led research group specializing in telehealth for PFMT, and relaunched it as PelviFly, a software-as-a-service product. The use of both names at present can be a little confusing.

The bright-blue kGoal internal probe is the largest of the vaginal devices described in the present review. Its size makes insertion trickier, but retention easier, than some of the more petite devices covered here. The probe is deflated to insert, and then a rather fiddly valve button is pressed to inflate it *in situ* and allow the device to recalibrate for each use. It charges with a USB connector. There do seem to be some connectivity issues to the iPhone because the product has predominantly been developed to serve the European Android smartphone market.

The visual biofeedback of the kGoal/PelviFly stands out because of its innovative and unique colour animation. There are diverse tasks to perform that disguise PFMT as gameplay, including a butterfly collecting flowers, a rocket passing through galactic star tunnels, basketball hoops to score and an endearing octopus character. The present author's discerning "test" patient thoroughly enjoyed the game aspect, and was inspired to develop many hilarious descriptors of her own PFM function! There is also an option for above-threshold vibratory feedback. Clinicians will particularly note the focus on detailed assessment tests, and low maximal voluntary contractions (MVCs) and endurance training programmes, during which the manometry gives a real-time measurement of any reduction in resting tone. Although the automated progression of exercises felt slow initially, the present author understands that these controlled and incremental sessions have been deliberately adopted by the physiotherapist developers, who believe that patients with feedback devices usually tend towards overuse, gripping too much and an incorrect focus on strength over endurance (G. Herman, personal communication). They have built in both automatic and clinician-led programmes to carefully manage the patient journey.

If the kGoal is purchased as a standalone device, a basic and fairly limited biofeedback training programme can still be followed for no further cost. However, the kGoal is now promoted in the UK as PelviFly. The intent is that it should be used as a hybrid clinic and remote service solution. The hardware device, smartphone application, real-time data transfer, access to a clinic portal for data storage and management, media communications (e.g. reminders to the user to exercise and contact the therapist, and chat facilities), and the clinician's involvement in the bespoke, remote real-time management of the patient's training programme are intended to be used together. At times, the present author found the PelviFly interface, instructions and data overly complicated, and some aspects have clearly been lost in translation. For further information about the UK-specific business model and training programme, it is important not to use the European-focused website (http://pelvifly.com), but rather, to access the information tailored for British practitioners (www.pelvifly.co.uk, which redirects to https://pioneermedicaleurope.co.uk/brands/pelvifly/). This will probably involve a monthly subscription, which will be paid by the clinician and based on number of product users, and an option to buy the hardware on a wholesale basis to sell to clients.

As with the PeriCoach team, those behind PelviFly are clearly committed to empowering women to access and succeed with physiotherapy-led PFMT.

Discussion

Considerations for using of biofeedback devices during pregnancy

The relevant POGP good practice statement, which was published in this journal (POGP 2019), clearly identifies pregnancy and actively trying to conceive (i.e. a time when a woman may already be pregnant) as contraindications to NMES. The rationale is that "the effect of electrical stimulation on foetal development is unclear; however, because the potential effects of an adverse reaction could be devastating, it is advisable not to use it" (POGP 2019, p. 56). Although most biofeedback devices are electrically powered,

these measure an output from the user's body, and do not deliver any form of electricity to it. However, some devices can operate in both the biofeedback and NMES modes. Great care would be needed to be sure that the correct mode was utilized when working with these units.

There is no contraindication to sexual activity, or to the insertion of objects in general into the vagina during pregnancy. The good practice statement regarding digital vaginal examination in pregnancy (POGP 2018) helps to inform reflective practice when discussing and recommending activities during pregnancy.

The Epi-No Delphine Plus is specifically marketed as an aid to antenatal preparation for delivery. In the frequently asked questions sections of the relevant websites, Elvie, PeriCoach and kGoal all advise that these products can be used during pregnancy. The limitation on the use of other devices during pregnancy is not necessarily the biofeedback unit *per se*. Rather, the majority of the most well-known vaginal or anal electrodes that are required to operate the units list pregnancy as a contraindication in the small print of the accompanying leaflets, rendering these products unsuitable for use during pregnancy by default.

Research and development

Although the individual technologies may not have been validated against a gold standard, the broader scientific literature supports the benefits of biofeedback technology. There is a body of historical research into the physiological mechanisms of biofeedback within musculoskeletal rehabilitation, neurological disorders and sport, as well as the fields of incontinence and pelvic health. Since ultrasound is widely used in pelvic health research, it has a more substantial body of literature supporting its validity and reliability than other technologies, but there is not yet a low-cost, portable option for use at home.

All the more recently developed pelvic trainers and telehealth devices discussed in the present review have been the subject of clinical trials, case studies and conference presentations. Although only short reports can be easily accessed, all the companies approached were keen to engage with the present author, and were enthusiastic about collaborating with physiotherapists.

It is easy to criticize manufacturers for not performing more research. However, as discussed previously (Savage 2018; Gordon 2019; Te Brummelstroete *et al.* 2019), medical devices are not subject to the same approval process as drugs, and there are reasonable arguments why these should not be. These companies generally follow procedures that better reflect their commercial nature, and health professionals may need to learn new skills in order to engage and interact with research and development departments. Clinicians need to spend time coming to understand the world of focus groups, user surveys, anonymized data collection and customer service reports, as well as the significance of the ubiquitous online product review.

Although there has been little research into or comparison between competing devices, a body of expert opinion is developing that suggests potential superiority in specific clinical situations. For example, manometry may be more specific than EMG when assessing the function of both internal and external anal sphincters, training individuals to defer the urge to defecate (Herbert 2019), and measuring the relaxation component of muscle activity (G. Herman, personal communication). There are also subtle inferences to be drawn from the marketing material, which make multiple claims about advancements in the sensitivity, accuracy and effectiveness of all the various probes and sensors. Furthermore, several devices are each purported to be the first to "solve" the problem of incontinence.

Moving forward, the research and development questions may need to change in order to reflect real-world needs. If the clinical concept of the "5 Fs" (i.e. find, feel, force, follow-through and functional training) is applied (Berghmans 2020), research questions can focus on the methods that are the most effective ways in which to enhance a patient's ability to perform PFMTs and confidence in order to ensure adherence to a home exercise programme at each stage (Sacomori *et al.* 2015).

In pelvic health, the key focuses of research have been either biofeedback as an adjunct to PFMT for UI, or evacuation training for bowel disorders. It would also be pertinent to explore the clinical benefits of biofeedback for specific subgroups of the patient populations with incontinence or pain disorders, i.e. cases in which the underlying cause is hypertonicity or muscle dyssynergia rather than muscle weakness, or in which a lack of proprioception has been identified.

The restrictions imposed by the current COVID-19 pandemic have created new kinds of hybrid situation; for example, trying to instruct patients in the use of a device and progress their training via virtual consultations with no or only intermittent clinic visits. Products designed for both remote assessment and training are intended

to unite patients and clinicians by bridging the communication gap. Manufacturers depend on and learn from research into telehealth practices in other areas of healthcare, such as the strategies used to monitor cardiac patients or remotely support elite athletes on international tours.

Points of difference and clinical requirements

When deciding what products to trial or buy, the first question that needs to be considered is whether the device is intended to be predominantly clinician- or patient-facing. The type and complexity of the data gathered and displayed, the packaging and marketing, and most importantly for the patient and clinician alike, the instructions for use will answer this.

The second cluster of key points of difference concern what the clinician and/or the patient hope(s) to achieve.

Do you want a tool to assess and analyse patients in your clinic, puzzle out a complex form of functional incontinence in a high-level athlete, or build a data set of case studies? All of these things will require a sophisticated, computer-compatible display screen and data storage software. On the other hand, do you simply want a quick way to help a patient "find and feel" their pelvic floor? This will only require a simple, easy-to-understand interface.

Is the biofeedback needed to help a patient practise the difference skills sets needed to perform MVCs and endurance contractions? In this case, the priority might be a device that offers a simple programme of guided exercises. Alternatively, is biofeedback needed to enable a patient to progress to functional training with movement activities in standing? If so, you may need free-flowing feedback that is visible or audible at a distance from the device.

Are you and your patient looking for a device that you want to loan at a low cost to provide a few weeks of motivation when a client is flagging on what seems to her like a long journey, or will this be an investment purchase for long-term regular use to achieve "follow-through" as she leaves your care and moves on with her life?

If your goal is downtraining, you may choose manometry rather than EMG, and require guided programmes that are not biased towards traditional "strength" training. For this niche group, the size and/or intimidation quotient of the sensor becomes a valid consideration.

Does the biofeedback device need to be suitable for use with an anal rather than a vaginal electrode? Would it be useful for the unit to have a secondary function, such as transcutaneous electrical nerve stimulation, NMES or birth trainer, or hybrid ETS? Do you want it to be able to be used by multiple users as loan equipment (with individual client sensors), or are you happy for it to be a single-user-only purchase? Has your patient bought the product already, and is she looking to you for advice about how to optimize its use?

Finally, do you want to work as an early adopter of pioneering technology, and are you willing to work through the inevitable hitches in development? Are you prepared to experiment with telehealth products so that British physiotherapists can influence the development of the patient experience and associated business models?

Much as the present author doubts that any readers of this journal ever offer "routine" care, she also suspects that they frequently underestimate and undervalue their own clinical reasoning capabilities, their impressive under- and post-graduate skill sets, and their capacity to continue to learn and overcome the challenges of the rapidly changing world of healthcare.

Conclusion

The findings of the present equipment review are summarized in Box 1.

The present author's advice to her fellow clinical physiotherapists is that you should endeavour to maintain a healthy dose of pragmatism so that you can work with the product(s) that you already have, or that the patient has purchased (no matter how naively), in order to make these meaningful, relevant and useful.

Even as new forms of biofeedback are being developed, long-standing technologies are being modernized. Cosmetic improvements and the increasing care that is taken to create customer-facing information, instructions, videos and website support are to be welcomed on behalf of this often-stigmatized patient group.

The development of the telehealth functionality of biofeedback devices for pelvic health has been rapid and well-timed. Unfortunately, the current pandemic has raised awareness of the fragility and vulnerability of traditional face-to-face therapy sessions, which has led to the realization that alternative methods of managing, treating and supporting patients who are on a pelvic health journey are now urgently needed.

Looking to the future, clinical physiotherapists, and in particular, the highly passionate, skilled and pioneering members of POGP, are ideally placed to influence both patient choices, and

Box 1. Summary of the findings: (PFMT) pelvic floor muscle training; (NMES) neuromuscular electrical stimulation; and (EMG) electromyography

- If you are recommending that patients should acquire a device for long-term personal use to enhance traditional PFMT that they can purchase, set up and use completely unaided: Kegel8 Biofeedback Pelvic Trainer or Elvie Trainer
- For busy clinics that need to loan robust and easy-to-clean units to patients, who will buy an individually suitable internal sensor at a relatively inexpensive price (in case of loss): Kegel8 Biofeedback Pelvic Trainer, NeuroTrac Simplex, Neen Peritone or Nu-Tek Maxi Plus1
- For a more sophisticated loanable product (at a higher cost, if lost) that allows patients to seamlessly move between NMES and biofeedback: Nu-Tek Levator Elite (EMG), NeuroTrac Myoplus Pro (EMG) or evoStim P (manometry)
- For clinics that need to combine devices with software to create a computer-linked fixed unit: Nu-Tek Levator Elite or NeuroTrac Myoplus Pro
- To develop telehealth services in a clinic: PeriCoach or kGoal/PelviFly

also further product research and development. As a profession, we should endeavour to continue to take the initiative. We can acknowledge the inevitable limitations and sometimes somewhat misguided adventures of new technology in a kind-hearted way. We can support the move away from "routine care", or technology boffins squeezing things with their hands in a laboratory, to the development of medical devices for men and women with a variety of pelvic floor disorders and specific training needs in an uncertain physical world.

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